Constructing a Coherent Philosophical Basis for Research Ethics

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Declaration of Authorship

I hereby declare that this thesis is my own original work and that any sources used in its preparation have been acknowledged.

Signature:  

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Abstract

The purpose of this dissertation is to identify some of the most pressing problems in the dominant contemporary approach to research ethics, and to devise an alternative approach that avoids these problems. I contend that the fundamental ethical values invoked in human research are often appealed to in contradictory or ambiguous ways, or in ways that do not adequately capture or do not show an adequate understanding of the specific ethical concerns of human research. One significant problem in this domain is that values for ethical research are often unreflectively imported from medical therapy, producing ill-suited guidelines that cannot capture the different ethical situations that arise in the context of research. Furthermore, ethical guidelines in this area are often not developed with a sufficient understanding of the deep philosophical issues that they invoke. I suggest that we can address these problems through examining the fundamental ethical concerns of research on a philosophical level. This method will reveal severe problems with the approach to two of the ethical values underlying research; beneficence and respect for autonomy (or respect for persons). Once the nature of these problems has been revealed, and with reference to ethical problems that typically arise in the domain of research, I construct a coherent philosophical foundation for research ethics, which both avoids these deep-seated problems and better captures the ethical issues that arise in the domain of human research. I argue that we need to radically depart from the values of beneficence and autonomy/respect for persons as they are currently understood in the guidelines. We need an idea of beneficence that is clearly distinct from that which is used in the therapeutic medical context from which this notion is currently drawn. I also contend that we need to move away from autonomy as a central value in research ethics. I posit an alternative choice-based approach to informed consent which is concerned both with respecting agents’ freedom of choice, and also with their wellbeing, as providing a good means of protecting and promoting the interests of the individual research subject. Although these two imperatives are often thought to clash on a fundamental level, I will show that, in research ethics, they can be reconciled with minimal conflict.
Though this represents a departure from the ethics of medical therapy, this approach is far more suited to the context of research. This theoretical basis for informed consent can help to clarify the ethical problems that are specific to this domain and provide us with relevant ethical guidance in research ethics.
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Chapter 2: The Ethical Values Underlying Contemporary Approaches to Research

Contemporary Research Documents: Tracing them back to the Belmont Report and the Declaration of Helsinki

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Beneficence in the Declaration of Helsinki

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Autonomy: The Philosophical Model
Chapter 1: Introduction

The purpose of this thesis is to identify some of the most pressing problems in the dominant contemporary approach to research ethics, and to devise an alternative approach that avoids these problems. I contend that many current research ethics documents contain stipulations that are contradictory, ambiguous, or that do not adequately capture or do not show an adequate understanding of the specific ethical concerns of human research. I will suggest that these problems can only be addressed through bringing out the ethical values that underlie these research guidelines, thereby revealing the deep ethical problems that plague these approaches. Once these problems have been revealed at their most fundamental level, a coherent philosophical foundation for research ethics can be constructed, which both avoids these problems and captures the ethical issues that arise in the domain of human research. By addressing these problems at their most fundamental level, this philosophical foundation can form a basis for research ethics guidelines which is coherent, clear and provides relevant guidance for the issues that arise in this specific domain.¹

My attempts to draw out the problems in contemporary research ethics, and to propose an alternate approach to research ethics, will take the following form. In Chapter 2, I will focus on context, providing an historical account of why contemporary guidelines take the approach that they do, and highlighting several significant events in the history of research ethics that we must be mindful of when attempting to construct an adequate new approach to some elements of research ethics. In chapters 3 and 4, I will draw out what I contend are two significant ethical problems with contemporary approaches to research ethics. Chapter 3 will be concerned with the value of beneficence in research; I will argue that the notion of beneficence in research is too influenced by therapeutic medical ethics, and that it thus fails to adequately distinguish concerns of individual benefit and harm from overall societal benefit. Chapter 4 will be dedicated to

¹ While I will deal chiefly with the content of research ethics documents, my concern is with philosophical reflection about the issues, rather than proposals to engage in practical reform of the documents or institutional procedures.
autonomy, respect for persons and informed consent in research. I will draw out the various ideas associated with the concept of autonomy in philosophical work, bringing out the links between these notions and the value of respect for persons. I will argue that research ethics documents draw on these ideas in inconsistent and problematic ways. In Chapter 5, I will suggest a solution to both of these problems; what I deem a choice-based approach to informed consent. Rather than conceived of as protecting autonomy, the role of informed consent should be to protect and promote the valuable choices of research subjects. I will argue that this approach provides us with a means of protecting and promoting the interests of the research subject, including wellbeing. I will suggest that this allows us to uphold the value of respect for persons in research, drawing upon some of the valuable elements of various theories of autonomy, while rejecting the problematic elements. In the second appendix, I will briefly consider how my proposed approach can be applied to ethical issues that are more central to social science research. The remainder of the present chapter will function as a guide through the rest of the thesis, wherein I outline my strategy and approach to these issues.

Chapter 2: The Ethical Values Underlying Contemporary Approaches to Research

This chapter will be dedicated to revealing the philosophical, ethical roots of contemporary research documents. This allows us to draw out the deep ethical issues that underlie contemporary approaches to research ethics. Approaching these issues on a philosophical level is, I will argue, the only means of sufficiently identifying, understanding and avoiding the most significant problems in research ethics. This process will involve several steps. Firstly, I will show how the treatment of issues surrounding beneficence and autonomy, respect for persons and informed consent in four significant contemporary research ethics documents (two prominent international documents, and the documents guiding ethical research in Europe and the United States) is informed by two foundational research

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ethics documents; the Belmont Report and the Declaration of Helsinki. This will allow me to simplify further discussion by focusing on these two sets of guidelines.

The next step will involve providing an historical account of the genesis and development of the field of research ethics, with a particular focus on the development of the Declaration of Helsinki and the Belmont Report. This will show the development of foundational research ethics guidelines in the context of events that had a significant influence on their development, including academic work at the time, notorious cases in research that generated widespread public backlash, and broader social movements that influenced what was regarded as ethically important. There are two reasons that I take this historical approach.

Firstly, this will allow us to put together important contextual information concerning the content of these guidelines. The Belmont Report and the Declaration of Helsinki both utilise ethical values which form the basis for much discussion in philosophy (we focus here on the concepts of beneficence and autonomy/respect for persons). However, these notions are vague and multifaceted; there is much contention concerning these broad concepts. Furthermore, there is little information in these documents about the philosophical justifications behind these concepts.

The Belmont Report contains some limited information, to which we can add, to a certain extent, by looking at commentary and other theoretical work from the one of the primary authors, while the Declaration of Helsinki has nothing at all. We require more information to get a real handle on the philosophical ideas behind these guidelines. In order to discern what is intended when certain values are invoked, we must look at the concerns that motivated the formulation of these documents. It is only then that we are

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2 One of the contemporary documents I will be looking at is the contemporary version of the Declaration of Helsinki, one is based upon the Belmont Report, and the other two amalgamate these two approaches to research ethics.
able to piece together a reasonably nuanced picture which can form the basis of philosophical discussion.

Secondly, these contextual clues are drawn, in part, from practical situations that have arisen in research ethics. By exploring significant cases which changed the course of the development of research ethics, we can highlight factors which are of ethical importance in research, which will allow us to ensure that these factors are taken into account in my alternate picture of a philosophical foundation for research ethics in Chapter 5.

This section will open with the earliest international research guidelines, the Nuremberg Code (1947). I will explore the factors that motivated the adoption of the first international research ethics guidelines. The earliest approaches to research ethics present a stark contrast to how we view the field today. It is generally assumed in contemporary research ethics that the requirement for informed consent comes from the requirement to respect the autonomy of the research subjects (the same view is often touted in therapeutic medical ethics). However scrutiny of the earliest research ethics guidelines shows that before autonomy was posited as a primary ethical value motivating research, informed consent guidelines were aimed towards protecting the wellbeing of individual research subjects. This can come as a surprise, because, as I will show, contemporary informed consent guidelines in both research and medical ethics are generally understood as a means of promoting and protecting the autonomous decisions of individuals. Furthermore, beneficence and respect for autonomy are generally thought to constitute separate domains of ethical concern, and the demands from these two principles are often thought to conflict.\(^3\) An understanding of the historical context in which the Nuremberg Code was created will help to reveal some of the dramatic differences between research ethics now and the principles outlined in this document, and will give possible indications of how we might approach certain issues differently.

\(^3\) Drawing these views out, and ultimately criticising them in Chapter 5, will form a central theme of this thesis.
Historical context is also crucial for understanding the development of the next major international research ethics document, the Declaration of Helsinki (1964). By looking at the circumstances under which this document was created, we can explore its heavy focus on beneficence as the driving force behind the protection of individual wellbeing in this document. I will show that this can be understood as both a reaction to the Nuremberg code, and a result of who devised it (doctors). As a result, the Declaration of Helsinki translates the obligation of doctors in a therapeutic context to act in a beneficent manner by prioritising and promoting the wellbeing of their individual patients into the context of medical research. I will use this historical basis to argue that the notion of beneficence in the Declaration of Helsinki has enduring problems that are still present in the contemporary (2013) version of the document, in Chapter 3.

The intervening events between the publication of the Declaration of Helsinki in 1964 and the release of the Belmont Report in 1978 led to some significant differences in the approach to research ethics, which can only be adequately understood through an appreciation of these events. One of the primary motivating factors behind the new approach advocated by the Belmont Report was the emergence of several notorious research cases during the 1960s and 70s. We will thus next turn in Chapter 2 to an account of four prominent, ethically controversial cases in research ethics. In addition to giving us insight into some of the crucial factors which influenced the development of the Belmont Report, these cases will allow us to keep in mind some of the situations which an adequately-designed code of research ethics should successfully avoid. These cases led to several changes in the ethical approach to research. For example, one of the primary insights to emerge from these controversial research cases involved the need for research to undergo external review. This was recognised and incorporated into subsequent guidelines. But I contend that there are other important insights that can be drawn from these cases that have not been fully recognised.
There were also significant social movements during this period which led to autonomy being given much greater significance in society, and subsequently in medical ethics. Again, the influence of the rise in autonomy in medical ethics translated into a research context. I will scrutinise the events which led to social changes concerning how we view research ethics. I will show the extent to which therapeutic medical ethics continued to exert their influence over research ethics guidelines through reference to the Belmont Report, noting differences between this document and the Declaration of Helsinki, and points of continuity. Through looking at the societal changes that led to the rise of autonomy, we can begin to discern what was intended by the inclusion of this value in the Belmont Report. As we will see in the discussion of autonomy in Chapter 4, the use that was made of autonomy in the Belmont Report departs quite significantly from the theoretical philosophical work on the concept. An understanding of what precisely is meant by the term “autonomy” in the Belmont Report must involve some understanding of these historical factors.

I will conclude this chapter through engaging with the content of the Belmont Report and academic commentary surrounding it. I will show how the historical events outlined above influenced the focus and structure of the Belmont Report, including the use of broad ethical principles instead of the more specific edicts seen in the Declaration of Helsinki, the centrality, for the first time, of concern for the autonomy of research subjects, a shift in the understanding of the principle of beneficence in research, and the expansion of the scope of a research ethics document to cover non-medical research. This will allow us to develop a comprehensive picture of the document. Through this process, we arrive at an understanding of the deep philosophical values behind the Belmont Report and the Declaration of Helsinki, enabling the critical philosophical scrutiny of the expression of these values, which will form the basis of chapters 3 and 4.

There are three crucial factors which I will draw from this historical account of research ethics. I will show that informed consent was used in the earliest research guidelines as a means of protecting wellbeing. This will
form part of the basis of my argument in Chapter 5 that it can and should return to this role. Secondly, I will highlight the continual blurring of the ethical mores surrounding therapeutic medicine and research ethics. This sheds light on the approach taken to beneficence in the Declaration of Helsinki, and allows us to see that this method endures to a certain extent in the Belmont Report. In Chapter 3, I will show the damaging nature of the assumption that ethical values from medical therapy can be imported into research ethics. In Chapter 5, I will advocate taking an approach to research ethics that radically breaks with this historical tendency. Finally, I will explore the factors that led to the rise of autonomy in both research and medical ethics. I will use this to show, in Chapter 4, that the notion of autonomy in these practical contexts bears little resemblance to the notion as often discussed in theoretical philosophy. I will then argue in Chapter 5 that in order to capture the benefits of both the theoretical philosophical and practical models of autonomy, we need to move away from autonomy as a fundamental guiding principle for research ethics, and the primary basis for informed consent, and that we should focus instead on protecting and promoting the choices that the research subject has reason to value.

**Chapter 3: The Problem of Beneficence**

Chapter 3 will be concerned with outlining and exploring what I will contend is one of the most significant and enduring problems in research ethics, which I refer to as the problem of beneficence. This chapter will take the form of bringing out inconsistencies and contextual problems with the approach to beneficence in the Declaration of Helsinki and the Belmont Report. Beneficence is quite a simple concept on a general, philosophical level. The problems arise when we attempt to apply this general principle to a specific context, without an adequate understanding of the issues that arise in this context. The main problem with beneficence in research is that the specific obligations that it generates in the context of medical therapy are often used as a basis of the obligations that it generates in a research context. However, beneficence in research plays a significantly different role than in medical therapy, and attempts to translate the obligations from medical therapy to research generate various problems. The difference
between the obligations generated in these different contexts is well understood and documented in work on bioethics, but this confusion remains in research ethics guidelines. I will show the problems that arise from the treatment of beneficence in both the Declaration of Helsinki and the Belmont Report, and begin to argue that these problems can only be overcome by a radically different approach to the concept of beneficence in research; an ethical framework that is designed with the specific ethical concerns of research in mind. I will expand on this argument in Chapter 5, where I will outline a new philosophical basis for informed consent in research ethics in response to the problem of beneficence, and the problems concerning respect for persons, autonomy and informed consent which I will detail in Chapter 4.

The most obvious problems with beneficence in research are generated through the approach taken in the Declaration of Helsinki, which does not distinguish between the obligations of therapeutic physician and researcher, and which attempts to apply the norms governing the ethical conduct of therapeutic physicians to the context of medical research. I will show that this approach is misguided and problematic. Unlike the Nuremberg Code, which reflected a deep suspicion of the motives of researchers, protection of the wellbeing of the research subject in The Declaration of Helsinki, which is designed only to provide ethical guidance in medical research, relies upon the beneficent motives of doctors. The Declaration of Helsinki imports the obligation of the doctor to act beneficently into a research context. This obligation is constantly stressed throughout the document. However, even if we accept the Declaration of Helsinki’s contention that doctors will always uphold their obligations to act beneficently, this obligation does not translate into a research context.

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4 As I will explain below, this is partially aimed to deal with situations in which the physician acts simultaneously as physician to a patient and researcher to a subject – the Declaration of Helsinki aims to provide a single set of guidelines under which the physician can operate when she is bound by these dual sets of obligations. In Chapter 3, I will detail the problems with this approach.
Beneficence is not able to play the same role in research, because the different interests that come into the equation in this context mean that the principle of beneficence makes very different demands than in medical therapy. Beneficence, on its most general level, can be understood as including all forms of action which benefit other persons. However, once we understand the general meaning of beneficence, we can see that it will mean different things in different contexts. In medical therapy, the beneficent concerns of the doctor are directed towards protecting and promoting the wellbeing of the patient. However, in research, the relationship between even doctors undertaking it and research subjects is not the same as a doctor/patient relationship. In addition, there is no special reason why a research subject should benefit from the research that is being undertaken, while there are others beyond the research subject that stand to benefit. When we speak of beneficence in research, then, we must take into account the benefit that research can generate for society as a whole. If we attempt to bring the principle of beneficence as it is understood in medical therapy into research, with its corresponding obligation to prioritise and promote the wellbeing of the individual research subject, we risk precluding a great deal of benefit that can be generated through research. Research, after all, will often involve putting subjects at risk of harm in order to conduct research with the potential to benefit others in the future.

It is clear, then, that the idea of beneficence in the Declaration of Helsinki cannot be used to generate useful research ethics guidelines. The Declaration of Helsinki holds that the obligation of beneficence will always involve doctors/researchers prioritising the wellbeing of the research subject over the interests of science and society. This does not recognise that researchers might have obligations to promote the wellbeing of the population as a whole as well as obligations to their research subjects. Because the imperative to conduct research will often clash, at least to a certain extent, with the imperative to prioritise the wellbeing of the research subject, the guidelines in the Declaration of Helsinki, if read literally, will not allow us to conduct much research at all.
Historically, however, what turned out to be more of a problem is that physicians took the substantial discretion they were granted (on the understanding that they would always use this discretion to act in the best interests of the patient/research subject) and used it in ways that risked sacrificing the wellbeing of the research subject for the ends of research. I turn to an example to illustrate this risk. The Jewish Chronic Disease Hospital Case involved researchers injecting cancer cells into patients without their consent. The researchers defended their actions through relying on a confused notion of beneficence. They used a research-focused notion of beneficence to argue that the research was worthwhile and justifiable due to its potential to produce great scientific benefit. At the same time, they used a therapeutic notion of beneficence to argue that they did not tell the patients/subjects that they were involved in an experiment, because they did not want to distress them. Though the doctors here could be argued to be acting from motivations of beneficence in a broad sense, a failure to distinguish between the good of the patient/subject and the good that research could generate as a whole led to insufficient regard for the patient’s interests. Where failing to inform patients in a therapeutic context might be justified on the grounds that this will contribute to their wellbeing, failing to inform subjects in research might lead to their interests being disregarded altogether for the good of others. Failure to understand the differences between beneficence in research and medical therapy, then, can lead to an inadequate recognition of the fact that the subject’s interests are not all that is at stake in this equation, and thus risks paying inadequate attention to the interests of the subject.

To further emphasise the pressing nature of this problem of beneficence, I turn to cases in which it presents a severe problem; cases that involve what has been called “the therapeutic misconception”. The Declaration of Helsinki merges the beneficent concerns of doctors and researchers partially so it can provide guidance for medical research situations that also have therapeutic intent. Ironically, however, an exploration of this problem reveals the importance of keeping the role of beneficence in medical and research ethics separate, particularly in therapeutic research. The
therapeutic misconception is the common belief, in medical research, that the research procedure is therapeutic.\textsuperscript{6} Even where research has therapeutic intent, research design makes it impossible for the researcher to prioritise the wellbeing of the subject as the therapeutic physician would the patient (as I shall explain). However, it can be difficult to shake the research subject’s belief that the same therapeutic norms apply in research, even when he is informed of the aspects of research design that will necessarily compromise pursuit of his wellbeing.\textsuperscript{7}

It seems, then, that simply informing subjects about the nature of the research project may have limited success. Overcoming this problem must instead be based on challenging the underlying and pervasive belief that doctors, whether they are acting in a therapeutic or research capacity, will always prioritise the wellbeing of their patients or research subjects. This, I argue, can only be achieved if we understand the ethics that govern research and medical therapy as completely distinct. In order to address these problems, I suggest that we need to recognise that balancing our obligations of beneficence towards the research subject, and our beneficent duties towards the population as a whole, presents one of the most fundamental ethical conflicts in research. The philosophical basis for research ethics must be reformulated to recognise this significant tension. To further explore this contention, I turn to the treatment of beneficence in the Belmont Report.

The Belmont Report seems to make progress in solving the problem of beneficence; it acknowledges that beneficence in research will involve concern both for the wellbeing of the individual research subject, and for the benefits that research can produce. Furthermore, it recognises that these values can conflict. However, I maintain that in subsuming all beneficent concerns under a single principle of beneficence does not sufficiently emphasise this conflict. Furthermore, the Belmont Report holds that the


\textsuperscript{7} Appelbaum, Roth and Lidz, “The Therapeutic Misconception”, p.325.
principle of beneficence is translated into practice through weighing the risks and benefits of the research. This kind of equation seems like it could well result in the interests of the subject being overridden by considerations of the good of others, and, though the Belmont Report does take some measures to temper this, the risk remains that the wellbeing of the subject will not receive adequate consideration in this document (and in ethical guidelines modeled after it). I suggest that there might be a hint of recognition of this problem in the Belmont Report, due to the fact that some stipulations in the principle of respect for persons seem geared towards protecting the wellbeing of the research subject.

The approach in the Belmont Report, therefore, does not fully resolve the problem of beneficence, despite acknowledging the existence of this problem. I suggest that in order to adequately combat the problem of beneficence, we need to make the conflict between the interest of the subject and the interests of society more apparent.\(^8\) I suggest that this might be achieved through reformulating the principle of beneficence so it is solely concerned with assessing risks and benefits, and calculating what will produce the greatest benefit overall. Considerations of the wellbeing of the individual research subject, I contend, should be incorporated into informed consent guidelines. Because informed consent is chiefly concerned with promoting and protecting autonomy, this might seem like a strange move, as these two values are often seen as routinely opposed in therapeutic medical ethics. However, I suggest that autonomy and wellbeing are not as mutually exclusive as is often held.\(^9\) I suggest that informed consent guidelines might be better conceived of as a mechanism to protect all the interests of the individual research subject.

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\(^8\) In their seminal work Principles of Biomedical Ethics, developed in conjunction with the Belmont Report, Tom Beauchamp and James Childress deal with this type of problem by separating concern for wellbeing into two principles – beneficence (concerned with the production of benefit) and nonmaleficence (concerned with the prevention of harm). Although this is an improvement on the situation in the Belmont Report, I will argue in Chapter 5 that my approach provides a better means of dealing with this.

\(^9\) This contention will be fully explored and defended in Chapter 5, after I have analysed the concepts of autonomy, respect for persons and informed consent in research in Chapter 4.
The suggestion that we consider concerns of individual benefit and harm separately from what produces the greatest overall benefit, and put a separate mechanism in place to protect these concerns, emphasises the most fundamental ethical tension in research ethics. It forces us to acknowledge the clash between the interests of society and the interests of the individual in research decisions. This also emphasises the fundamental difference between ethical therapy and research, addressing the problems with the conflation of these two fields that lead to the therapeutic misconception. This strategy does not dispel the tension between the demands of individually-focused beneficence and beneficent concern focused towards society as a whole; this will always be a significant problem in research ethics. However, it pushes this problem into the spotlight; forcing us to acknowledge the conflict whenever we make a decision about research ethics.

However, before I am able to argue for my contentions about how we might resolve the problem of beneficence by incorporating the protection and promotion of individual wellbeing into informed consent guidelines, we must first look at the accepted contemporary function of informed consent; showing respect for persons by protecting and promoting their autonomous decisions. It is only upon inspection of this principle that we can determine if concerns for individual wellbeing can be coherently incorporated into informed consent guidelines alongside their other goals. I thus turn to an examination of the principle of respect for persons in Chapter 4, before exploring these ideas further in Chapter 5.

Chapter 4: Respect for Persons, Autonomy and Informed Consent in Research
Chapter 4 will be dedicated to pointing out another significant problem in contemporary research ethics, concerning the values of respect for persons and autonomy, and the relationship between these values and informed consent procedures. The problem of beneficence in Chapter 3 concerned the application of this value in different contexts. Understanding the problems that form the focus of this chapter, however, requires more detailed
engagement with philosophical work. Before we are able to draw out the notions of autonomy, respect for persons, and informed consent in the Declaration of Helsinki and the Belmont Report and understand the links between various notions of autonomy and respect for persons, and the relationship between these values and informed consent guidelines, we must first have a deeper understanding of the complicated concept of autonomy in philosophical work. I thus first turn to the notion of autonomy in the context of theoretical philosophy.

Through a survey of the major ideas that have been associated with autonomy throughout philosophical history, I bring out the fact that autonomy has been conceived of in many different ways. I first turn to the Kantian notion of autonomy, though it bears little resemblance to how we employ the concept of autonomy in medical and research ethics today. However, an understanding of Kantian autonomy is crucial to understanding an aspect of the links between the concept of autonomy and respect for persons. I will draw on some Kantian ideas concerning respect for persons in Chapter 5. I then turn to the equally influential but very different work of Mill. Mill’s idea of autonomy was much closer to the individually focused notion, concerned with freedom of choice, that we associate with ideas of autonomy today. Mill’s theory also stresses the connections between autonomy and wellbeing, which will also form a crucial part of my argument in Chapter 5.

I then look at the way that autonomy has developed in the 20th century. I show that theoretical philosophical work on autonomy begins to focus on showing that the actions are a true reflection of the agent’s self. This is often referred to as the condition of authenticity; the requirement that the actions of an agent are somehow authentically theirs. After surveying some influential seminal accounts of autonomy that emphasise the notion of authenticity, I turn to an interrogation of what the “self” in this context is. This leads us an exploration of Locke’s notion of selfhood, a concept that underlies, to some extent, many contemporary authenticity-based accounts of autonomy. As well as better allowing us to understand the concept of
authenticity that is central to many contemporary accounts of autonomy, an understanding of a Lockean view of the self will better allow us to see where a contemporary authenticity-based account of autonomy is relevant to evaluating certain decisions of research ethics; an issue that I return to in Chapter 5. I then turn to some contemporary work on autonomy, emphasising how these notions relate to a broadly Lockean conception of selfhood.

The next section of this chapter explores a very different notion of autonomy – what I refer to as the biomedical model. This notion of autonomy is exemplified by the work of Ruth Faden and Tom Beauchamp. Their theory of autonomy departs from the contemporary theoretical philosophical notion in rejecting authenticity as a condition of autonomy. Faden and Beauchamp’s practical focus on informed consent in bioethics leads them to reject the notion of authenticity as too restrictive. Instead, they suggest that intentionality, understanding and noncontrol should form the conditions for autonomous action.

An understanding of these two very different notions of autonomy allows us to explore the notion of autonomy as deployed in the Declaration of Helsinki and the Belmont Report, and to draw out problems with the approaches in each document. The Declaration of Helsinki utilises a biomedical model of autonomy – as can be seen by the very close relation between Faden and Beauchamp’s criteria for autonomy and its criteria for informed consent. The Belmont Report draws from both the theoretical and biomedical models of autonomy. However, both the biomedical approach taken in the Declaration of Helsinki and the mixed approach taken in the Belmont Report are fundamentally flawed. In order to show this, I will show why both the biomedical model and the theoretical philosophical model of autonomy do not provide an appropriate basis for informed consent on their own, and why these approaches are fundamentally incompatible and thus cannot function as a sufficient basis for informed consent together. Each model contains significant advantages, but also significant drawbacks, and because of their disagreement on whether an
authenticity criterion is required, they cannot be combined into one coherent model.

Authenticity is an important component of autonomy because it provides the link between showing respect for persons, and informed consent procedures. As noted above, the Belmont Report sees respect for autonomy (secured through informed consent procedures) as a fundamental and primary means to achieving respect for persons. The reason that respecting autonomy is seen as best showing respect for the self, is because of the link between the self and (authenticity-based) autonomy. Because autonomous (authentic) actions have a clear theoretical link to the self, respecting these actions provides an ideal means of showing respect for the person. In eliminating authenticity from their model of autonomy, Faden and Beauchamp present us with a concept that can no longer function as a bridge between informed consent and respect for persons. Though their criteria work well as a practical guide, they have given us no underlying reasons why the actions they designate are worthy of respect, or why honouring them particularly shows respect for persons. Conversely, they give us no indication of why the actions that do not meet their criteria may be ignored without disrespecting the agent.

However, Faden and Beauchamp are correct in maintaining that an authenticity-based model of autonomy is too restrictive to function as a practically viable basis for informed consent guidelines. I suggest that to resolve the stalemate between these two models, and combine the strengths of each – the links to the notion of respect for persons provided by the authenticity-based model and the inclusiveness of the biomedical model – we must take a new approach; attempting to find a theoretical basis that can show us which decisions are linked to the value of respect for persons and why. This will enable us to ensure that informed consent guidelines are achieving the aims of upholding the value of respect for persons. I suggest that, due to the deep-seated confusion that the use of the term autonomy has caused in this context, we reject this label in our attempts to link certain actions with the value of respect for persons. In Chapter 5, I will outline a
theoretical means of achieving this – rather than being concerned with protecting and promoting autonomous action (conceived of in either an authenticity-based or biomedical sense) informed consent guidelines can express the value of respect for persons by protecting and promoting the choices that people have reason to value.

Chapter 5: An Alternative Philosophical Basis for Research Ethics

Chapter 5 will be dedicated to outlining a solution to the problems concerning the approach to both beneficence and autonomy/respect for persons in contemporary research ethics guidelines. I will suggest that these two problems can be avoided through a new theoretical basis for informed consent guidelines in research ethics; what I term a choice-based approach. Rather than a focus on the promotion and protection of autonomous decisions, informed consent guidelines should be based on protecting and promoting the choices that research subjects have reason to value. I will draw from the work of Scanlon to catalogue some reasons that people generally have to value making their own decisions. I will show that respecting, protecting and promoting these decisions is an important part of showing respect for persons. I will argue that this approach will also allow us to protect the wellbeing of research subjects, in many cases, while allowing research subjects substantial scope to make their own decisions. This approach will rely on informed consent guidelines, in the majority of cases, as a means of pursuing both the value of respect for persons, and beneficent concern for individual wellbeing. I will argue that the specific ethical circumstances in research ethics allow this approach.

However, in order for informed consent guidelines to function as a good means of protecting and promoting the wellbeing of research subjects, there must be some restrictions on the choices that are honoured in the context of research. I will argue that by disqualifying subjects from participation in research based on the fact that they show insufficient concern for their own interests, we can ensure that subjects will generally use an opportunity to make valuable choices to pursue their own interests, including their wellbeing. I will argue that these restrictions will not substantially interfere
with expressing respect for persons; these same restrictions can be justified on respect-based grounds, because agents who are not showing sufficient concern for their own interests are not showing sufficient respect for themselves, thus freeing us from a respect-based obligation to uphold these types of decisions.\(^\text{10}\) I will argue that this approach also allows for less paternalism in research ethics, as protection of wellbeing, in the majority of cases, will be achieved through informing subjects; a non-paternalistic method of promoting wellbeing. It allows for minimum interference in the self-regarding actions of research subjects.

Two crucial aspects of this choice-based theory also allow us to honour a wider range of decisions – it recognizes that we have reason to respect actions on grounds that are not related to outcome, and it recognizes that concern for wellbeing provides a motivation to place restrictions on the decisions we honour in this context. These two elements suggest that where decisions are low risk, the requirements for informed consent should be relaxed, and that as the risk of decisions climbs, more should be required for informed consent.\(^\text{11}\) I will suggest that this feature of my choice-based model for informed consent provides us with the means to achieve goals outlined by Faden and Beauchamp’s account of informed consent, and the informed consent guidelines in the Belmont Report, which seem difficult to achieve without a theory of this type.

My theory is particularly able to give superior guidance where decisions are of low risk. But there is a potential problem in combining concerns of wellbeing and of respect for persons (that is, respect for the decisions people have reason to value) as the risk involved in potential decisions grows. Because my choice-based standard of informed consent also aims to uphold

\(^{10}\) Of course, any attempt to define ‘sufficient concern’ in a non-paternalistic manner is very difficult; in justifying this on the same grounds that are generally used to support respecting the decisions of others, I hope to avoid paternalism to the greatest extent possible.

\(^{11}\) In this respect, my proposal resembles Jim Drane’s ‘sliding scale’ of competency. See J. Drane, “Competency to Give an Informed Consent: A Model for Making Clinical Assessments”, Journal of the American Medical Association, Vol. 252, No. 7, August 1984, pp.925-7. I will return to Drane’s useful work on this topic in the first appendix, where I outline what the application of the considerations in my theory might look like.
the value of respect for persons, we must be careful to avoid a standard that collapses into paternalism (often viewed as the antithesis of respect) where decisions involve significant risk. I suggest that we can draw on a Lockean, authenticity-based account of autonomy in high-risk cases to ensure that the requirement that an agent adequately values her wellbeing doesn’t become a requirement that she must act in a way that others feel is in her best interests.

In this way, we are able to devise informed consent guidelines which protect all of the interests of the research subject, simultaneously and with minimal conflict. We can thereby emphasise the crucial ethical divide in research between the interests of the individual and the interests of society. We can ensure that informed consent guidelines are an appropriate means of showing respect for persons in research, and we can put adequate mechanisms in place to ensure that the wellbeing of the research subject is protected, with minimal paternalism. My proposed choice-based approach to informed consent provides a theoretically cogent and practically viable theoretical basis for informed consent guidelines that avoids the major problems plaguing the Belmont Report and the Declaration of Helsinki. It can be used as a theoretical basis for research ethics which avoids the most significant problems in contemporary documents. This approach will not call for a radical reformulation of existing informed consent guidelines; many of its aims, I will argue, are implicit in existing research ethics guidelines. But it will provide us with a means of ensuring that informed consent guidelines are appropriately structured to achieve their ethical goals – that we can clearly see the links between abstract ethical principles and practice in research ethics. It will ensure that we iron out ambiguities in contemporary approaches to informed consent, and that informed consent guidelines are optimally structured to pursue these values in a wider range of circumstances.

**Scope of the Argument**

Before I turn to the main argument, it will be useful to outline what the scope of this thesis is. The purpose of this thesis is not to talk about the
specific policy surrounding ethical review of research, including policy concerning the make-up and conduct of Institutional Review Boards, the bodies responsible for the external review of research. This is a topic which is amply covered in many of the contemporary guidelines I have mentioned above. This thesis aims to provide a coherent, philosophically sound account of the ethical values that come into play in research ethics, which I hope will provide a more suitable basis for the development of more specific guidelines that are able to better respond to the ethical questions that arise in the context of research. In the first appendix, I provide a sketch of how my account of these values might be utilised to reform existing research ethics guidelines.

I do not aim to perfectly resolve conflicts between (and within) ethical principles through my arguments here; as with any complicated ethical situation, research ethics involves different concerns, that will inevitably conflict to a certain extent. I also do not purport to give an answer to exactly how these competing values should be weighed against each other in any given situation – no general approach can adequately anticipate the specific circumstances involved in a wide range of situations, and judgments concerning application must be made, to a certain extent, on a case by case basis. I do aim to clarify what is at stake in research, and how the abstract values of beneficence and respect for autonomy should be understood when invoked in the context of human research. This will reveal that the points of conflict between these principles are not where we might expect. My approach will show how we can minimise conflict between these values in many cases, and show how we can, in many situations, simultaneously satisfy the demands of beneficence and respect for autonomy in many situations, rather than having to engage in a trade-off between these two values.

I will also focus only on beneficence and autonomy/respect for persons in this thesis, omitting any discussion of a third value that commonly takes a central place in research ethics guidelines; distributive justice. This is because the most pressing problems that I have identified with
contemporary research ethics guidelines involve the use and understanding of beneficence and respect for persons, and my solution to these problems involves an alternative philosophical approach which changes how we look at these values in their application to research, but it leaves the notion of justice as employed in the guidelines untouched. It should be noted that issues of justice do form an important aspect of an ethical evaluation of human research, and thus considerations stemming from this value will also come into play, and will also need to be balanced against the other two values that form the focus of my thesis, in any ethical assessment of human research.

It is also important to note that the WMA, Council of Europe and CIOMS guidelines are only designed to apply to medical research, whereas the US guidelines, and the Belmont Report upon which they are based, are designed to apply to all types of research. Though I will touch on issues to do with social science research – the approach in this thesis is more focused on medical research. In the second appendix, however, I will give an indication of how the approach outlined here might give us increased insight into ethical problems that are more central to social science research. I will revisit questions concerning the scope of my choice-based theory when I present it in Chapter 5.
Chapter 2: The Ethical Values Underlying Contemporary Approaches to Research

Introduction

This chapter will be concerned with revealing the underlying ethical concerns of contemporary research ethics, by way of the consideration of key formulations of codes of research ethics. Because very little is said in these documents about the philosophical foundations that guide the choice and explication of certain principles, this will need to be done in several steps. Firstly, I will show that many prominent contemporary research guidelines draw heavily from two foundational research ethics documents: the Declaration of Helsinki (1964; 2013) and the Belmont Report (1979). Once I have established this, I will interrogate the ethical foundations of these documents. The Belmont Report contains information concerning the choice and explication of its principles and the motivation behind the chosen edicts in the Declaration of Helsinki can be revealed through an exploration of the historical circumstances that led to its creation and development. This approach can also shed additional light on what is intended by certain principles in the Belmont Report. After establishing the roots of the contemporary approach to research ethics in the Belmont Report and the Declaration of Helsinki, I will thus turn to a historical account of some significant factors that influenced the development of these two documents. Once the deeper ethical values have been revealed in this way, I can turn, in the two subsequent chapters, to the problems that continue to plague contemporary research ethics.

I contend that two significant ethical problems in research ethics centre around the treatment of beneficence in research, and in the links drawn between autonomy, respect for persons, and informed consent. Therefore, I will first give a brief summary of the relevant areas in the Declaration of Helsinki and the Belmont Report, and then show, that in these two areas, the other contemporary documents I will be looking at take their cues from these two documents. This will allow me to make the Declaration of Helsinki and the Belmont Report the focus of my scrutiny, under the understanding that the philosophical problems I will draw from it will also
apply to these influential contemporary research documents. I will sometimes return, throughout the thesis, to specific passages from specific contemporary documents to highlight a point, but generally I will focus my criticism just on these foundational documents, with the understanding that these criticisms apply to the contemporary documents that draw from them.

**Contemporary Research Documents: Tracing them back to the Belmont Report and the Declaration of Helsinki**

*The Belmont Report*

The Belmont Report, with its flexible, principle-based approach to research ethics, remains one of the most influential research ethics documents ever produced. Due to perceived shortcomings in the approach to research ethics in the United States (the reasons for which will be explored below) the National Research Act was passed in the United States in 1974. This Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was assigned the task of identifying the basic principles that should guide ethical research on human research participants, and developing guidelines to ensure adherence to these principles.\(^{14}\) The National Commission produced the Belmont Report in 1978, outlining three ethical principles that were to provide a framework for the resolution of ethical problems in human research.\(^ {15}\)

The three principles outlined in the Belmont Report are respect for persons, beneficence, and justice. The value of respect for persons, according to the Belmont Report, includes two components: respect for autonomy, and protection of the non-autonomous.\(^ {16}\) For the first time, autonomy is explicitly stated as a justification for informed consent requirements. Beneficence is expected to provide both the obligation to conduct research in order to generate benefits for society, and also to protect the well-being of


individual research participants. Justice is concerned with the fair distribution of research benefits and burdens. The Report also outlines the corresponding applications of the three principles: respect for persons is secured by informed consent, beneficence through an assessment of the risks and benefits of the research, and justice through fair procedures in the selection of research participants.

The principle of respect for persons was seen as incorporating “at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.” The Belmont Report thus contends that the principle of respect for persons produces two separate moral requirements; “the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.” An autonomous person is defined as an individual “capable of deliberation about personal goals and of acting under the direction of such deliberation.” The principle of respect for persons can be achieved, according to the Belmont Report, through its corresponding application: informed consent. The Belmont Report states that “[r]espect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.” Informed consent is seen as containing three elements: “information, comprehension and voluntariness.” This requires that a subject is given sufficient information, displays adequate comprehension of this information, and is not subject to coercion or undue influence when making the decision whether to participate in research. If these three standards are met, the requirements for informed consent are satisfied. A person is respected in a research context if her autonomy is acknowledged through ensuring that her informed consent is sought for any participation in research. If a potential subject is not able to meet the standards of informed consent

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consent and is thus considered to have “diminished autonomy”, the value of respect for persons may be achieved through ensuring that there are sufficient measures in place to ensure their protection (just what this means will be discussed in Chapter 5).

The principle of beneficence is understood in the Belmont Report as an obligation to protect research subjects from harm, and to make “efforts to secure their well-being”. The Belmont Report presents two rules that they see as complementary expressions of beneficence in research: “(1) do not harm and (2) maximize possible benefits and minimize possible harms.” Though the Belmont Report sees these two imperatives as essentially complementary, they do acknowledge that the principle of beneficence involves making decisions about “when it is justifiable to seek certain benefits despite the risks involved”. When considering risks and benefits, the Belmont Report notes that the beneficiaries of research may not be the individual research subjects, and that precluding all research that presents more than minimal risk to research subjects when there is no likelihood of direct benefit risks prohibiting research that could greatly benefit society as a whole. In these cases, the Belmont Report acknowledges, “the different claims covered by the principle of beneficence may come into conflict and force difficult choices.” The principle of beneficence finds its expression in a systematic assessment of the risks and benefits of research, and a requirement to ensure that the benefits of any proposed research are sufficient to outweigh any risk of harm.

U.S. Federal Policy for the Protection of Human Subjects (“Common Rule”)
The Belmont Report remains a key document in United States research ethics regulations. In 1991, human research regulations were unified into a single regulatory framework accepted by all U.S. government

departments.\textsuperscript{24} The Federal Policy for the Protection of Human Subjects or the “Common Rule” is heavily influenced by the Belmont Report, using the basic principles and its corresponding applications as “foundational background”\textsuperscript{25} for its more specific guidelines. Most of the Common Rule concerns the operation of Institutional Review Boards (IRBs), which are concerned with the approval, monitoring and review of human research. Discussion of the ethical guidelines is given in the relatively short section “§46.111 Criteria for IRB approval of research”. All seven criteria focus on the applications of the principles set out in the Belmont Report: risk/benefit assessment (1-2), equitable selection of subjects (3) and informed consent (4-7). The strong influence of the Belmont Report can also be seen in other federal guidelines; both the current Australian\textsuperscript{26} and Canadian\textsuperscript{27} Guidelines contain a similar choice of principles, and these principles are explicated in a similar way.

\textit{Declaration of Helsinki}

The Declaration of Helsinki, the set of research ethics guidelines formulated by the World Medical Association (WMA), is widely regarded as one of the most influential international research documents.\textsuperscript{28} This document is often regarded as the cornerstone of ethical decision-making in biomedical research, and as we will see in this chapter, is often explicitly incorporated into or cited in a variety of national and international research guidelines.\textsuperscript{29}

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\begin{itemize}
  \item \textsuperscript{24} D. Resnik, \textit{Research Ethics Timeline}, National Institute of Environmental Health Sciences, 2012, accessed at: \url{http://www.niehs.nih.gov/research/resources/bioethics/timeline/}.
  \item \textsuperscript{29} D. Human and S. Fluss, “The World Medical Association's Declaration of Helsinki: Historical and Contemporary Perspectives”, World Medical Association, accessed at: 
\end{itemize}

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First published in 1964, the Declaration of Helsinki has been revised several times, most recently in 2013. The Declaration of Helsinki differs from the Belmont Report in its format; rather than providing broad ethical principles to guide research, it consists of 37 more specific edicts. Also, unlike the Belmont Report, which is designed to provide guidance in all sorts of human research, the Declaration of Helsinki is only designed to apply to medical research, especially research undertaken by physicians. It is partially for this reason that it takes quite a different approach to concerns of beneficence.

The first principle of the Declaration of Helsinki states strongly that the benefit of the research subject is the paramount concern of the physician, stating that physicians are bound by the edict: “The health of my patient will be my first consideration”.30 The physician’s duty to protect the interests of her patients is a theme that surfaces continually in this document; principle 4 states that “it is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research” while principle 9 stipulates that “The responsibility for the protection of research subjects must always rest with the physician”. The primacy of the interests of the research subject is espoused in principle 8, where it is suggested that though “the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects”.31 In certain parts, however, the Declaration treats risk and benefit similarly to the Belmont Report, as displayed, for example, in the stipulation that “Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.”32

The Belmont Report provides informed consent guidelines in order to satisfy the principle of respect for persons, which they see as largely

consisting of respect for autonomy. The Declaration of Helsinki, however, does not contain broader principles, so, although informed consent forms a central part of the document, we are not given an indication of what deeper ethical purpose these requirements meet. However, in the explication of the requirements for informed consent, the Declaration of Helsinki is very similar to the Belmont Report. In order for the requirements of informed consent to be met, the subject must be given “adequate information” and it must be ensured that he has understood this information. In addition, consent “must be voluntary”, with special care taken where the subject might be compelled to consent under duress. This clearly bears close resemblance to the Belmont Report’s requirements of information, comprehension and voluntariness.

CIOMS: International Ethical Guidelines for Biomedical Research Involving Human Subjects

Other contemporary international research ethics guidelines take an approach which incorporates aspects of both the Belmont Report and the Declaration of Helsinki. The Council for International Organizations of Medical Sciences’ (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) provides an example of a set of prominent contemporary research ethics guidelines that take such an approach. The stated aim of this document is to “indicate how the ethical principles that should guide the conduct of biomedical research involving human subjects, as set forth in the Declaration of Helsinki, could be effectively applied”, with a particular concern for developing countries.

Though these guidelines do not mention the Belmont Report as an influence, a strong resemblance is evident. The CIOMS guidelines open with three general ethical principles for human research, before presenting 20 more focused guidelines. The general ethical principles, respect for persons, beneficence and justice are identical to the Belmont Report, and

their explication is very similar. As in the Belmont Report, respect for persons is conceived of as incorporating

at least two fundamental ethical considerations, namely:
  a) respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination; and
  b) protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.\(^{35}\)

As in the Belmont Report, the link between autonomy and informed consent is posited, when it is explicitly noted that informed consent “protects the individual’s freedom of choice and respects the individual’s autonomy.”\(^{36}\) Informed consent requirements are met when a competent individual has “received the necessary information...adequately understood the information; and has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.”\(^{37}\) These criteria for informed consent, as noted, are quite similar in the Belmont Report and the Declaration of Helsinki, though the links between autonomy and informed consent, and the mention of self-determination, are not found in the Declaration of Helsinki.

The explication of the principle of beneficence in the CIOMS guidelines is also very similar to its elucidation in the Belmont Report; beneficence “refers to the ethical obligation to maximize benefit and to minimize harm”, and requires both that “the risks of research be reasonable in the light of the expected benefits” and that the welfare of the research subject is safeguarded. These guidelines further state that beneficence “proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, nonmaleficence (do no


CIOMS’ treatment of the risks and benefits in research also resembles the Belmont Report’s approach to this issue. The risks of research that contain no therapeutic benefit\(^{39}\) for the individual research subject, it is stipulated, “must be justified in relation to the expected benefits to society (generalizable knowledge).”\(^{40}\) However, the influence of the Declaration of Helsinki is also clear in the CIOMS’ discussion of this issue. Specific reference is made to the Declaration of Helsinki’s edicts that “considerations related to the well-being of the human subject should take precedence over the interests of science and society” and that “the risks and burdens to the subject must be minimized, and reasonable in relation to the importance of the objective or the knowledge to be gained”.\(^{41}\)

*Council of Europe: Guide for Research Ethics Committee Members*

The Steering Committee on Bioethics of the Council of Europe’s *Guide for Research Ethics Committee Members* (2012) takes a similar hybrid approach in their research ethics guidelines. The Council of Europe is a human rights organisation with 47 member states.\(^ {42}\) Their research ethics guidelines do not define new principles, but rather aim to highlight, from a European perspective, the key issues that Research Ethics Committees (RECs) are likely to face. They aim to reveal the ethical basis for principles utilised in European guidelines concerning biomedical research, which, they state, are also widely accepted at an international level.\(^ {43}\) They note that the Declaration of Helsinki and the CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects* are two such internationally

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\(^{39}\) I will return to the issue of the ethical differences between therapeutic and nontherapeutic research in Chapter 3.

\(^{40}\) CIOMS, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, p.47.

\(^{41}\) CIOMS, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, p.47.


influential documents.\textsuperscript{44}

The Council of Europe stipulates that all human research should be conducted according to the ethical principles of autonomy, beneficence and non-maleficence, and justice. They state that these “principles are reflected in biomedical ethics guidance from various sources.”\textsuperscript{45} The influence of the Belmont Report is again very apparent in this choice of principles. Rather than choosing respect for persons as a principle under which autonomy is subsumed, however, these guidelines hold that the “need to respect and protect human dignity” underpins all of these principles and provides the basis from which other ethical considerations flow. They refer to this as the “principle of primacy of the human being”.\textsuperscript{46}

The principle of autonomy, or respect for autonomy, is seen as involving acknowledgment of “a person’s capacity to make personal choices.” As in the Belmont Report, the principle of autonomy “is exercised in particular through the process of free and informed consent.”\textsuperscript{47} This explication differs from the Belmont Report in that there is no mention of the term “self-determination”.\textsuperscript{48} The informed consent guidelines, however, emphasise the same elements that we have seen in both the Belmont Report and the Declaration of Helsinki. They stress the necessity of the provision of “appropriate, accurate and understandable information about the research project” to the research subject, emphasise that the information provided must be “comprehensible” and stipulate that informed consent cannot involve coercion or undue influence through inducements or threats.\textsuperscript{49}

The underlying notion of the primacy of the human being is revealed in the Council of Europe’s approach to the principles of beneficence and non-maleficence. Akin to the Declaration of Helsinki, they unequivocally state that “the interests and welfare of the human being participating in research

\textsuperscript{44} Council of Europe, \textit{Guide for Research Ethics Committee Members}, p.8.
\textsuperscript{45} Council of Europe, \textit{Guide for Research Ethics Committee Members}, p.9.
\textsuperscript{46} Council of Europe, \textit{Guide for Research Ethics Committee Members}, p.9.
\textsuperscript{47} Council of Europe, \textit{Guide for Research Ethics Committee Members}, p.9.
\textsuperscript{48} We will return to the significance of this terminology in Chapter 4.
\textsuperscript{49} Council of Europe, \textit{Guide for Research Ethics Committee Members}, p.9.
must always prevail over the sole interest of science and society. Priority
must always be given to the former and this must take precedence over the
latter in the event of conflict between them.”

However, they also suggest

that “an element of risk, including risk of harm to participants, is inherent in
the research process.” They distinguish between medical practice and
medical research, pointing out that while “medical practice is expected to
confer a health benefit for the patient, the very nature of biomedical research
means that it is uncertain whether an individual will benefit from research
participation and any benefit to the person is not the main purpose of
research.”

In discussing the obligations that stem from the principles of
beneficence and non-maleficence, they take a similar approach to the
Belmont Report, advocating the need for an assessment of the risks and
benefits, and a favourable overall risk-benefit ratio. They suggest that these
principles generate a moral obligation to “maximise potential benefit and
minimize potential harm”, and that a “research project should proceed only
if its foreseeable risks and burdens are not disproportionate to its potential
benefits. In practice, this means that all research projects must undergo a
thorough comparative risk/benefit assessment.”

Now that we can see the profound influence of the ethical approaches in the
Declaration of Helsinki and the Belmont Report on the treatment of issues
concerning beneficence and respect for persons/autonomy/informed consent
in contemporary research ethics, we can focus further interrogation on these
two documents. More light can be shed on the ethical motivations behind
these documents, and the meanings of the central terms invoked, through
scrutiny of the circumstances that surrounded their creation and formation.

Through placing these documents in a historical context, we are able to

50 Council of Europe, Guide for Research Ethics Committee Members, p.9.
51 Council of Europe, Guide for Research Ethics Committee Members, p.10.
52 Council of Europe, Guide for Research Ethics Committee Members, p.9.
53 Council of Europe, Guide for Research Ethics Committee Members, p.10.
54 Though the Declaration of Helsinki has been reformulated several times, I contend that
we are only able to understand the ethos behind the contemporary document by looking
at the ethical concerns that motivated the creation of the original, 1964 version. In
Chapter 3, I will look at some of the subsequent developments in later versions of the
Declaration of Helsinki, arguing that despite some changes, the ethical foundation of
the contemporary document remains the same as the original.
discover more about the fundamental ethical values that are relevant to the context of human research. This will allow me to draw out some fundamental ethical problems with these documents, which require philosophical interrogation.

**History of Research Ethics: Introduction**

This section will examine some of the most significant developments in research ethics, drawing out several themes and features which will be used as a basis for the arguments in the subsequent chapters. This will take the form of a chronological account of some of the most important developments in the history of research ethics. I will introduce some of the most fundamental and influential research ethics codes throughout history, as well as giving an account of some of the most notorious research that has taken place, in order to draw out the ethical insights that followed, and to highlight the ways in which these cases changed our view of what was ethically acceptable in research. I will also give an account of some more general societal developments that influenced our view of what was important in research. This will help us to understand the motivations behind the specific formulation of earlier research ethics guidelines, and will thus shed light on the contemporary documents that have been influenced by them. This will also help to clarify what is intended by the use of certain terms, for example “autonomy” in a research context. This chapter will include some discussion of ethical developments in therapeutic medical ethics, which, I will contend, have had a profound influence on our view of research ethics. This chronology will be interspersed with some commentary about what we might draw from an understanding of some of these historical events, and an indication of how I will be picking up and developing upon these insights in the subsequent chapters.

There are three major points that I wish to make about this historical material. The first is to stress the original wellbeing-promoting and protecting function of informed consent in research. I will thus open with the earliest use of informing and consent as a means of promoting wellbeing in therapeutic medicine, and will introduce the earliest international research
ethics guidelines; the Nuremburg Code, in which informed consent was given a central place as a wellbeing-protecting measure. Through this, I will point out the reasons that informed consent can be a good means of protecting and promoting wellbeing, particularly in the context of research. Through a comparison of beneficence-based justifications for informed consent in therapeutic medical and research ethics, I will show that beneficence-based justifications for informed consent can take different forms. This will be crucial groundwork for part of my argument in Chapter 5, where I will argue that informed consent can be a good means of promoting and protecting the wellbeing of the individual research subject, and that it should return in part to this role.

The second point I wish to stress concerns the influence of therapeutic medical ethics on research ethics, and the problems that have arisen from the application of ethical guidelines from this field to research. This is particularly well illustrated by the Declaration of Helsinki, the next fundamentally significant code of conduct for ethical research. Through looking at this document, and through documenting some of the most notorious research cases that followed in the immediate aftermath of its introduction, I will highlight how and why this kind of approach fails to adequately cater for the specific concerns of research. A chief contention here, which will form the basis for Chapter 3, is that importing guidelines from therapeutic medicine into research has led to serious problems with an understanding of the role of beneficence in a research context. The expectation that beneficence can play a similar role in research as it does in medical therapy, I will argue in Chapter 3, has led to enduring problems in research ethics.

Thirdly, I wish to point out, through documenting the societal events and concerns which lead to the rise of autonomy in research ethics, that this notion of autonomy is quite different from the idea as it is understood in theoretical philosophy. This is important to keep in mind for my argument in Chapter 4, where I point out the differences between the ideas in autonomy in a theoretical philosophical context, and autonomy in a
biomedical and research context. I will suggest that the Declaration of Helsinki does not have a sufficient theoretical basis for its informed consent guidelines, and that the Belmont Report utilises both of these two distinct notions of autonomy in an incompatible manner. I will then argue that both the theoretical and practically oriented ideas of autonomy contain essential insights, and if we wish to retain the crucial features of both of these models of autonomy, we must radically reformulate the theory behind informed consent in research. I will conclude by providing some critical discussion of the principles utilised in the Belmont Report, which will form the means by which I point out many of the enduring problems in research ethics in the next three chapters.

Though I will point out some factors that I will build upon in the arguments of the next three chapters, the primary purpose of this chapter is to present a historical account which allows me to lay the groundwork for my subsequent arguments, and allows the reader to approach my arguments about specific aspects of research ethics with a sufficient understanding of the general field. Therefore, presenting this history will be the main focus of this chapter. I will not develop any of my arguments here; rather, I will point out avenues of potential inquiry, which will be explored in other chapters. Additionally, as with the previous section, my concern will be to look at elements which form the focus of the arguments in subsequent chapters. For this reason, then, this history will focus on issues and developments related to beneficence, respect for persons, autonomy and informed consent. I will not include discussion of concerns relating to justice, research design, and the issues that arise from, for example, research on children.\(^{55}\)

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\(^{55}\) It is for this reason that I don't cover the influential Willowbrook research case in this thesis. Though it is of fundamental importance for the development of research ethics, the ethical commentary on this case is chiefly concerned with the use of children in research, and what constitutes coercion. As these issues, while important to research, do not form the focus of the arguments in this thesis, I have omitted this case from my account. For an account of this case see D. Rothman and S. Rothman, The Willowbrook Wars, Harper and Row, New York, 1984 and G. Annas, L. Glanz and B. Katz, Informed Consent to Human Experimentation: The Subject's Dilemma, Ballinger Publishing Company, Massachusetts, 1977, p.79-83.
*Informed Consent and the Protection of Wellbeing*

Although autonomy is generally accepted as the justification for informed consent procedures in both clinical and research ethics,\(^{56}\) upon an inspection of the various historical factors that contributed to the development of informed consent guidelines it becomes far from clear that autonomy has been the sole or even primary justification for informed consent guidelines.\(^{57}\) A look at the earliest uses of informed consent in both medical therapy and in research show that the initial justification for informed consent guidelines was based on a concern for the wellbeing of the individual. This section will look at some early uses of informed consent, geared towards protection of wellbeing rather than autonomy.

I will open with the first documented espousal of informing patients in therapeutic medicine. There are two reasons for opening with an account of the earliest uses of consent in medical therapy as opposed to research. Firstly, this will help to illustrate the fact that until quite recently, the deepest driving force behind medicine was beneficence. This will allow us to understand more about the context in which the Declaration of Helsinki was developed, as this document makes the physician’s obligations of beneficence an essential part of its research ethics guidelines. Secondly, when contrasted with the use of consent as a wellbeing-protecting measure in the Nuremberg Code, this allows us to see that even in circumstances in which beneficence is the ethical justification for informed consent, there are different types of beneficent concern that can motivate this strategy.

I will then introduce the earliest international research ethics guidelines, the Nuremberg Code, with a particular focus on informed consent. As well as providing important contextual information which helps us piece together the story of the motivations behind the development of more recent research


ethics guidelines, this document provides an example of informed consent being used as a means of protecting wellbeing in the context of research, helping to reveal the reasons that informed consent might be a particularly good candidate for this role in research ethics. I will finish this section by contrasting the use of consent as a wellbeing-promoting measure in therapeutic medicine with the use of consent as a wellbeing-protecting measure in early research ethics. While both of these uses of consent are motivated by concern for wellbeing, consent was used in the Nuremberg Code as a means of protecting the subject from harm, while consent has been used in therapeutic medicine as a positive measure to better increase the wellbeing of the patient. I will draw on both types of justification in Chapter 5, where I argue that there are many reasons to suggest that informed consent can be a good means of protecting and promoting wellbeing, particularly in research.

Birth of Consent in Medicine

In their history of informed consent, Ruth Faden and Tom Beauchamp stress the fact that though autonomy is currently seen as the predominant value in therapeutic medical ethics, this has been a recent development. As they put it, autonomy was “discovered” in medical and research ethics in the 1960s.\(^\text{58}\) However, there are certain instances in which the value of informing patients was espoused prior to this. In looking at some of the earliest circumstances in which informing and seeking consent was advocated, we can see that informed consent can be valuable for other reasons than as a means of promoting and respecting autonomy.

Prior to the rise of autonomy in therapeutic medicine, the value of beneficence had dominated medical ethics from its inception. It is understandable that beneficence enjoyed such prevalence in medical ethics prior to the 1960s, as it provides the impetus for medicine; the driving force behind therapeutic medicine is to benefit the patient.\(^\text{59}\) This heavy focus on the obligation to act in a beneficent manner can be traced back to the

\(^\text{58}\) Faden and Beauchamp, A History and Theory of Informed Consent, p.18.
\(^\text{59}\) Faden and Beauchamp, A History and Theory of Informed Consent, p.64.
Hippocratic Oath, a document written between 470 and 360 BCE, which “has had profound significance for the general ethos of medical practice and medical ethics.” This document explicitly states that the obligation to benefit the patient is the most central guiding tenet and ethical requirement of medicine. Furthermore, the relationship between the doctor and patient is often characterised as a fiduciary relationship, which brings with it attendant obligations of beneficence. The unequal relationship between physician and patient (generated by the special knowledge the physician has in the field) demands that physicians be held to the highest standard of conduct, and that they are entrusted to use their power to benefit the patient. The strict obligations of beneficence to which doctors are held meant that for a long time in medicine, the doctor’s primary motivation was pursuing the course of action which was most likely to benefit the patient, regardless of what the patient thought or whether they consented. However, even from within this firmly beneficent context, the practice of informing patients has been advocated.

The idea that there was value in informing patients was posited in the writing of several prominent physicians in the early nineteenth century, most notably John Gregory and Benjamin Rush. Gregory emphasised the fallibility of the physician, endorsing the right of the patient to speak on matters concerning his health, and suggesting that the patient (or even his friends) may have useful suggestions about treatment that the physician might overlook. He notes that deceiving the patient or his family when the patient is stricken by serious illness might deprive them of the opportunity

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63. We will look more at the focus on beneficence in medicine later in the chapter, where we examine the emergence of autonomy as an ethical value of primary importance in medicine.
64. J. Gregory, Lectures on the duties and qualifications of a physician, M. Carey and Son, Philadelphia, 1817, pp.32-3.
to put their affairs in order, thus undermining their health and happiness. Rush similarly spoke out against the harms that could be caused by the falsehoods of physicians, advocating truth-telling “with respect to the cause, nature, and probable issue of diseases”, in order to give patients an opportunity to put their affairs in order, and to make peace with their death.

However, it is important to note that, in contrast to the autonomy-based justifications for informed consent that are popular today, the value of informing a patient in this context was seen as entirely parasitic on its beneficial effects. The idea of seeking a patient’s consent also does not appear. Gregory suggests that “deviation from the truth is…both justifiable and necessary” where the truth may harm the patient. Rush argues that obedience to the physician is essential, as a failure to obey may render treatment “useless or hurtful”. He advocates yielding to patients only in matters of little consequence, while maintaining “an inflexible authority…in matters that are essential to life.” He repudiates doctors who prescribe treatment “for the whims of their patients, instead of their diseases,” and he suggests that truth-telling can be a useful means of securing the obedience of patients. The value of informing here, then, was not linked to the intrinsic good of autonomy, but was ultimately extrinsic, and was only advocated insofar as it was thought to produce beneficial effects. This begins to illustrate a theme which will become important in this text – informing patients, and seeking their input on decisions concerning their health, can be valued purely based on concern for wellbeing. This point becomes more significant in the context of research, as we will now see by turning to the Nuremberg Code.

65 Gregory, Lectures on the duties and qualifications of a physician, pp.34-5.
67 Gregory, Lectures on the duties and qualifications of a physician, p.34.
69 Rush, Medical inquiries and observations (Volume 1), p.442.
70 Rush, Sixteen introductory lectures, p.127.
71 B. Rush, Medical inquiries and observations upon the diseases of the mind, Grigg and Elliott, Philadelphia, 1835, p.178
72 A similar idea is also found in Mill’s consequentialist views about the value of autonomy produced around the same time, as we shall explore in Chapter 4.
Genesis of Consent in Research Ethics

The Nuremberg Code

The Nuremberg Code is generally recognised as providing the foundation for the contemporary debate on human experimentation. It consists of 10 ethical principles for human experimentation that were set out in the final judgment of “The Doctors’ Trial” of 1946, in post-World War II Nuremberg, Germany, at which 23 Nazi physicians were indicted for war crimes and crimes against humanity. These physicians had carried out extensive human experimentation, conducting a variety of gruesome and harmful experiments which resulted in the death, disablement and severe injury of some subjects. While the tribunal was focused on the criminal conduct of the Nazi physicians, the judges used this trial as an opportunity to explore the broader ethical concerns surrounding human research. The physicians defended their conduct throughout the trial by arguing that there were no universally accepted principles governing human experimentation. The Nuremberg Code thus represented the first attempt to provide universally acceptable principles for ethical human research, based on natural law. By incorporating the Nuremberg Code into the judgments of this international tribunal, and thus introducing it into international law, it was hoped that these principles would establish a universal idea of human research ethics, as well as providing a standard to which researchers could be held accountable. These attempts to establish universal principles for ethical human research made the Nuremberg Code the foundation of modern research ethics.

The development of the Nuremberg Code also occurred at a time at which

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81 The judges used natural law as a basis of these pronouncements due to the fact that in at least some cases with which they were dealing, gruesome conduct could be argued to have been legitimate under then-existing German law.
rigorous scientific research was becoming more commonplace. Before this was the case, physicians were operating from the beneficence-based model of medicine, sketched above, in which the physician was motivated by the imperative to benefit the patient. All interventions, even those that were experimental in nature, were for the welfare of the patient. As scientifically rigorous research became more common, shortly before the outbreak World War II, the situation in medicine changed drastically. For the first time, experimental medical interventions were not solely (or even at all) intended to benefit the patient, but to benefit future patients, or the interests of science. The unprecedented nature of the atrocities revealed in the Nuremberg Trials underlined the need for an ethical code that dealt with human research.

As the Nuremberg Code was formulated in direct response to these cases of involuntary and gruesome exploitation of research subjects, it is no surprise that it presented very exacting standards, firmly espousing the paramount importance of protecting the research subject. Indeed, the first principle of the Nuremberg Code states that “the voluntary consent of the human subject is absolutely essential” to ethical research. As the Nuremberg Code represents the foundation of the contemporary approach to research ethics, and as the heavy emphasis on consent reflects the primacy given to informed consent in contemporary guidelines, it is natural to assume that the function of informed consent is similar to that in the contemporary research guidelines; that is, that it was designed to protect and promote autonomy. However, an understanding of the historical context in which the Nuremberg Code was created suggests that a different reading of the purpose of this requirement is possible; rather than solely concerned with the free choice of the research subject, the strict requirement for informed consent here can also be seen as a measure which protects the research subject from harm.

84 Faden and Beauchamp, A History and Theory of Informed Consent, p.151.
There are several considerations supporting this reading of the Nuremberg Code. Firstly, the notion of autonomy as we know it in medical ethics, that is, as a value in conflict with and independent from considerations of wellbeing, can be traced to after the publication of the Nuremberg Code, during the 1960s and 70s (we will return to this later in the chapter). Secondly, a preoccupation with protection from harm can be seen throughout the Doctors’ Trial. The two medical expert witnesses for the trial, Andrew Ivy and Leo Alexander, who were “the primary sources of the principles upon which the Nuremberg Code is based,” focused exclusively on the ethical concerns encapsulated in the Hippocratic Oath in condemning the Nazi experiments, in which the patient’s autonomy does not form a consideration. The focus on the Hippocratic Oath as the, in Ivy’s words; “Golden Rule of the medical profession” was also underscored in the opening statement of the prosecution, where prosecutor Telford Taylor asserted that the crimes with which these doctors were charged were particularly repugnant due to the fact that they had “violated the Hippocratic commandments which they had solemnly sworn to uphold and abide by, including the fundamental principles never to do harm – ‘primum non nocere.’” The final judgement of the tribunal, in which the 10 principles for ethical research which became the Nuremberg Code were first presented, also focused on harm, emphasising the “unnecessary suffering and injury” inflicted on the subjects, and the lack of precautions “taken to protect or safeguard the human subjects from the possibilities of injury, disability and death.”

Thirdly, the focus on risk of harm can be seen in the Code itself. The

\[\text{Grodin, “The Historical Origins of the Nuremberg Code”, p.122.}\]
requirement for consent in the Nuremberg Code stresses the risks involved in outlining the information that must be conveyed to a potential research subject, including “all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.” The other nine principles of the Nuremberg Code are largely concerned with risks to subjects. The subsequent principles stipulate that research is only undertaken when it is likely to yield fruitful results for society that are “unprocurable by any other methods or means of study” (Principle 2), demand that all human research should be based on prior animal research (Principle 3), and require that research should be designed to avoid all unnecessary suffering or injury. Principle 5 places a limit on the maximum allowable amount of risk, stipulating that “No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.” Principle 6 requires that the risk involved should not exceed the benefit (defined as “humanitarian importance”), while Principle 7 states that proper preparations must be made to protect subjects from “even remote possibilities of injury, disability or death”. The remaining principles stipulate that research may only be carried out by scientific professionals, that the subject should be able to end the experiment at any time, and that the scientist must be prepared to terminate the experiment at any stage where “continuation of the experiment is likely to result in injury, disability or death to the experimental subject.”

Though these considerations strongly suggest that these stringent consent guidelines were motivated, at least in part, by a concern for protecting the research subject from harm, it is not necessary, for my purposes, to arrive at a definitive answer concerning the intentions behind the consent provisions here. I do wish to establish that consent can serve this purpose – particularly where the motives of the researchers are considered dubious. The cases

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prosecuted in the Doctors’ Trial are extreme cases in which the researchers could clearly not be trusted to promote and protect the interests of the research subjects. The research subjects, in contrast, can be trusted to have the strongest and most straightforward interest in protecting their own wellbeing. Consent can thus function in these cases as a means to ensuring that the wellbeing of the research subject will not be ignored or discounted. Though these cases are extreme, I will draw upon this general point in Chapter 3, where I argue that adherence to research protocol can compromise the doctor’s ability to protect and promote the wellbeing of the research subject. In the context of research, there may be particularly good reason for consent requirements to play a role in the protection and promotion of wellbeing.

The Influence of Medical Ethics on Research Ethics
The previous section has documented the motivations behind the earliest uses of informed consent. I have shown that informed consent was geared towards wellbeing in its earliest uses in both medical therapy and research, and have documented a variety of reasons that it might be expected to play this role; some stemming from the value that informing can have in benefiting the patient, and some from the idea that the researcher cannot be trusted to protect the wellbeing of the research subject. Now, we turn to another significant development in research ethics, which gives us another insight about why research ethics has developed in the way that it has. The Declaration of Helsinki rejects the notion that underlies the use of informed consent as a primary means of the protection of wellbeing in the Nuremburg Code. While the Nuremburg Code shows great suspicion concerning the motives of researchers, thus making informed consent a crucial requirement in order to ensure the research subjects are protected, the Declaration of Helsinki takes the opposite approach, making the beneficent motives of the physician the primary means by which the protection of the research subject is assured. I will show why and how the Declaration of Helsinki took this approach in its original 1964 version. In Chapter 3, I will argue that this idea is still central to the contemporary document, and that it creates problems in the context of research.
The Declaration of Helsinki was devised by the World Medical Association (WMA) in 1961, and finally adopted in 1964. The WMA saw a need to develop this document due to perceived shortcomings in the Nuremberg Code. As we have seen, the Nuremberg Code was written in response to very specific events; namely, the cases of research abuse documented in the Doctors’ Trial. Because of this, the guidelines in the Nuremberg Code have a very specific focus. The Declaration of Helsinki was designed to “amplify and explicate outside the Code’s conditioning environment of outrageous crimes against humanity.” 101 The Nuremberg Code concentrates on nontherapeutic research conducted on prisoners (which, as we have seen, leads to a preoccupation with consent, coercion and protection). This focus became increasingly problematic as medical research became more common and sophisticated in the post-World War II period. A lot of medical research was being undertaken that also had therapeutic intent, and some clearly legitimate research could not be carried out in accordance with the Nuremberg Code’s absolute ban on research without consent. 102

Though doctors and policymakers viewed the Nuremberg Code as a fitting response to the events that led to its development, they viewed the conduct of the Nazi doctors as “an unprecedented, singular aberration in the history of medical research ethics.” 103 The edicts contained in the Nuremberg Code, especially the strict requirement for consent in all circumstances, were seen as too uncompromising, and inhospitable to the advancement of science. 104 The Nuremberg Code was seen as an appropriate measure in the specific context in which it was created, but it was viewed as unnecessarily stringent for ordinary physician-researchers in the Western world. 105 The Declaration of Helsinki reflected the contention that “research extends beyond the exploitive sacrifice of vulnerable subjects that framed the

Nuremberg Code”. 106

As a result, the Declaration of Helsinki relaxed the absolute requirement for consent. This opened up the possibility of conducting research on subjects who were unable to consent, allowing research “with mentally disabled people and with infants and children”, which, it was maintained, “[it] is ethical to undertake and may be unethically discriminatory to deny.” 107 In place of the strict requirements for consent, the responsibility for protecting the interests of the research subject was placed in the hands of the physician-researcher. In the original version, there were no provisions made for oversight or accountability. The 1964 Declaration of Helsinki gives the researcher substantial discretion in pursuing research objectives, and in balancing the interests of the research subject against the wider interests of medical science and society. 108

The considerable discretion accorded to researchers, reflecting a much more trusting attitude to physician-researchers than the suspicious attitude taken by the Nuremberg Code, can perhaps be explained by the fact that the Declaration of Helsinki constituted the first attempt at internal regulation of human research practices by a professional medical organization. 109 The Nuremberg Code was created in a legal context, attempting to establish an ethical and legal framework that would prevent similar gross violations to those perpetrated by the Nazi physician-researchers, thus, it reflected a deep suspicion of the motives of researchers, and emphasised the imperative to protect research subjects from exploitation. The Declaration of Helsinki takes the opposite approach, drawing from the notion that doctors are obligated to act in a beneficent manner. Though the researchers that were prosecuted in the Doctor’s Trial were themselves doctors, viewing these events as a singular aberration, completely outside the scope of normal conduct for physicians, allowed the writers of the Declaration of Helsinki to disregard these events.

This strong notion of the doctor’s obligation of beneficence is evident throughout the document. While the first principle of the Nuremberg Code makes the unequivocal demand for consent, the 1964 Declaration of Helsinki opens with the statement: “It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfilment of this mission.” This is firmly enforced by two statements in the next paragraph, where it is claimed that the doctor is bound by the edict “The health of my patient will be my first consideration” and that “Any act or advice that could weaken physical or mental resistance of a human being may be used only in his interest.” As we have seen, similar strong and prominent pronouncements emphasising the obligation of the doctor to prioritise and protect the wellbeing of his patient are also found in the contemporary (2013) Declaration of Helsinki.

The 1964 Declaration of Helsinki departs from the contemporary version in positing a “fundamental distinction...between clinical research in which the aim is essentially therapeutic for a patient, and the [sic] clinical research, the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.” The Declaration provides three sets of principles; firstly, five general or “basic principles” for research. These resemble the principles of the Nuremberg Code; requiring that research is based on prior animal experiments or established scientific fact, that researchers should be appropriately qualified, that risks and benefits are carefully assessed prior to research and that research is not undertaken “unless the importance of the objective is in proportion to the inherent risk to the subject.” It also counsels that “[s]pecial caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.”

The next two sets of guidelines apply to therapeutic and non-therapeutic

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research respectively. The split approach taken in this document affirms the extent to which physicians were given a great deal of discretion, and that therapeutic norms governing the conduct of the physician were expected to play same roles in research. The Nuremberg Code did not address research that also has therapeutic intent, but a primary premise behind the Declaration of Helsinki was that a great deal of research is also therapeutic, which is to say, it is also undertaken in order to provide therapeutic benefit to the patient/subject.\textsuperscript{113} The therapeutic research guidelines stipulate that where research is justified through therapeutic value to the patient, “[i]f at all possible, consistent with patient psychology, the doctor should obtain the patient’s freely given consent”.\textsuperscript{114} This suggestion that the requirement to seek consent might be avoided if it is not consistent with patient psychology rests upon the idea of the “therapeutic privilege” which is common notion in therapeutic medicine; the physician may withhold information from a patient if she believes that disclosure threatens significant risk of harm.\textsuperscript{115} The physician’s obligation of beneficence, that is, their obligation to benefit the patient, may, according to the notion of therapeutic privilege, sometimes require deliberately failing to inform or seek the patient’s consent to a procedure. When a patient might be so distressed by details of his condition or treatment that it might affect his health, for example, or if informing the patient may cause him to refuse life-saving treatment, the therapeutic privilege allows the doctor to withhold these details. This clearly bears close resemblance to the idea of consent 19\textsuperscript{th} century medicine, as discussed above. The value of informing or seeking consent can be overridden where it might conflict with the doctor’s imperative to act in a beneficent manner, that is, to prioritise the health and wellbeing of the patient, which constitutes the most important ethical obligation in medicine. This also gives the doctor a great amount of discretion in deciding when consent is necessary or advisable.

The same provision is not made for non-therapeutic research. As the subject


\textsuperscript{115} Faden and Beauchamp, \textit{A History and Theory of Informed Consent}, p.36-7.
will not receive any direct benefit from the research, it is not possible to justify withholding information on these grounds. The guidelines for non-therapeutic research consist mainly of requirements for informed consent. However, it is emphasised that in the “purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.” This is reiterated later, when it is stated that “the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.” The consent guidelines emphasise that the potential research subject must be competent to consent, that is, in a “mental, physical and legal state [such] as to be able to exercise fully his power of choice.” Where a subject is incompetent, “the consent of [a] legal guardian should be procured.” The consent guidelines in the Declaration of Helsinki lack the heavy emphasis on avoiding coercion that we have seen in the Nuremberg Code, further cementing the different attitudes of these documents.

Since this original 1964 version, the Declaration of Helsinki has changed in some significant ways. After the details of several infamous research cases (some of which I document in the next section) emerged in the 1960s and 70s, it became clear that ethical violations in research could not be treated as an aberration, and that doctors could not necessarily be trusted to protect the wellbeing of their research subjects. This led to the introduction of requirements for external review of research in the 1975 Declaration of Helsinki. After much criticism and debate, the distinction between therapeutic and non-therapeutic research was removed from the guidelines in 2000, representing an acknowledgement that all research must be subject to the same standards of ethical scrutiny. These two changes served to limit the doctor’s discretion, and strengthened requirements for informed consent by removing the ability to invoke the therapeutic privilege. However, the proclamations of the obligations of the doctor to

117 Williams, “The Declaration of Helsinki and public health”, p.651.
118 I will discuss this further in Chapter 3.
behave in a beneficent manner still form a prominent part of the contemporary version of Helsinki. In Chapter 3, I cover these changes in more detail, arguing that the approach to beneficence in the most recent Declaration of Helsinki is fatally flawed and cannot provide useful ethical guidance in research situations. Having looked at the original version of the Declaration of Helsinki and the circumstances that motivated its creation, we will better understand why the contemporary version takes the attitude that it does to beneficence and to the obligations of physician-researchers.

**Significant Events that Influenced Research Ethics**

After the first version of the Declaration of Helsinki was released, several important events occurred that fundamentally shifted the way society viewed the ethics of human research. These intervening events will allow us to make sense of the next fundamentally important research ethics document in the history of human research; the Belmont Report. I will first document two notorious cases in medical research, which were publicised in the 1960s and 70s. These cases (among others) led to calls for the strengthening of regulations regarding human research in the United States, and for requirements for the external review of research. The response to these cases also shows a growing concern for the value of autonomy, which led to a fundamental shift in the values underlying research ethics. I will then turn to two significant cases in social science research which involved questionable ethical conduct. This type of research was not covered by the Declaration of Helsinki, which focuses only on medical research. However, they will help us to approach the Belmont Report, which was extended to cover research from these areas. These cases help to highlight that the ethical issues that emerge in the context of social science research are very different to the ethical issues that typically arise in medical research. I will address some of the specific issues that arise in the domain of social science research in Chapter 5. They also allow us to trace the growing concern with autonomy in research ethics, independent of concern for wellbeing. Finally, I will explore some of the wider societal events that led to autonomy being incorporated into research ethics as a central value. This will help us to understand the motivation behind the promotion of this value in the 1978
research document the Belmont Report, and will give us important clues about the content of autonomy as understood in this document.

In subsequent chapters, I will return to the research cases documented in this section in order to critically scrutinise the contemporary approach to research ethics, and to show that my alternate philosophical basis for research ethics is better equipped to deal with some of the ethical problems in research that were illuminated as the details of these cases emerged. In this chapter, however, discussion of these cases will simply be used to illustrate the historical emergence of certain ethical concerns in research, which enable us to shed light on the values and concerns underlying subsequent codes of research ethics.

Though the Declaration of Helsinki was published in 1964, it was not legally binding under international law, and the prescriptions therein were not immediately incorporated into federal regulations in the United States. Though the Nuremberg Code was incorporated into international law, it had little influence on domestic research. The National Institute of Health of the United States released a report in the same year as the publication of the Declaration of Helsinki which revealed that “within the American medical profession, there were no generally accepted codes on clinical research.”\textsuperscript{119} The potential for abuse of this situation became clear when a review of this report exposed an experiment in which physicians in the United States injected live cancer cells into patients. The reaction to this experiment helps to reveal the ethical concerns of this time period, and led to the strengthening of guidelines for human research in the United States.

\textit{The Jewish Chronic Disease Hospital Case}

One of the first medical research cases to generate substantial controversy was conducted in the Jewish Chronic Disease Hospital in New York. During the summer of 1963, Chester M. Southam, with the help of another researcher, injected live cancer cells into the bodies of 22 elderly, debilitated

patients at the Jewish Chronic Disease Hospital in Brooklyn.\textsuperscript{120} Southam wished to determine how long it would take for the bodies of these patients to reject the cells. The primary purpose of this experiment was to study immune reaction. The investigators claimed that there was no risk to the research subjects, as they were being injected with foreign cells that the body would necessarily reject. As a result, they believed that there was no reason to inform the patients of the nature of the experiment, as the word ‘cancer’ would be likely to cause unnecessary worry.\textsuperscript{121} The patients were told that they were being given injections to test their immune capacity, and no mention was made of the fact that this was a research experiment, unrelated to their treatment.\textsuperscript{122} As a result of publicity arising from the study, the case was brought before the Board of Regents, the state licensing authority at the time, in 1966. The Board of Regents condemned this experiment on several grounds.

Some of the grounds upon which the Board of Regents condemned this study reflect an emerging concern with autonomy and personal dignity independent of concern for wellbeing. One of Southam’s defences concerning his conduct was the contention that there was no reason to reproach his behaviour due to the fact that there had been no risk of harm. Southam, based on previous studies that he had undertaken, argued to the Board of Regents that “the injection of cultured cancer cells from an extraneous source into the human body posed no appreciable risk.”\textsuperscript{123} On this issue, the Board of Regents concurred. It should be noted that although this contention has since been established as true, this conclusion was not completely uncontroversial at the time of the experiment.\textsuperscript{124} However, because the Regents concluded that this study did not involve any risk, it provides an ideal means of revealing the other, non-wellbeing based concerns that they had about the interests of the subjects. The Regents

\textsuperscript{121} Annas, Glantz and Katz, Informed Consent to Human Experimentation, pp.19-20.
\textsuperscript{122} Arras, “The Jewish Chronic Disease Hospital Case”, p.74.
\textsuperscript{123} Arras, “The Jewish Chronic Disease Hospital Case”, p.75.
\textsuperscript{124} Arras, “The Jewish Chronic Disease Hospital Case”, p.75.
maintained that “Southam’s failure adequately to inform his subjects constituted a ‘dignitary insult’ and a legal wrong, quite apart from the question whether anyone was physically harmed.”\textsuperscript{125} While the Nuremberg Code and the Declaration of Helsinki were both very much focused on the wellbeing of subjects, this provides us with an indication of an emerging concern for the other interests of the subjects, entirely separate from the question of wellbeing.

The Board of Regents deplored not just what was done but how it was done; that is, without adequate consent. The Regents had two issues about consent in this case; they were concerned both about the chosen subjects’ competence to consent, and with the “nature and extent of disclosure required for informed consent.”\textsuperscript{126} The Regents determined that due to the frailty and vulnerability of these elderly, hospitalised subjects, their competence to consent to research was highly questionable. Furthermore, they were concerned about the limited nature of the consent obtained. They rejected the assumption on the part of the researchers that eschewing consent was justifiable if the research served to benefit scientific inquiry.\textsuperscript{127} Additionally, they disputed the relevance of Southam’s argument that he was justified in withholding the fact that this experiment involved the injection of cancer cells, as any negative reaction to the word cancer would have been irrational.\textsuperscript{128} They stated that “No consent is valid unless it is made by a person with legal and mental capacity to make it and is based on a disclosure of all material facts. Any fact that might influence the giving or withholding of consent is material. A patient has a right to know he is being asked to volunteer and to refuse to participate in an experiment for any reason.”\textsuperscript{129}

The Regents also took issue with the doctors’ assumption that they could operate under the therapeutic notion of a doctor-patient relationship, acting

\textsuperscript{125} Arras, “The Jewish Chronic Disease Hospital Case”, p.78.
\textsuperscript{126} Arras, “The Jewish Chronic Disease Hospital Case”, p.77.
\textsuperscript{127} Faden and Beauchamp, A History and Theory of Informed Consent, p.162.
\textsuperscript{128} Arras, “The Jewish Chronic Disease Hospital Case”, p.77.
\textsuperscript{129} Annas, Glantz and Katz, Informed Consent to Human Experimentation, p.20.
in what they considered to be the best interests of the patient/subjects, without informing them. As well as wishing to prevent an irrational reaction in patients that would make them less likely to consent to any research that involved the word cancer, Southam claimed that “withholding the word cancer was dictated by a genuine concern for patients’ wellbeing.”\footnote{Arras, “The Jewish Chronic Disease Hospital Case”, p.77.} The Regents rejected this defense, pointing out that in Southam’s case, there was no existing doctor-patient relationship that would justify this conduct. They made it clear that as Southam was acting primarily as a researcher, he was not entitled to make use of the therapeutic medical norms of the time that allowed physicians significant discretion pursuing the best interests of their patients.

On a related note, the Regents were concerned that the subjects were not told the purpose of the injections, or that they were taking part in a research project which had nothing to do with their health and wellbeing. They were simply told that the injection was designed to test their immune capacity. The Regents recognised that the patients would naturally assume that the doctor was acting in a therapeutic capacity. Failure to inform patients that they were conducting non-therapeutic research, the Regents held, was akin to deception. Based on these concerns about consent, the Regents stated that “[t]here is evidenced in the record of this proceeding an attitude on the part of some physicians that they can go ahead and do anything which they conclude is good for the patient, or which is of benefit educationally or experimentally and is not harmful to the patient, and the patient’s consent is an empty formality. With this we cannot agree.”\footnote{Annas, Glantz and Katz, \textit{Informed Consent to Human Experimentation}, p.20.}

The Regents make it clear that the researcher-subject relationship is distinct from the doctor-patient relationship and there is thus no room for the researcher to use discretion in what is revealed using any notion akin to the therapeutic privilege. It should be noted that this case would not be one for which the Declaration of Helsinki would allow the researcher to eschew informed consent for therapeutic reasons, as this research had no therapeutic
intent. At this time in the United States, however, due to the fact that there were no clear codes governing the conduct of medical research, the norms of medical therapy were often used to guide the conduct of physicians in medical research, even non-therapeutic research. This included the assumption held by most physicians and physician-researchers at the time that “obtaining the subject’s consent was a matter of individual professional discretion.”132 The various ways in which Southam invokes the value of beneficence to justify his conduct is an interesting issue that warrants further discussion. We shall return to this in Chapter 3.

This case, and the Regents’ judgment, led to an awareness that “in the setting where the patient is involved in an experimental effort, the judgment of the investigator is not sufficient as a basis for reaching a conclusion concerning the ethical and moral set of questions in that relationship.”133 As a result, the United States Public Health Service (USPHS) released their first guidelines concerning clinical research in 1966. The guidelines introduced a system of peer review of research, to be undertaken by colleagues within the investigator’s institution. However, these guidelines were criticised for “being weighted in favor of the investigators;”134 a criticism that turned out to be well founded, as shown by the emergence of the details of one of the most notorious cases in human research, the Tuskegee Syphilis study, in the 1970s.135

Tuskegee Syphilis Study

Perhaps the most notorious case of the long-term exploitation and abuse of research subjects was the Tuskegee Syphilis Study. This study, conducted by the USPHS, took place in Macon County, Alabama. The details of this study came to the attention of the press in 1972 and was subsequently terminated, though by that stage, it had been running for 40 years. The

132 Arras, “The Jewish Chronic Hospital Disease Case”, p.77.
133 Faden and Beauchamp, A History and Theory of Informed Consent, p.162.
134 Jones, Bad Blood, p.189.
135 Though the Tuskegee Syphilis Study began in the 1930s, prior to the introduction of any requirements for review, it was reviewed several times in its final years (after the introduction of the USPHS guidelines); each time, the continuation of the experiment was recommended.
The experiment was designed to determine the natural course of untreated syphilis in black males. It involved 400 poor black men, diagnosed with syphilis, who were monitored periodically to track the course of the disease. Another 200 men served as controls. When penicillin became widely available as a safe and highly effective treatment for syphilis by the early 1950s, the men did not receive medical therapy. In several instances, the USPHS attempted to ensure that none of the subjects received treatment from other sources.

In order to have the men agree to participate in the study, the researchers deceived the subjects into thinking that they were receiving treatment. Rather than being told that they were participating in a study, the men believed that they had “bad blood” (a local colloquialism for syphilis), and that the doctors were giving them free treatment. To elicit the cooperation of the subjects, they were given noneffective or inadequate dosages of drugs. The subjects were deceived into thinking that painful spinal taps, conducted for diagnostic purposes, were therapeutic. Subjects were encouraged and induced through cash payments to not see any physicians besides the ones who were connected with the experiment. The researchers also distributed lists of subjects to physicians in Macon County, requesting that they refer the men back to the USPHS if they sought care. When several subjects were drafted into the army in 1941, the researchers requested that the subjects be exempted from standard antisyphilitic treatment, a request with which the draft board complied. It is estimated that 107 subjects ultimately died from the effects of the disease.

The experiment was still being conducted when the story first appeared in 136

Many accounts of this study suggest that prior to this time no effective treatment for syphilis was available, however, the extent to which this is true is debatable; see A. Brandt, “Racism and Research: The Case of the Tuskegee Syphilis Study” in the Hastings Center Report, Vol. 8, No. 6, Dec 1978, pp.22-23.

137 Brandt, “Racism and Research” p.21.
140 Jones, Bad Blood, pp.126-7.
the press, on the 25th of July, 1972, in the *Washington Star*.\textsuperscript{144} Following public outrage, and opposition to the idea of an internal review, the government appointed a nine-member citizens panel to investigate the experiment, and assess the general policies concerning experimentation with humans.\textsuperscript{145} The panel recommended that the Tuskegee study be terminated immediately, and that care be provided to treat any disabilities that resulted from participation. In terms of general policy, they stressed that this ethically objectionable case was not an isolated phenomenon. They suggested that this case had simply brought attention to “unresolved problems which have long plagued medical research activities.” They identified the central problem in medical research as “the unresolved conflict between two strongly held values: the dignity and integrity of the individual, and the freedom of scientific inquiry.”\textsuperscript{146}

The panel argued that researchers were given too much discretion in overriding the interests of subjects for the advancement of knowledge. They pointed out that there was no uniform policy for the protection of research subjects, recommending that US Congress “establish a permanent body with the authority to regulate at least all Federally supported research involving human subjects.”\textsuperscript{147} Though they acknowledged the policy, instituted in the wake of the Jewish Chronic Disease Hospital Case, requiring that research undergo prior peer review, they were concerned that under this policy, “regulation of research practices is largely left to the biomedical professions.” They argued that as “the conduct of human experimentation raises important issues of social policy, greater participation in decision-making by representatives of other professions and of the general public is required.”\textsuperscript{148} Society, they suggested, “can no longer leave the balancing of individual rights against scientific progress to the scientific community

\textsuperscript{144} Jones, *Bad Blood*, p.206.
\textsuperscript{147} DHEW, “Final Report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel”, p.23.
The language in which the panel refers to the interests of the individual research subjects is very suggestive of a shift away from a sole concern with wellbeing. They consistently separate concerns of wellbeing from concerns about informed consent or the rights of subjects, as evidenced by the statements “the infliction of unnecessary harm and infringements on informed consent are frequently accepted”, and “concern for the lack of attention that has been given to the protection of the rights and welfare of human subjects in research.” These statements suggest both that informed consent is seen by the panel as protecting something beyond the wellbeing of the research subjects, and that subjects have rights beyond wellbeing that are worthy of protection in research. A clue to what this is referring to is given in the proclamation that “[h]uman experimentation reflects the recurrent societal dilemma of reconciling respect for human rights and individual dignity with the felt needs of society to overrule individual autonomy for the common good.” The explicit mention of the term “autonomy” here is notable, for as we have seen, earlier discussions and guidelines tend to talk about informed consent, or the interests of the patient, without using this term. We will explore the reasons for this, tracing the rise of autonomy as a value in research ethics later in this chapter. The notions of autonomy and human dignity, as used in both research and philosophical thought, will be scrutinised in Chapter 4.

The panel also noted that “the issues we explore also arise in the context of non-medical investigations with human beings, conducted by psychologists, sociologists, educators, lawyers and others.” The US Congress responded to the findings of the panel, as well as controversy concerning other ethically questionable research, by appointing a National Commission in

1974 to examine both behavioural and biomedical research. The Belmont Report was the eventual product of this progress. Therefore, in order to illustrate the full spectrum of problems in research ethics that such an approach must deal with, we will now turn to two of the most significant cases of ethically problematic research in the behavioural sciences.

**Significant Social Science Research Cases**

The following two cases are representative of controversial research in the social sciences, the first is a psychological study; the second, a sociological study. As well as further displaying the emergence of concerns for the interests of individuals that go beyond wellbeing, they highlight some ethical problems that are characteristic of these fields, and thus must be addressed by any code of ethics that extends its reach to behavioural research, as did the Belmont Report.

*The Milgram Experiment*

The Milgram Experiment, first published in 1963, raised problems about deception and consent in psychological research. The purpose of the experiment was to study obedience and disobedience to authority, through having an experimenter tell a subject “to obey a set of increasingly callous orders, and...to see when he would stop obeying.” Stanley Milgram was inspired to undertake this experiment due to an interest in the role of obedience in the Nazi extermination of European Jews during the Holocaust. This study generated surprising and significant results about the extent to which ordinary people would obey orders, and has become one of the most discussed psychological experiments today. However, Milgram’s methods also generated vast amounts of criticism on ethical grounds.

Due to an interest in studying a diverse range of individuals, Milgram drew

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156 Milgram, *Obedience to Authority*, pp.1-2.
his subjects from the New Haven community (of about 300,000 people). He recruited subjects by placing an advertisement in a local newspaper, calling for people of all occupations to take part in a study on learning and memory, offering a $4 payment and 50 cents carfare for one hour of participation. He selected subjects to ensure a range of ages and occupations were represented. One subject, and one “victim” took part in each experiment. Unbeknownst to the subject, the victim was not a fellow participant; he was in fact a 47 year old accountant, trained for the role. The subject and victim were told that they were taking part in a study that was designed to test the effect of punishment on learning. Both the victim and the accomplice drew ballots to see which would play the teacher and which the learner (but the ballots were rigged to ensure that the subject was always the teacher; both slips of paper said “Teacher”).

Immediately after drawing the ballots, the teacher and learner were taken to an adjacent room, where the learner was strapped into a device that resembled an electric chair. This was to convey the impression that he could not escape. The learner was told that he will be attempting to learn a list of word pairs, and that he will be given electric shocks of increasing intensity whenever he makes an error. The experimenter informed the teacher (in order to improve credibility) that although the shocks could be extremely painful, they would not cause “permanent tissue damage” (this assurance was repeated by the experimenter throughout the experiment whenever the teacher expressed concerns for the health of the learner). The teacher was then taken into another room and seated in front of a shock generator. The generator included 30 switches, increasing in increments of 15 volts, from 15 to 450 volts. In addition, there were labels under groups of four switches, designating them, from left to right as “Slight Shock, Moderate Shock, Strong Shock, Very Strong Shock, Intense Shock, Extreme Intensity Shock and Danger: Severe Shock.” The final two switches on the far right were simply marked XXX.

158 Milgram, Obedience to Authority, pp.14-19.
159 Milgram, Obedience to Authority, p.19.
160 Milgram, Obedience to Authority, p.20.
Prior to beginning the task as teacher, the subject was given a sample shock of 45 volts from the shock generator (this was the only real shock that was given over the course of the experiment). The subject was then told to administer a shock to the learner every time he got an answer wrong, moving one level higher on the shock generator with each wrong answer. He was also told to announce the voltage level of the shock before giving it, serving as a constant reminder of the intensity of the shock. The learner then undertook a word-association task, in which the teacher read him a series of word pairs, and he was required, when given the first word, to remember which word had originally been paired with it (when given four options). He indicated his answer by pressing one of four switches in front of him, which lit up one of four quadrants in an answer box located on top of the teacher’s shock generator. The learner gave predetermined responses, at a rate of about three incorrect answers to every correct one.\textsuperscript{161}

The learner also gave predetermined responses to increasing levels of shock. He indicated no discomfort until the 75 volt shock, where he gave a small grunt. At the 120 volt level, he cried to the experimenter that the shocks were becoming painful. At 135 volts he groaned in pain, and at 150 volts he shouted: “Experimenter, get me out of here! I won’t be in the experiment any more! I refuse to go on!”\textsuperscript{162} He continued to increase the intensity of his responses, and continued to insist on being released. At 270 volts he let out an agonized scream, and at 300 volts he refused to answer any more questions. The experimenter would instruct the teacher to treat no response as a wrong answer, and continue shocking the victim according to the schedule. The learner would continue to shriek in agony until 330 volts, where he fell silent.

When the teacher asked the experimenter whether she should continue with the experiment, or refused to continue, the experimenter would give four “Prods” of increasing insistence to encourage the subject to continue,

\textsuperscript{161} Milgram, \textit{Obedience to Authority}, p.22.  
\textsuperscript{162} Milgram, \textit{Obedience to Authority}, p.23.
ranging from “Please continue, or, please go on” to “You have no other choice, you must go on.” When the subject refused to continue after Prod 1 had been used, the experimenter moved on to Prod 2. If the subject refused to obey the experimenter after Prod 4 was used, the experiment was ended. Milgram found, through several incarnations of the study, that about 60 percent of the subjects were “fully obedient”, that is, they continued with the experiment up to the highest shock level.

After the experiment, the subject was debriefed about the real purpose of the experiment, and told that no shocks were administered to the learner. Each subject had a friendly reconciliation with the learner, and an extended discussion with the experimenter, where they were assured that their reactions were completely normal. During this interview, when subjects were asked why they continued with the experiment, the typical response was “I wouldn’t have done it by myself. I was just doing what I was told.” All subjects received a written report at the completion of the study that detailed the experimental procedure and results, and were invited to take part in a follow-up questionnaire, which allowed them to express their thoughts and feelings about the research and their behaviour.

Milgram’s research generated controversy on several ethical grounds. In 1964, a year after the study had been published, Diana Baumrind attacked the study on the basis that Milgram had not done enough to protect his subjects from harm. Baumrind was unconvinced that the follow-up interview was sufficient to dispel the emotional disturbance caused to the subjects, which was “nearly unprecedented in sociopsychological experiments.” She maintained that no psychological research can have significant enough benefits to justify causing subjects permanent harm, no matter how slight. She held that such research should not take place unless

163 Milgram, Obedience to Authority, p.21.
164 Milgram, Obedience to Authority, p.170.
165 Milgram, Obedience to Authority, p.8.
166 Milgram, Obedience to Authority, p.24.
the subjects were informed of the risk of serious after-effects, and that more evidence was needed to show that Milgram’s attempts at correcting the harm caused were successful.169

In response to Baumrind’s criticisms, Milgram maintained that “the extreme tension induced in some subjects was unexpected”170, as was the extent to which the subjects would obey the experimenter. By the time these effects became clear, Milgram held, he believed that he was justified in proceeding due to the fact that “the subjects themselves strongly endorsed the experiment”.171 The follow-up questionnaires endorsed this contention, he held, with 84 percent of subjects responding that they were glad to have been part of the experiment, 80 percent suggesting that more experiments of this sort should be carried out, and 74 percent holding that “they had learned something of personal importance as a result of being in the study.”172

Milgram held that the response from the subjects was overwhelmingly positive, with many subjects responding that participation in the experiment had been a valuable experience. He judged that participants had not been exposed to any risk of harm during the experiment, a judgment he suggested was vindicated when he had an impartial medical examiner interview 40 of the experimental subjects, who found that although several subjects had experienced extreme stress, none showed signs of having been harmed by the experience.173

It should be noted that Milgram underestimated the extent to which participation in this experiment had a profound and lasting effect on subjects, as can be seen by subjects’ accounts of their experiences 40 years later.174 However, even if Milgram was correct in asserting that the experience had generally been positive for the subjects, giving them “an opportunity to learn something about themselves and, more generally, about

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the conditions of human action”\textsuperscript{175}, Herbert Kelman argued that this was “beside the point.” He questioned the idea that social psychologists, “for the purpose of experimentation, have the right to provide such potentially disturbing insights to subjects who do not know that this is what they are coming for”.\textsuperscript{176} Kelman was concerned about the potential of Milgram’s experiment (and other psychological experiments) to cause harm, but his concerns reached beyond that. He was also concerned “about the less obvious cases, in which there is little danger of harmful effects, at least in the conventional sense of the term. Serious ethical issues are raised by deception per se and the kinds of use of human beings that it implies.”

Kelman holds that we would never think about using others this way in our normal interhuman relationships; “[w]e would view such behavior as a violation of the respect to which all fellow humans are entitled...we seem to forget that the experimenter-subject relationship...is a real interhuman relationship, in which we have a responsibility towards the subject as another human being whose dignity we must preserve.”\textsuperscript{177}

Kelman, however, recognises that it is “difficult to formulate an unambiguous position on the problem”\textsuperscript{178} of deception. As a social psychologist himself, he recognises that there are good reasons to use deception in psychological research, as there are many significant problems that could not be investigated without the use of deception. Whenever it comes to using deception in valuable research, Kelman maintains, “we are always confronted with a conflict of values.”\textsuperscript{179} Kelman was concerned, however, that deception in psychological research is becoming a matter of routine, and that it is used without question or consideration.\textsuperscript{180} He suggests that we think carefully about using deception in research, and actively try to come up with ways for conducting experiments that are not so dependent on deception. He holds that the routine use of deception in social psychology

\textsuperscript{175} Milgram, “Issues in the Study of Obedience”, p.850.
\textsuperscript{177} Kelman, “Human Use of Human Subjects”, p.5.
\textsuperscript{178} Kelman, “Human Use of Human Subjects”, p.2.
\textsuperscript{179} Kelman, “Human Use of Human Subjects”, p.2.
\textsuperscript{180} Kelman, “Human Use of Human Subjects”, p.3.
is of concern beyond undermining respect for and the dignity of the subject. He also argued that proceeding in this manner also risks undermining the whole enterprise of psychological research, for two reasons. When faced with routine deception, subjects will become increasingly aware of this, more sophisticated in dealing with it and it will become self-defeating. In addition, continuing this practice will lead subjects to become increasingly distrustful to the point at which the relationship between experimenter and subject is undermined.\textsuperscript{181}

The Milgram experiment highlights problems about quantifying harm. Where the risk of harm in medical research will often be physical, Baumrind’s criticism of Milgram’s research raises the possibility that risk of harm should also take possible psychological harm into account. This case also raises questions about deception. Even if deception is not seen as a direct harm, there seems something ethically problematic about it, although it may be hard to pin down exactly what that is. As we shall see in Chapter 5, philosophical accounts of this problem often argue that the wrong of deceiving is derivative from the value of autonomy. I will argue that this approach does not adequately capture the ethical issues here, and will propose an alternative approach that follows from my wider theory. As with the other cases, we see evidence of a growing concern for dignity of human subjects, independent of considerations of wellbeing.

\textit{Tearoom Trade}

The Tearoom Trade research, conducted by graduate student Laud Humphreys from 1965-8\textsuperscript{182}, represents a controversial case in sociological research which allows us to explore some of the ethical issues in this domain. At a time when homosexuality was illegal, Humphreys was interested in studying the then casual sexual encounters between men in public restrooms, or “tearooms” as they were referred to in the homosexual

\textsuperscript{181} Kelman, “Human Use of Human Subjects”, p.7.  
His research took part in two stages. Firstly, Humphreys stationed himself in public bathrooms in which these encounters took place, taking on the role of “watchqueen”; a voyeur and lookout who would alert others when strangers or police approached. This allowed Humphreys to observe hundreds of acts of fellatio without arousing the suspicion of the participants.

Secondly, he recorded the license plates of the cars of 134 men involved in homosexual activity in the tearooms. With the help of some policemen (whom he informed he was doing market research) he was able to identify 100 of these men and discover their addresses using license registers. After scoping out their houses and neighbourhoods, Humphreys had the chance to insert these men into a questionnaire he was asked to develop to survey the social health of men in the community. In this manner, he was able to interview 50 men, and to compare their responses to those of a control group. Humphreys took careful measures to protect the men surveyed; he kept the list of interviewees in a safe deposit box, and destroyed all identifying information upon completion of the survey. He allowed a year to pass between his observations and the survey process, and changed his appearance, dress and car before conducting the interviews. He was confident that none of the men he interviewed recognised him. Additionally, after gaining the confidence of 12 of the men he met during the tearoom encounters, Humphreys revealed his role as a researcher and was able to have them explicitly agree to be interviewed. He wished to go beyond these interviewees, however, because he was concerned that these willing participants did not constitute a representative sample.

Humphreys’ research began to generate controversy soon after he completed his dissertation. Critics were concerned about the use of deception in his research.

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183 Humphreys, Tearoom Trade, p.2.
184 Humphreys, Tearoom Trade, p.26.
185 Humphreys, Tearoom Trade, p.33.
186 Humphreys, Tearoom Trade, p.39.
187 Humphreys, Tearoom Trade, p.41.
188 Humphreys, Tearoom Trade, p.42.
189 Humphreys, Tearoom Trade, p.36.
190 Humphreys, Tearoom Trade, p.37.
research, and about whether he had taken adequate measures to protect his subjects.\textsuperscript{191} Nicholas von Hoffman published a scathing critique of the research in the \textit{Washington Post} in 1970, in which he brought out several related ethical issues. Von Hoffman was concerned that covert research undermined the dignity of the subjects through impinging on their privacy, contending that “to be a complete human involves having an aspect of ourselves that is unknown.”\textsuperscript{192} He was also concerned that collecting this type of information about participants without their knowledge left them vulnerable to blackmail and extortion.\textsuperscript{193} Collecting the type of data Humphreys did was particularly risky because it could have been used to prosecute the subjects involved, and as a social scientist he was not legally protected from being compelled to hand this information to the police if requested.\textsuperscript{194} Furthermore, he implies that this research compromised the liberty of the subjects, stating that “[n]o information is valuable enough to obtain by nipping away at personal liberty.”\textsuperscript{195}

In defence of his research, his supporters argued that this research in this area was of the utmost importance to society. A high percentage of police arrests were occurring among the men frequenting the tearooms, but nothing was known about the people who engaged in these behaviours.\textsuperscript{196} They contended that all information was currently collected and controlled by police, and that we were in need of a countervailing source of information.\textsuperscript{197} The findings of Humphreys’ research “could contribute to enlightened social policy.”\textsuperscript{198} The right to a full public discourse, they

\begin{itemize}
\item \textsuperscript{193} Von Hoffman, “Sociological Snoopers and Journalistic Moralizers: Part I”, p.179.
\item \textsuperscript{195} Von Hoffman, “Sociological Snoopers and Journalistic Moralizers: Part I”, p.181.
\item \textsuperscript{196} Glazer, “Impersonal Sex”, p.216.
\item \textsuperscript{198} Glazer, "Impersonal Sex", p.216.
\end{itemize}
argued, was more important than a right to privacy.\textsuperscript{199}

Humphreys suggested that deception concerning his purpose in the tearooms was necessary to collect this valuable data. A suspicion of outsiders meant that posing as one of the participants was the only way in which he would be permitted to observe this behaviour. Furthermore, even if he had been able to find men that were willing to continue their sexual behaviour under observation, he was concerned that his presence as a researcher would distort this behaviour. In order to observe normal activity, he contended that he must pose as an insider.\textsuperscript{200} In response to the charges that the research violated the privacy of the subjects, supporters pointed out that all the observations that Humphreys carried out were acquired in a public setting.\textsuperscript{201} Humphreys echoes this argument, stating that “[t]hese were, after all, public restrooms, and my role, a natural in one of those settings, provided extra protection for participants.”\textsuperscript{202} David Warwick questions this defence, however, suggesting that “the point of Tearoom Trade is to show that tightly private interaction networks develop in public places.”\textsuperscript{203} Warwick suggests that even though these encounters took place in public, their highly private nature might raise ethical questions about invasion of privacy.

The question of whether this research involved the infringement of liberty is a difficult one to answer. Irving Horowitz and Lee Rainwater maintained, against von Hoffman’s accusations, that it was not clear that the liberty of the subjects was actually undermined.\textsuperscript{204} However, in considering how and whether this research could be thought to impinge upon freedom, Warwick suggests that increased public awareness of the fact that covert social research is taking place may begin to limit freedom by instilling a tendency

\textsuperscript{199} Horowitz and Rainwater, “Sociological Snoopers and Journalistic Moralizers: Part II”, p.186.
\textsuperscript{200} Humphreys, \textit{Tearoom Trade}, pp.25-6.
\textsuperscript{201} Horowitz and Rainwater, “Sociological Snoopers and Journalistic Moralizers: Part II”, p.185.
\textsuperscript{203} Warwick, “‘Tearoom Trade: Means and Ends of Social Research”, p.203.
\textsuperscript{204} Horowitz and Rainwater, “Sociological Snoopers and Journalistic Moralizers: Part II”, p.188.
in individuals to live “for the record”. An awareness that they may be observed might lead to individuals basing their decisions, at least to a certain extent, on how they would be perceived by a third party. Warwick also maintains that allowing individual researchers’ freedom of inquiry can undermine freedom for researchers in general, if this research generates distrust and suspicion of researchers. This could lead to less societal support for and cooperation with researchers, and may limit valuable future research.

The risk of harm to subjects is also a matter of ethical concern in this study. In addition to the risk, noted above, that the information collected by Humphreys could be used for extortion, blackmail or prosecution if it fell into the wrong hands, Myron Glazer points out that the publicity surrounding this research might lead men to realise that they had been a subject of it, and thus fear exposure. Though Humphreys took great care to protect the information identifying his subjects, he had no legal means to prevent the police from demanding that he hand it over; something that subjects may well have been aware of when they realised that their information had been collected. Glazer suggests that research subjects should not be put at such risk of harm without their consent.

At the time of conducting the research, Humphreys believed that deception concerning the purpose of his study when approaching men with the questionnaire was the most appropriate means of collecting the necessary data while minimising risk. Upon scoping out the houses of the men he had gathered information on, he realised that many of them were married, and most were very secretive about their behaviour, so approaching them directly at their home would be inappropriate. He also wanted a chance to observe the home lives of the subjects, so he believed that the only way to gather this data was to mislead his subjects about the intention of his

208 Glazer, “Impersonal Sex”, p.221.
Horowitz and Rainwater defended Humphreys’ method, suggesting that deceiving the subjects about the purpose of the interviews was a necessary means of protection, as Humphreys “could not control the destructive impact” of telling subjects he was aware of their behaviour.²¹⁰

However, upon engaging with the criticisms that stressed the risks of collecting data which identified the subjects, Humphreys came to agree that the danger posed by his actions was too great. As he states in a reflection upon the ethics of his research:

I am forced to agree with my critics regarding that part of the study in which I traced license numbers and interviewed respondents in their homes...It seemed to me that I was interviewing subjects in the least disturbing and least dangerous manner possible. I now think my reasoning was faulty and that my respondents were placed in greater danger than seemed plausible at the time.²¹¹

Though Humphreys admits that he placed subjects at unnecessary risk of harm, stressing that if he were to conduct the study again, he would seek informed consent from all subjects,²¹² he remained convinced that he was justified in his covert observation in the tearooms.²¹³ Humphreys also stressed that his research had generated positive consequences, citing the fact that “this study is increasingly cited by attorneys seeking acquittal for clients arrested in public restrooms.”²¹⁴

Humphreys’ research highlights problems about privacy and covert observation, which, like deception in social psychology, are central to the design of some sociological research. As with deception, the questions of when and why this conduct might be justifiable are very difficult to answer. Any research ethics guidelines in this field must, however, have some way of dealing with these issues. This highlights the diverse range of interests

²⁰⁹ Humphreys, *Tearoom Trade*, p.41.
²¹² Though it is not clear that he could have obtained consent under the circumstances.
that individual research subjects might have that go beyond a risk of harm.

**Ethical Issues: Summary**

These cases highlight some ethical issues that arise in the context of various types of research, as well as drawing attention to some of the shifting ethical values during this time period. The publication and subsequent controversy surrounding all four cases lead to a growing realisation that leaving identification of the ethical issues in research and determination of ethical conduct to the discretion of the researchers themselves was an insufficient means of making sure the interests of the subjects were adequately protected. More specifically, in the medical research cases, the idea that doctors should be able to exercise discretion over what to reveal in a research capacity is brought into question. The US government responded to this problem by strengthening the requirements for external ethical review. Requirement for external review was also incorporated into the 1975 revision of the Declaration of Helsinki,\textsuperscript{215} which, as we have seen, placed the responsibility for ethical conduct entirely on the researcher in its original incarnation. These measures were certainly a necessary and appropriate response to the proliferation of unethical research conducted by physicians. I contend, however, that the root of some of the problems that we saw in these cases was deeper than this, and can be traced to the Declaration of Helsinki’s approach to beneficence, an approach which is central to the document, and remains in its most recent version. I will critique the contemporary version of the document, and explore this issue, in Chapter 3.

We can also see, across all four cases, emerging concerns for respecting humans, where this is conceived as going beyond simply showing respect for wellbeing. This can be shown by concerns about failure to seek consent that are not based on concerns about risk of harm, and the frequent references to human dignity across discussion of these cases. The

background factors that contributed to this shift in concerns will be brought out in the next section where I talk about the rise of autonomy. I will fully explore the concepts we have seen emerge in discussion of these cases: human dignity, respect and autonomy in Chapter 4, revealing the philosophical foundations and links between these notions.

The social science research cases also reveal problems that cannot be completely solved by improved standards of informed consent; the problems posed by deception and covert surveillance. As we have seen, these methods seem necessary to the design of much research in this domain, however, as well as generating potentially negative consequences, they seem to undermine respect for research subjects. I will suggest an approach to these problems in Chapter 5.

**The Rise of Autonomy**

As details of the research cases outlined above were emerging, events were taking place which led to a fundamental shift in the traditional, beneficence-based model of medical ethics, which in turn had a significant effect on research ethics. We will now explore some of the primary reasons behind this shift, and get a better idea of what was of concern here. This will help to clarify what is being referred to when we talk about autonomy in the context of medical and research ethics, which I contrast with the idea of theoretical philosophical autonomy in Chapter 4. Though Faden and Beauchamp have already provided an excellent account of the rise of autonomy in medical and research ethics in their *History and Theory of Informed Consent*, I provide my own account here because I will draw upon this material in Chapter 4 to show that their idea of autonomy is at odds with autonomy as it is employed in theoretical philosophy, and to argue that their model of autonomy has a severe shortcoming which makes it unable to fulfil its purpose in research ethics. The factors I will outline in this section will help to explain why Faden and Beauchamp take the approach that they do to autonomy, and will allow me to devise a model of respect for persons in Chapter 5 that takes these factors into account.
Although, as we have seen, consent formed an essential ethical consideration in research ethics from its inception, it was not until the late 60s and 70s that it really began to be associated with respect for persons and autonomy in the way that it is in contemporary discussions. This was a result of several drastic, interlinking societal shifts, chiefly surrounding the rise in a concern for civil liberties and reactions to rapidly advancing medical technology.\textsuperscript{216} It is worth tracing out some of these events to understand the societal context from which informed consent guidelines were being produced. As I shall suggest below, it is easy to see, in a general sense, the effects of this revolutionary period on the way that research ethics have developed. When these historical events are coupled with an analysis in the shift of the language used and the way that various values are conceived in research ethics guidelines, it is possible to piece together some insights into the changing aims of and motivations behind informed consent guidelines.

Autonomy’s displacement of beneficence as the fundamental guiding value in medical ethics can be dated to roughly 1970.\textsuperscript{217} Eric Cassell notes that when he went into practice in 1961, the beneficence model of medicine was firmly entrenched, but by the end of the decade it had largely and permanently disappeared. Cassell does an exceptional job of highlighting the many, complicated, intertwined factors that led to the rise of autonomy.\textsuperscript{218} In what follows, I will simply attempt to identify some of the significant themes covered by Cassell.

Several significant changes in society came to affect the way people viewed the medical enterprise, and themselves. A growing suspicion of medical authority in particular and authority in general made people less willing to assume that doctors would act in a benevolent manner. Several high-profile

\textsuperscript{216} Faden and Beauchamp, \textit{A History and Theory of Informed Consent}, p.87.
cases of abuse of research subjects, two of which have been documented above, raised doubts about the trustworthiness of the medical profession.\textsuperscript{219} In addition, the antiwar protests during the 1960s generated social unrest, challenged the top-down structure of society, and resulted in a diminishing respect for the government, and for authority generally.\textsuperscript{220}

At the same time, an increased interest in individualism and self-determination was spurred by the growing prominence of several rights movements. Civil rights, women’s, gay, patients’, disability, and prisoners’ rights movements, among others, all emerged into society during this period of time. The rise of a patient rights movement and its focus on autonomy and consent was modelled directly on these other rights movements, which provided an essential map for progress and the inspiration that ensured its success.\textsuperscript{221} The civil rights movement in particular became a crucial influence on the other rights movements that followed including those impacting the domain of medicine, fostering a distrust of authority and scepticism concerning paternalism.\textsuperscript{222} Some aspects of these movements also directly intersected with health care. In the women’s movement, for example, reproductive rights, abortion and contraception all became important issues. The application of these rights-based movements to health care reinforced this rights-based approach to health care in general.\textsuperscript{223} This was also tied up with a growing suspicion and distrust of doctors. For example, hysterectomies were routinely performed to treat a range of illnesses until the 1970s, but a wide variation in the prevalence of the operation in different places led to the suspicion that the surgery was often being performed for other reasons. These concerns were incorporated into the women’s movement in the 1970s, which led to the denunciation of physicians and calls for women to take back their bodies from medicine.\textsuperscript{224}

\textsuperscript{219} Faden and Beauchamp, \textit{A History and Theory of Informed Consent}, p.87.
\textsuperscript{220} Cassell, “The Principles of the Belmont Report Revisited”, p.79.
\textsuperscript{222} Rothman, \textit{Strangers at the Bedside}, p.99.
\textsuperscript{223} Faden and Beauchamp, \textit{A History and Theory of Informed Consent}, p.87.
In addition to this significant social upheaval, the rapidly advancing medical technology decidedly changed the way that medicine was practiced. Robert Veatch describes the increasingly advanced, technology-driven and impersonal medical care in the 60s and 70s as a “tyranny of technology.”

Medical advances led to chronic diseases, rather than infections or acute diseases, overwhelmingly becoming the cause of death and medical care. Life-extending therapies kept patients alive for far longer than was possible before, and for far longer than a decent quality of life could be maintained. Patients began to react against these excessive and aggressive interventions, and the goods that had traditionally been upheld by medicine (for example, extending life at all costs) were increasingly questioned. In addition, as medicine became progressively more technological, physicians began to change the way they administered care. Rather than treating the patient as a whole, physicians started to treat patients based on their symptoms. As patients took a more active role in their medical decisions, physicians were moving further away from taking responsibility for the whole patient.

The advance in medical technology also contributed to the rise of autonomy and the value of decision-making in a more positive way. Cassell argues that the fall in death rates and increases in health and wellbeing led to a new optimism in medicine, and gave a new significance to the value of truth and freedom of choice. Prior to advances in technology, there were many more situations in which there was no possibility of a positive outcome, and thus no room for meaningful choice. When a patient’s prognosis was bleak, and there was not much that could be done about it, it made sense for physicians to lie – protecting patients from the truth was all that could be done for them. With the increased array of options that advances in technology enabled, however, knowing the truth about one’s situation, and having the freedom to choose, took on a new value.

What, then, came of these fundamental social and technological changes?

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226 Cassell, “The Principles of the Belmont Report Revisited”.
Cassell posits that as society and medicine changed, the very nature of persons, and as a result, the meaning of respect for persons changed too. In the early 1960s beneficence and non-maleficence were seen as the expression of respect for the person. A shift in medicine to a view of people as entities with rights, however, created a situation where it is not only possible to harm people, but to wrong them. This view of persons was completely unprecedented in medical ethics. Cassell contends that these changes have completely redefined the notion of respect for persons, moving it away from concerns of beneficence and instead seeing it expressed “almost solely [through] the right of the patient to choose independently from among all options.” How this relates to the notion of autonomy as understood in a philosophical sense will be taken up in Chapter 4.

**The Belmont Report**

I have already presented a basic outline of the Belmont Report earlier in this chapter. After this historical account, however, we can see why, for the first time, autonomy was made a central value in the document. The Belmont Report also reflects the realisation that obligations that stem from the beneficent concern for individuals can conflict with the desire to benefit society generally.

As a result of the high profile cases of ethically dubious research practices, discussed above, the National Research Act was passed in the United States in 1974. This Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was assigned the task of identifying the basic principles that should guide ethical research on human research participants, and developing guidelines to ensure adherence to these principles. The National Commission issued the Belmont Report in 1978 (it was subsequently published on the U.S. Government’s Federal Register in 1979), outlining three ethical principles.

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228 Cassell, “The Principles of the Belmont Report Revisited”, p.84.
231 Office for the Protection of Research Subjects, “History of Research Ethics”.
that were to provide a framework for the resolution of ethical problems in human research.\textsuperscript{232} The Belmont Report represents a shift from guidelines that focused specifically on medical research to guidelines that are also meant to apply to behavioural research, though, as was noted by Tom Beauchamp, who was involved in the production of the Belmont Report, the explication “of the values being advanced was heavily influenced by the context of biomedicine (and rather less influenced by contexts of the social and behavioral sciences).”\textsuperscript{233}

For the first time, we see the development of a framework of broad, flexible guiding principles which can be applied to a wide range of concrete situations. This principle-based framework represents a departure from both the Nuremburg Code and the Declaration of Helsinki, which instead took the form of a set of prescriptions. Whereas both the Code and the Declaration give set rules that ethical research must adhere to, the Belmont Report instead provides three ethical values that research must take into consideration, with compliance judged by an independent committee. The principle-based approach of the Belmont Report has been very influential in subsequent research guidelines, due to its unparalleled flexibility and its resulting applicability to many different types of research. However, despite its advantages, it still contains several significant problems, which we will discuss in the next three chapters.

I have already summarized the contents of the Belmont Report, but to briefly recap, with an eye to the effects of the historical events documented above: the three principles outlined in the Belmont Report are respect for persons, beneficence, and justice. The value of respect for persons, according to the Belmont Report, includes two components: respect for autonomy, and protection of the non-autonomous.\textsuperscript{234} For the first time, autonomy is explicitly stated as a justification for informed consent.

\textsuperscript{232} McNeill, \textit{The Ethics and Politics of Human Experimentation}, p.139.
\textsuperscript{234} The National Commission, \textit{The Belmont Report}, Part B: Basic Ethical Principles.
requirements. Beneficence is expected to provide both the obligation to conduct research in order to generate benefits for society, and also to protect the well-being of individual research participants.\textsuperscript{235} Justice is concerned with the fair distribution of research benefits and burdens. The Report also outlines the corresponding applications of the three principles: respect for persons is secured by informed consent, beneficence through an assessment of the risks and benefits of the research, and justice through fair procedures in the selection of research participants.\textsuperscript{236}

The Belmont Report, produced in 1978, comes definitively after the rise of autonomy in research ethics. Evidence of the new value of autonomy in the document is clearly visible. For the first time, autonomy is explicitly stated as the justification for informed consent requirements in research. A separate principle of beneficence incorporates considerations of the wellbeing of the individual, as well as a concern for the other benefits which can come from research. Beauchamp explicitly states that the purpose of informed consent is to protect “autonomy and personal dignity”\textsuperscript{237}, and that it has moved away from consent provisions in earlier ethical research documents, which imply that protection of wellbeing is the aim of consent requirements.\textsuperscript{238} These principles, therefore, are each designed to cover a separate “zone of moral concern”.\textsuperscript{239 240}

The principle of beneficence reflects the concerns raised by the Ad Hoc Advisory Panel in response to the Tuskegee Syphilis study and the state of research ethics in the United States in general. As we have seen, the panel continually noted that the most significant conflict in research ethics involved balancing the interests of the research subjects against the interests of society. The Belmont Report notes that beneficence in research includes concerns about the wellbeing of individual research subjects, and concerns about providing benefit to science and society through research.

\begin{footnotesize}
\textsuperscript{235} Levine, “Reflections on Rethinking Research Ethics”, p.2.  \\
\textsuperscript{236} The National Commission, \textit{The Belmont Report}, Part C: Applications.  \\
\textsuperscript{237} Beauchamp, “The Origins and Evolution of the Belmont Report” p.18.  \\
\textsuperscript{238} Beauchamp, “The Origins and Evolution of the Belmont Report” p.18.  \\
\textsuperscript{239} Beauchamp, “The Origins and Evolution of the Belmont Report” p.18.  \\
\textsuperscript{240} I will critically appraise this claim in Chapter 5.
\end{footnotesize}
Furthermore, it notes that these imperatives can sometimes clash, producing difficult ethical conflicts. I will critically appraise the Belmont Report’s approach to beneficence in Chapter 3.

**Conclusion**

This chapter has traced the approach in several prominent, contemporary research guidelines back to the Declaration of Helsinki and the Belmont Report, and has aimed to come to an understanding of the values behind these documents through situating them in an historical context. Based on this material, it is now possible to turn to an interrogation of two specific ethical problems that plague both the approaches of the Declaration of Helsinki and the Belmont Report, and that remain in the contemporary research ethics documents. The historical material will aid in clarifying some of the terms that I will now go on to discuss, and helps us to understand the various factors that influenced our perception of the role of informed consent, and the notions of autonomy and beneficence, and their proper role in research.

Through looking at the earliest uses of informed consent in both medicine and research, we can see that the notion of informed consent in both medicine and research has fundamentally changed, and that consent may, for various reasons, function as a good means of protecting and promoting the wellbeing of research subjects or patients. After I have argued that some aspects of the contemporary approach to research ethics do not show a full appreciation of the ethical issues specific to the research, I will suggest, in Chapter 5, that informed consent guidelines, if appropriately formulated, may provide a better means of protecting and promoting the wellbeing of research subjects than the current, beneficence-based approach.

From looking at the original Declaration of Helsinki, we have seen the extent to which it relies on a notion of beneficence (akin to that found in medical therapy) to protect the wellbeing of individual research subjects. My next chapter will show that despite the various reformulations of the Declaration of Helsinki throughout time, the notion that this idea of
beneficence is a good means of protecting and promoting the wellbeing of the research subject still undergirds the contemporary version of this document. I will argue that a proper understanding of research ethics necessitates understanding and emphasising the differences between beneficence in medical therapy, and beneficence in a research context. I will argue that the Belmont Report does not sufficiently recognise this either, and that this has led to enduring problems in research ethics.

The rising value of autonomy was also apparent in the discussion of the specific cases of notorious research. The discussion of the wider social factors which contributed to the increased prominence of this value in the context of research and medical ethics began to give us an idea of what autonomy might be thought to involve in this field, and what people who espouse this value are interested in promoting and protecting. This understanding will aid our discussion of autonomy in Chapter 4.
Chapter 3: The Problem of Beneficence

Introduction

This chapter will be concerned with illustrating a significant problem with both the Declaration of Helsinki and the Belmont Report (and thus a problem with the contemporary approach to research ethics); I will term this the “problem of beneficence”. The problem of beneficence, in short, is the failure of contemporary research ethics guidelines to adequately recognise the different obligations generated by a principle of beneficence in research and medical therapy and a tendency to thus rely on a notion of beneficence which is too influenced by medical therapy, leaving guidelines unable to deal with the special challenges that arise through the consideration of the role of this value in research.

Where beneficent concern in medical therapy is directed towards the individual patient, beneficence in research involves a more complicated mix of interests. As well as the imperative to take the wellbeing of the individual research subject into account, beneficence in research demands that we facilitate research that can benefit society as a whole. In research, therefore, we must balance the protection and promotion of the wellbeing of the individual research subject against the promotion of the wellbeing of society through beneficial research. The question of the extent to which the interests of society can legitimately trump the interests of the individual, or vice versa, is one of the most difficult ethical questions in human research. The Belmont Report and the Declaration of Helsinki, however, still contain an idea of beneficence which is too influenced by the ethics of medical therapy, and are thus unable to recognise, or to do justice to the challenges that attend the application of this value in a research context.

After a short introduction to the role of beneficence in research, I will illustrate the extent of this problem, and the need for a different approach, by first turning to some of the most significant revisions in the Declaration of Helsinki, which were made in part as an attempt to combat this problem. I will argue that these revisions do not adequately address the problem of beneficence in research, and that the contemporary version of the
Declaration of Helsinki is still based upon a notion of beneficence that is overly influenced by medical therapy. I will then look at the phenomenon of the therapeutic misconception in research (the research subject’s belief that research has therapeutic intent, or is conducted according to therapeutic norms of conduct) to further illustrate the shortcomings of the Declaration of Helsinki’s approach to beneficence, and the need for an ethical framework for research that is distinct from the ethical framework in medical therapy.

Next, I will turn to the treatment of beneficence in the Belmont Report, arguing that although the Belmont Report makes significant progress in acknowledging the problem of beneficence, and clarifying its role in the context of research, it is still too influenced by therapeutic medical ethics, and is thus also unable to deal with the problems highlighted by the therapeutic misconception. By the end of this chapter, the significance of this problem to research ethics, and the need for a different approach to beneficence in research, will be established. I will conclude by providing some suggestions for an alternate approach to beneficence in research, which will be fully fleshed out in Chapter 5, after I have dealt with problems concerning autonomy, respect for persons and informed consent in Chapter 4.

**Beneficence in Research**

Beneficence is broadly understood in ethical theory as “including effectively all forms of action intended to benefit or promote the good of other persons.” 242 Though some philosophers argue that many beneficent acts are supererogatory, in the context of medical and research guidelines, acting beneficently is regarded as obligatory. 243, 244 In fact, beneficence is regarded as a major justification for medical research. 245 The aim of medicine is to promote and protect health and wellbeing, research in this context thus

attempts to work out how best to achieve this aim, through, for example, developing new and more effective treatments against various types of illness. Beneficence, as we have seen in Chapter 2, also provides the major impetus for therapeutic medicine. The obligation to benefit the patient has been seen, from the time of the Hippocratic Oath, as the most fundamental obligation of the physician.

Production of benefit can also be regarded as a motivation for social science research. We saw, in Chapter 2, that Humphreys justified his controversial research by stressing the beneficial consequences that his results had generated. However, whether benefit can be said to provide the impetus for social science research is more contentious, and will clearly depend on how one defines what constitutes a social benefit. Social science research is more likely to be geared towards the acquisition of knowledge, with only a secondary, if any, emphasis on the beneficial applications of that knowledge.246 Whether this knowledge in itself should be regarded as a societal benefit is an open question. I explore the specific issues that arise in the context of social science research in the second appendix. This chapter will focus primarily on medical research.

When we see that beneficence simply amounts to an obligation to produce benefit for others, it becomes apparent that the requirements of this obligation will vary in different contexts. Though beneficence forms the driving force behind both medical therapy and research, the obligations that are generated by the imperative to act in a beneficent manner in these two fields are fundamentally different. In medical therapy, the beneficent concern of the doctors is, generally, primarily aimed towards protecting and promoting the wellbeing of the patient.247 Medical research can involve putting subjects at risk of harm, in order to determine what might benefit

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247 This is not to say that concern for the wellbeing of the patient is always the sole and foremost concern of the therapeutic physician; therapeutic physicians also have obligations to take the wellbeing of friends and family of the patient (e.g. when delivering a diagnosis, or dealing with a disease that may be transmitted to them) and society as a whole (e.g. concerning infection prevention methods such as vaccines and quarantines) into account.
others. Prioritising and promoting the wellbeing of the individual may function as an appropriate goal in medical therapy, but to adopt the same goal in research would be to preclude much potential overall benefit. This problem is compounded by the fact that advances in medical therapy are contingent on developments in research. By prioritising the wellbeing of the individual in research ethics, we prevent developments in patient care that will allow us to better benefit individual patients. The more complicated mix of interests involved in research requires a different approach to the principle of beneficence.

The most fundamental challenge of beneficence in research involves balancing the imperative to generate benefit to science and society through research with the requirement to promote, or at least protect, the wellbeing of individual research subjects, two objectives that, although they are both based upon obligations of beneficence, will routinely clash. The fundamental nature of this challenge and conflict should not be underestimated. As we have seen in the previous chapter, the Tuskegee Syphilis Study’s Ad Hoc Advisory Panel continually emphasised that balancing the interests of the individual against the interests of society as a whole is the most fundamental problem of human research. Unless we understand the differences in what beneficence demands in these two different fields, we will not be properly equipped to approach this significant challenge.

**Beneficent Motives in the Jewish Chronic Hospital Disease Case**

In order to illustrate what can happen when the different roles of beneficence in the context of medical therapy and medical research are not adequately understood, it is useful to return to the Jewish Chronic Hospital Disease Case, focusing specifically on the ways in which beneficent motives, broadly conceived, were used by the researchers as a justification.

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249 DHEW, “Final Report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel”, p.21. The interests of the individual research subjects are not limited to concerns of wellbeing; I will be looking at the other interests of the individual research subject in Chapter 4, and discussing how these interests are to be balanced against each other and against wider societal interests in Chapter 5.
for their conduct. This displays that in practice, where it is simply stipulated or understood that the physician must act in a beneficent manner, there is a risk that physicians, though acting from beneficent motives, will fail to protect the wellbeing of their research subjects, and will fail to appreciate the ethical concerns that are specific to the context of research ethics. The researchers’ use of beneficence to defend their conduct in the Jewish Chronic Disease Hospital Case highlights the differences between beneficence in research and in therapeutic medicine and displays the importance of adequately recognising the distinction through demonstrating the potential confusion that may result when these different obligations of beneficence are confused. The several different ways that the researchers invoke beneficence in defense of their conduct highlights the ambiguities that can result from a lack of clear delineation between obligations of beneficence in research and in medical therapy, affirming the importance of recognising the separation between these fields.

As we have touched upon in the previous chapter, the researchers involved in the Jewish Chronic Disease Hospital Case defended several of their actions by arguing that their motives were beneficent. However, they invoked different notions of beneficence, some of which were judged by the Board of Regents as not providing appropriate standards of conduct in the context of research. Take, for example, the various arguments employed by Southam and his colleagues to justify eschewing consent. The researchers argued that failing to acquire the subjects’ consent was justified due to the fact that the research was motivated by considerations of beneficence. This justification is akin to the kind of discretion commonly allowed to doctors at the time to exercise the therapeutic privilege; avoiding consent could be justifiable if informing a patient is likely to lead to harm. However, the researchers here attempted to justify their conduct by arguing not that conducting this research would be beneficial to the patients, but rather that it would benefit scientific inquiry.251

Even if this conduct is justifiable in therapeutic medicine, where failing to inform the patient is justified due to the fact that he will be likely to benefit through this omission, it is a different proposition entirely to avoid gaining a patient’s consent because this will be likely to prevent research that will benefit others. In therapeutic medical ethics, failing to inform a patient does not necessarily mean that their wellbeing will not be adequately protected and promoted, because the physician is obligated to prioritise the wellbeing of the patient. In research, however, failing to inform the subject risks leaving the subject vulnerable to exploitation and abuse, because the subject’s benefit is not the researcher’s only goal. The researcher, though acting from beneficent motives, may avoid the subject’s consent in order to produce benefit for others, leaving the subject at risk of harm. The researchers involved in this case were attempting to defend their actions by invoking norms that were specific to therapeutic ethics, but these norms were not an appropriate means to ensure ethical conduct when the physician took on the motivations of the researcher.

The researchers also invoked the therapeutic privilege in a different way in their justification for conducting the study without consent. They argued that informing the patients that they were being injected with cancer cells might cause distress, and for this reason, it was justifiable to withhold information about the nature of the experiment (or even the fact that the patient was taking part in an experiment). This involves a more straightforward use of the therapeutic privilege, as the omission here is aimed towards benefiting the subject, or avoiding causing him harm. However, even when the therapeutic privilege is used for its therapeutic purpose, the fact that the ultimate aim of the research is not to benefit the patient, but to benefit scientific inquiry, means that the failure to seek consent here still leaves the subject vulnerable to exploitation and abuse. Non-disclosure in a research context, where the interests of people other than the research subject come into play, presents a more difficult ethical

252 Or may show a lack of respect for the subject by treating them simply as a means; I will come back to issues concerning respect in research ethics in chapters 4 and 5.

situation that must be assessed on different terms. The risk that the interests of the subject will be sacrificed in order to produce benefit for others is a problem which is specific to the context of research, and is not adequately addressed simply by doctors acting with beneficent motives.

This study took place prior to the introduction of formal research protocols, and the violations here mainly came about as a result of these physician-researchers unquestioningly applying the ethical standards of medical therapy, or using substantial discretion in deciding what course of conduct would be appropriate. A significant development following this case, and from the Tuskegee Syphilis Study, was the introduction of requirements for prior external review of research, conducted by a panel including people from other professions and members of the general public, on the basis of set guidelines. This was an important development that forms the foundation of contemporary ethical research guidelines, and that would certainly prevent doctors from exercising the substantial discretion that they were accustomed to having, at this time, in therapeutic situations. This kind of case would, in consequence, be very unlikely to be repeated today. This, then, is not intended as a criticism of current research ethics guidelines, but rather gives us an insight into the necessity of understanding the differences between beneficence in medical therapy and in research. When the kind of beneficent conduct that may be accepted in a therapeutic situation is simply translated to research, the outcome, and the potential for exploitation and abuse, can be very different. Any adequate approach to beneficence in research must be cognisant of these substantial differences.

Research Beneficence in Philosophical Commentary

The ideas that beneficence in research is very different from the situation in therapeutic medicine, and that beneficence in research necessarily involves addressing the conflict between the wellbeing of the individual and benefit to science and society, have been discussed in philosophical work on research ethics. The philosopher Jay Katz, who was one of the members of the Ad Hoc Advisory Panel (created, as we have seen in the previous chapter, as a response to controversy surrounding the Tuskegee Syphilis
Study, to report on this case and the adequacy of research guidelines in the United States in general), has stressed the significance of the confusion between these two areas, and the extent to which the various requirements of beneficence might conflict in research. Katz is concerned about what he sees as a pervasive “obfuscation of the distinction between therapy and research and the accompanying confusion of patients and subjects.”\(^{254}\) He notes that in “therapeutic encounters, unlike research encounters, physicians are expected to attend solely to the welfare of the individual patient before them…In clinical research, on the other hand, patient-subjects are also being used for the ends of science.”\(^{255}\) Katz suggests that the lack of a clear distinction between research and therapeutic ethics leads to a belief that physician-researchers (both researchers who are conducting therapeutic and non-therapeutic research on their patients, and researchers who also just happen to be physicians) can be trusted because they will put the interests of the patient-subject first. He maintains that without a clear delineation between therapeutic and research ethics, the potential research subject’s belief that physicians will always act according to therapeutic norms persists even in cases in which there is no existing therapeutic relationship between the physician and the research subject. Unless it is clear that the aims of research are distinct from medical therapy, the assumption that doctors will always act according to therapeutic norms endures. He contends that this belief is untenable in research situations, where physician-researchers have “dual allegiances to their patient-subjects and the research protocol.”\(^{256}\) The other interests that come into research, he posits, “can only be kept in check if both physician-investigators and patient-subjects fully appreciate that both are engaged in an enterprise in which patient-subjects are also being asked to serve as means for science’s ends”.\(^{257}\)


\(^{255}\) Katz, “Human Experimentation and Human Rights”, p.15. Again, it is worth noting here that even the therapeutic physician must sometimes take the wellbeing of others into account, and this can sometimes clash with his obligations to prioritise the wellbeing of the patient before him. It is, however, fair to say that the therapeutic physician generally prioritises the health and wellbeing of the individual patient, while this is generally not the case in research.


For this reason, Katz is concerned about the “lack of separate justifications for novel interventions employed for the benefit of future patients and science, in contrast to those employed for patients’ direct benefits.”

It is imperative, Katz contends, that we recognise that the ethical situation in research is fundamentally different to medical therapy. He holds that this must involve acknowledging the importance of consent requirements in a research context. Even if there are cases in which consent might legitimately be dispensed with in medical therapy, he argues, it is a very different matter in research, where the subject’s interests are not, or are only in part, what is at stake. Respect for the person, Katz contends, is the only counterweight to situations in which the interests of the research subject are overridden by other interests, leaving them vulnerable to exploitation and abuse. He understands respect for persons as achieved through respect for their autonomy, which is secured through informed consent procedures.

We see the same idea touted by the Ad Hoc Advisory Panel, when they phrase the fundamental challenge of human research as the need to reconcile “respect for human rights and individual dignity with the felt needs of society” which involves working out when “to overrule individual autonomy for the common good.”

I will explore, in the following two chapters, the notion of respect for persons, what it might be thought to involve in a research context, and how it intersects with notions of wellbeing and beneficence. For now, however, I will focus on Katz and the Ad Hoc Advisory Panel’s point that the benefits in research and in medical therapy are significantly different, and that this necessitates adopting a different ethical approach to pertinent issues concerning beneficence and the protection of the wellbeing of the individual research subject.

We see similar concerns raised in the context of social science research,
where Herbert Kelman, a prominent writer on the ethical issues in this field whose criticism of the Milgram experiment was covered in the last chapter, notes that in research, “calculations of the risk-benefit ratio are complicated by the fact that those who are most likely to benefit from a research study are often not the ones that bear the attendant risks.”\textsuperscript{263} It is clear that in all research situations, the balancing of risks and benefits, while taking the various interests that come into play into account, will be a complicated task that often involves a trade-off between the interests of different people or groups. Research guidelines must be developed with an appreciation of the centrality of this challenge to research ethics.

Though this philosophical discussion shows recognition of the importance of approaching questions of beneficence in research as distinct from beneficence in therapeutic medical ethics, this is not adequately reflected in contemporary research guidelines. Using the therapeutic misconception, I will display the extent to which problems concerning the principle of beneficence endure in research ethics guidelines. I will also suggest, in this chapter, and develop, in Chapter 5, a means of addressing these problems, through providing a coherent philosophical basis for research ethics that is distinct from therapeutic medical ethics, and is thus able to recognise the centrality of the conflict between the interests of the individual research subject, and the interests of science and society, as well as ensuring that the interests of the research subject, including wellbeing, are adequately represented.

**Beneficence in the Declaration of Helsinki**

We have already looked, in Chapter 2, at the original 1964 Declaration of Helsinki, as I placed it in a historical context in order to understand its origins and the motivations behind its development. In that chapter, I argued that the original Declaration of Helsinki can best be understood as a reaction to the stringent standards of the Nuremberg Code. While the strict

requirements of the Nuremberg Code reflected a suspicion of doctors, The Declaration of Helsinki, written by medical professionals, treated the events that had motivated the creation of the Nuremberg Code as an anomaly.\footnote{Katz, “The Consent Principle of the Nuremberg Code”, p.228.} Though the Nazi researchers who committed the violations which led to the creation of the Nuremberg Code were themselves doctors, treating this as a singular aberration, completely out of character for “normal” physician-researchers, allowed the Declaration of Helsinki to posit that doctors could generally be expected to uphold their obligations of beneficence.\footnote{Katz, “The Consent Principle of the Nuremberg Code”, p.228.} The Declaration of Helsinki thus utilises the physician’s obligation of beneficence in a medical context as the primary means of protecting and promoting the wellbeing of individual research subjects.

Furthermore, the 1964 Declaration of Helsinki was concerned with providing ethical guidance for a type of research that was neglected in the Nuremberg Code; research that was combined with patient care, that is, research which is also aimed, in some measure, towards providing therapeutic benefit for the patient. The authors of the Declaration maintained that a great deal of medical research falls into this category.\footnote{Williams, “The Declaration of Helsinki and public health” p.650.} With a concern for dealing with situations in which patient care and medical research are combined, it seems plausible that the authors of the Declaration of Helsinki might attempt to extend the obligations of doctors in a therapeutic context to research situations. The emphasis on providing guidelines for research which is combined with patient care, coupled with the assumption that doctors could be generally be trusted to act in a beneficent manner, provides us with some indication of why the Declaration of Helsinki emphasises the doctor’s obligations of beneficence as the central means of protecting and promoting the wellbeing of the research subject.

However, as we have seen in the previous chapter, subsequent events in human research undermined the contention that the ethical violations of the Nazi doctors represented a singular deviation, and that doctors could
generally be expected to uphold their obligations of beneficence. Additionally, as the Jewish Chronic Hospital Disease Case reveals, even if we could expect physician-researchers to always act in a beneficent manner, the obligations of beneficence in a research context differ significantly from those in a therapeutic setting. This section will be dedicated to scrutinising two of the significant changes made to the Declaration of Helsinki’s approach to beneficence. I will argue that despite these changes, which reflect a recognition of some of the shortcomings of the approach to beneficence in the original document, the contemporary version of the Declaration of Helsinki still utilises a flawed and inappropriate notion of beneficence, which does not provide an adequate means of dealing with the ethical issues that arise in the context of research. The next section will be dedicated to pointing out some of the specific problems with this approach.

For the purposes of considering the evolution of the approach to beneficence in the Declaration of Helsinki, there are two significant amendments that should be considered. The first is included in the substantial 1975 revision of the document, which introduced requirements for external review and strengthened informed consent requirements. The second is the controversial 2000 revision which removed the distinction between therapeutic and non-therapeutic research.

*Declaration of Helsinki – 1975*

As we have seen in the previous chapter, the events following the publication of the 1964 Declaration of Helsinki challenged the idea that the ethical violations which led to the formulation of the Nuremberg Code could be dismissed as an aberration in research ethics. Subsequent publicity surrounding other ethical violations in medical research undermined the idea, central to the original Declaration of Helsinki, that doctors could generally be trusted to protect and prioritise the wellbeing of their research subjects, and that relying on the discretion of doctors was the most appropriate means of protecting the wellbeing of individual research subjects. Both the Tuskegee Syphilis Study and the Jewish Chronic Disease Hospital Case affirmed that the violations of subjects encountered at
Nuremburg did not represent an isolated incident, and led to questioning of the idea that physicians should have the discretion to weigh the relevant ethical principles in research.

As a result of this, new requirements were added to the 1975 revision of the Declaration of Helsinki, introducing prior review of research projects by an external, independent committee. This amendment introduced, as a basic principle, the requirement that all proposed research projects be submitted to an independent committee for “consideration, comment, and guidance.”

This requirement is designed to ensure that the ethical principles in the document are upheld, as shown by the requirement that the “research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.”

This represented a crucial step in the development of what is now a central part of the ethical evaluation of human research; the requirement that research is reviewed by research ethics committees. These changes represented a recognition that it was insufficient to rely on the discretion of the physician-researcher to ensure that, and determine how, the ethical standards contained in this document are applied. As we saw in Chapter 2, the continuation of the Tuskegee Syphilis study after reviews from other doctors and researchers also suggested, as was strongly emphasised by the Ad Hoc Advisory Panel, that review of research from the scientific community alone was also insufficient to prevent abuses in human research.

The 1975 version of the Declaration also gives more primacy to the notion of informed consent. Informed consent guidelines were shifted from the...

section on non-therapeutic research to the basic principles governing research, cementing the idea that these requirements govern all research. Though this document still allows for informed consent to be eschewed in therapeutic research, the requirements for such an exemption are strengthened, with the stipulation that if “the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee”.

This removes the possibility of the researcher unilaterally determining that informed consent can be forgone for therapeutic reasons, even in therapeutic research. It is not clear whether the more stringent and prominent informed consent guidelines in the 1975 Declaration of Helsinki are designed to function in a similar manner to informed consent in the Nuremberg Code, operating as a check on the power of researchers, and giving research subjects the ability to protect their wellbeing, or are more similar to the autonomy-based justification in the Belmont Report (or perhaps a bit of both). This is because the Declaration of Helsinki gave (and continues to give) no justification for its informed consent requirements. In Chapter 4, I will scrutinise the content of the informed consent guidelines in the contemporary (2013) Declaration of Helsinki, linking these requirements to philosophical ideas concerning autonomy, in order to draw out the implicit links between autonomy and informed consent in this document, and to better make sense of the purpose and function of these requirements.

Declaration of Helsinki – 2000
The 2000 revision of the Declaration of Helsinki involved the most substantial changes to this document since the 1975 version. This revision involved the removal of the distinction between therapeutic and non-therapeutic research. While the original intention of this distinction in the Declaration of Helsinki was made in order to accommodate the fact that a lot of medical research has therapeutic intent, the limited ability of properly designed research to accommodate the therapeutic needs of individual

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subjects\textsuperscript{273} led to a recognition that research necessarily could not be governed by the same ethical standards as medical therapy.\textsuperscript{274} Critics of the distinction between therapeutic and non-therapeutic research argued that the inherent difficulty of separating therapeutic and nontherapeutic components of research can lead to non-therapeutic measures being justified and judged by the relatively permissive standards of therapeutic research. The unrealistic stringency of some of the standards for non-therapeutic research, furthermore, encourage researchers to routinely contravene the requirements in the document, thus undermining its legitimacy.\textsuperscript{277}

\textit{Declaration of Helsinki – continuing problems}

The revisions catalogued in the previous section all represented important steps towards recognizing the difference between research ethics and medical ethics, particularly when it comes to beneficence. External review of research, strengthening of informed consent requirements (1975) and the requirement that all research is subjected to the same standards of review, even if it has a therapeutic component (2000) are all measures that serve to limit the freedom of the doctor to decide what is best, representing a recognition that the norms of medical therapy (that is, substantial discretion for the doctor, coupled with the assumption that the doctor will use this discretion to prioritise the wellbeing of the individual patient/research subject) cannot be applied to research. The application of these two therapeutic norms to research can result in two possibilities, either we are hardly able to do any research (because much research will not allow us to prioritise the research subject above all else) or the doctor will use this discretion in a way that risks sacrificing the interests of the research subject (as we have seen above, the doctor could still be acting from broadly beneficent motives here, just not patient-centred, therapeutic beneficence).

These changes seem to acknowledge that the beneficent norms of medical therapy simply cannot be applied to research without generating problems.

\textsuperscript{273} I discuss and argue for this in the next section.
\textsuperscript{274} Williams, “The Declaration of Helsinki and Public health”, p.650.
Despite these promising signs, however, the overall approach to beneficence in the Declaration of Helsinki has not substantially altered. The changes here rather appear to be a reactive response to physician’s abuses of their powers of discretion, rather than a recognition of the deeper philosophical problem with their approach to beneficence. This can be displayed by another 1975 revision that actually made the Declaration of Helsinki’s problem of beneficence worse. This revision, which has been retained to the present day, is the inclusion of an explicit statement that “the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.” As the discretion of the doctor is limited, the idea that the therapeutic obligations of the physician can be upheld in research are entrenched. This is reinforced by the continued emphasis (as we have seen in Chapter 2) on the obligations of the physician to make patient wellbeing her first priority. Though the limits on the scope of the doctor to decide what is best will surely mean that there is less risk to the individual research subject, the requirement that the individual benefit take precedence simply does not make sense in research. Research always needs to involve balancing the interests of the individual research subject against the interests of society. This will be revealed through discussion of a practical problem in research; the therapeutic misconception.

The Therapeutic Misconception

Discussion of the therapeutic misconception helps to highlight both the inadequacy of the Declaration of Helsinki’s stipulation that the goals of research “can never take precedence over the rights and interests of individual research subjects” and the need for an approach to beneficence in research ethics that is distinct from that used in therapeutic medicine. It is important that patients, research subjects and physician-researchers recognise the distinction between medical therapy and research, and the difference between the norms that govern the conduct of medical researchers and therapeutic physicians. There is the risk that if the

patient/subject does not adequately understand this distinction, he will assume that the intent of the research procedure is therapeutic. This belief, termed the therapeutic misconception, generates a significant problem in medicine. The phenomenon of the therapeutic misconception was first outlined by Paul Appelbaum in the 1980s, and has subsequently received substantial attention and is well accepted as a common phenomenon in research. As Appelbaum puts it; “To maintain a therapeutic misconception is to deny the possibility that there may be major disadvantages to participating in clinical research that stem from the nature of the research process itself.” If the obligations of doctors and researchers are blurred, this misconception is in danger of being perpetuated. It is important to look at these cases, due to the Declaration of Helsinki’s continuing importation of the obligations of physicians in a therapeutic context into its guidelines. Work on the therapeutic misconception will highlight why these imperatives are not achievable in a research context, and will reveal the harm in taking this approach to research ethics.

We have seen in reference to the Jewish Chronic Hospital Disease Case how blurring the lines between therapeutic physician and researcher can be problematic. However, though this case involved researchers misleading patients into thinking that they were administering a research procedure for the therapeutic benefit of the patient, this research was not aimed in any way towards contributing to their medical care. This made the researchers’ arguments that they were justified in exercising the therapeutic privilege particularly problematic. Whether they were failing to inform patients in order to conduct research that would be beneficial for society, or because they were concerned that revealing pertinent information might cause subjects distress, the ultimate goal of the research was not benefit for the patient, but benefit for others; a situation which leaves the individual

vulnerable to exploitation. Because this situation presents very different ethical challenges to medical therapy, I have argued that an adequate approach to these problems must also be distinct from the ethics of medical therapy.

One might think, then, that situations in which research is conducted, primarily or at least in part, in order to bring therapeutic benefit to the patient-subject, present a rather different set of ethical circumstances. A physician enrolling his patient in an experimental trial because he believes that this is the means of accessing the best treatment, for example, clearly resembles a situation in therapeutic medicine much more closely than the non-therapeutic research conducted in the Jewish Chronic Disease Hospital Case. One might therefore suggest that it is sensible to take an approach similar to the original Declaration of Helsinki; providing a separate set of guidelines for therapeutic research that attempt to bring the ethical standards that govern therapeutic medicine into research. Even in situations where participation in a research study might be beneficial for the patient/subject, however, the risks of conflating the roles of therapeutic physician and researcher in these ambiguous cases does more harm than good. In fact, in research that also has therapeutic intent, the therapeutic misconception is in more danger of being perpetuated, to the detriment of the patients/subjects. Whether research also has therapeutic intent or not, the therapeutic misconception reveals the importance of emphasising the differences between research and therapy, and between the therapeutic physician and the researcher.

Appelbaum brings this out by pointing out some of the distinctive features of clinical research. He notes that it is commonly held that a physician enrolling a patient in a study where the relative efficacy of multiple treatment methods are tested does not involve abandoning patient care, when the physician genuinely does not know which method is best. This, it is suggested, simply allows chance to determine the nature of the patient’s treatment, and when there is no idea of which treatment will benefit that patient/subject, and each treatment method has potential benefits, this is a
valid way to proceed with treatment. However, even in cases such as this, there are obstacles to prioritising the patient’s wellbeing in a research situation. This is because certain aspects of the research process limit the conduct of both physician and patient.

Randomized assignment to groups, the use of placebos and control groups, and the use of a double blind are all routine aspects of research that inhibit patient care. Typical clinical research studies will involve assigning subjects to groups at random, with no thought about what method of treatment might best reflect the needs of the patient/subject. This can involve placing subjects in control groups, where no treatment is administered, or in a group that is given placebos. Further, research is often undertaken in a double blind situation, where neither the researcher/physician nor the patient/subject is aware which group they have been assigned to and thus which kind of treatment (or lack of treatment) they are receiving until after the experiment is concluded. These features are essential to the design of valid research; in order to determine what the effects of a given treatment are, the treatment needs to be contrasted with no treatment at all or with treatment with placebos, and the bias in the findings must be removed by making sure neither the physician/researcher nor patient/subject is aware of their course of treatment.

However, these features of clinical research necessarily undermine the optimal pursuit of patient care. Enrolment in research is contingent on only receiving treatment that is permitted by the research protocol. This might mean that a patient/subject has to give up or forgo another type of treatment that their physician concludes might be helpful to them, and there is the risk that they will be assigned to a group where no treatment is given at all. If the patient must cease existing treatment to enrol in the study, withdrawal from this treatment might constitute a harm with the risk of no corresponding benefit. Furthermore, the treatment that is administered must be given in “a regimented manner, with little or no allowances made for

282 Appelbaum et al, “False Hopes and Best Data”, p.20.
283 Appelbaum, Roth and Lidz, “The Therapeutic Misconception”, p.320.
[the] individual needs"\textsuperscript{284} of subjects/patients. Where, in a purely therapeutic situation, physicians will adjust the dosage of a drug if it is having no effect, or producing negative side effects, the design of research does not allow for the same regard for the individual circumstances of the patient/subject. The randomization of groups similarly does not allow the physician/researcher to take personal factors about the patient/subject, which would normally influence their decision on how to best provide for their personal care, into account.\textsuperscript{285}

These features of research, which are often essential to attaining scientifically valid results, will necessarily compromise, at least to some extent, the physician/researcher’s ability to prioritise the wellbeing of individual research subjects.\textsuperscript{286} The commonplace nature of these features of research design renders the Declaration of Helsinki’s imperative to always give precedence to the rights and interests of the individual research subject impossible to achieve. This is not to say that a patient cannot benefit from participation in a research study, or even that some medical research may not be carried out in a way that does not compromise patient care (a physician could, for example, simply provide what she sees as being the best patient care, and publish the results afterwards as a case study). However, these features are central enough to medical research to necessitate a clear separation of therapeutic and research ethics. This becomes clear when we turn to the problems that arise from the conflation of these ethical frameworks in the cases in which the research protocol does interfere with patient care.

The likelihood that medical researchers will be adhering to research protocol which may compromise optimal patient care is generally poorly understood by research subjects. There is a tendency for research subjects to “assume (especially, but not exclusively, in therapeutic research) that decisions about their care are being made solely with their benefit in

\textsuperscript{284} Appelbaum, Roth and Lidz, “The Therapeutic Misconception”, p.325.
\textsuperscript{285} Appelbaum et al, “False Hopes and Best Data”, p.20.
\textsuperscript{286} Appelbaum et al, “False Hopes and Best Data”, p.20.
mind”.  Even in cases where subjects are informed about the aforementioned features of experimental design, the risk remains that certain aspects of their understanding of the research process will be distorted in order to accommodate their deeply ingrained assumptions that “physicians (at least ethical ones) always provide personal care.” Based on several studies, Appelbaum reveals the pervasive nature of this phenomenon. It was common for subjects to exhibit a belief that the treatment group that they would be assigned to would take their situation into consideration, and the decision would be based upon what kind of treatment would best suit their needs. This belief persisted even when subjects had been informed that the treatment groups would be designated at random.

It is clear that participation in research under these conditions will compromise the subject’s ability to act autonomously, and to assess the risks and benefits of the situation. Many subjects enrol in research studies “solely to receive additional help, but they are unable to identify and take into consideration those aspects of the research design that might interfere with that goal.” Even when subjects are informed that research, for example, might involve them receiving placebos rather than effective treatment, their belief that the physician will act in their best interests leads them to believe that they will not be placed in the placebo group, as that will be unlikely to do them much good. As I have pointed out above, this kind of misunderstanding is particularly dangerous in a research situation. The vulnerability of research subjects to exploitation, due to the fact that others may stand to benefit from research, makes it particularly important that subjects have a clear idea about what is involved in research. We have seen that Katz has argued that informed consent is the key to ensuring that the interests of research subjects are adequately taken into account; but informed consent is predicated on subjects understanding what they are

288 Appelbaum et al, “False Hopes and Best Data”, p.23.
290 Appelbaum, Roth and Lidz, “The Therapeutic Misconception”, p.325.
291 Appelbaum, Roth and Lidz, “The Therapeutic Misconception”, p.327.
consenting to. Therefore, the therapeutic misconception is a particularly significant problem for research ethics. It is clear that if subjects have a false idea that their interests are being protected and prioritised when they are not, this may lead to subjects unwittingly compromising their own interests. These factors make it imperative to address the therapeutic misconception in research. Appelbaum contends that finding the means to dispel this misconception may even be necessary for protecting the enterprise of research, as subjects who became aware of the nature of the research process after participation tended to feel deceived, which, especially if publicised widely enough, risks undermining trust in the research enterprise.  

Though the importance of dispelling the therapeutic misconception is clear, it is difficult to work out how best to achieve this, especially, as I have noted, because research subjects are likely to cling to the belief that doctors will act according to therapeutic norms even if they are informed of features of experimental design which will undermine this aim. Ensuring that research subjects do not fall prey to the therapeutic misconception will need to involve more than making sure the design of the research is understood; it will need to involve the understanding that the very norms of research are fundamentally different to the norms of medical therapy. As Appelbaum puts it, “it may be necessary to assault the beliefs that underlie therapeutic distortions.”

Appelbaum’s description of the therapeutic misconception reveals two fundamental problems with the Declaration of Helsinki. First, it shows that the Declaration of Helsinki’s requirement of prioritising the subject in research is not possible. Certain standard features of much medical research, including therapeutic research, will necessarily interfere with the promotion of the research subject’s interests above all other concerns. Secondly, the continued adherence to the mistaken idea that the researcher can prioritise the wellbeing of the research subject in the same way that the

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doctor prioritises the wellbeing of the patient risks perpetuating the therapeutic misconception. The Declaration of Helsinki’s contention that the researcher can never do anything to compromise patient care represents the very problem that makes the therapeutic misconception so common.

An Alternative Approach to Beneficence

The prevalence of the therapeutic misconception makes two things clear; the Declaration of Helsinki’s approach to beneficence does not represent a realistic standard for research ethics, and an alternative approach is required in order to avoid this misconception. Appelbaum contends that simply informing research subjects is not sufficient to dispel the therapeutic misconception; in order to address this problem, we may need to dispel the beliefs that underlie it. I contend that this can only be achieved through a clear separation of research ethics and therapeutic medical ethics. It must be made apparent that these two fields operate according to entirely different ethical standards. The Declaration of Helsinki, in importing the physician’s obligations of beneficence into research ethics, does not only provide a standard that cannot be achieved in the context of research, but it blurs the boundaries between therapeutic medical ethics and research ethics, perpetuating the therapeutic misconception.

As a result, I suggest a radically different approach to research ethics, which I present in full in Chapter 5. My philosophical theory of research ethics gives us a means of combating the therapeutic misconception through eschewing the influence of therapeutic medical ethics and emphasising the distinction between these two fields.

I argue that the principle of beneficence should be left purely to evaluating the risks and benefits in research, working out how best to pursue the benefits that research offers for society; making it clear that this is a fundamental aim of, and the guiding force behind, research. Concern for all interests of the research subject, including concerns for their wellbeing, should be represented through appropriately structured informed consent guidelines. Treating the interests of the research subject together, and
separating them out from the interests of others, acknowledges that these two goals in research are often at odds and present great potential for ethical conflict. It reduces the risk that concern for the individual will be subsumed by the interests of the majority. In addition, it clearly separates the notion of beneficence in research from the idea of beneficence in medical therapy. This, I believe (among other benefits), gives us a more effective means of combating the therapeutic misconception. This alternative approach to research ethics clarifies, for researchers, research ethics committees, and research subjects, that physicians cannot be expected to uphold the norms of conduct expected in therapeutic medical ethics. It promotes understanding that the ethical norms in these different fields will necessarily differ. We have seen, based on the material above, that there needs to be a clear understanding that the norms of conduct in research and in medical therapy, and thus the roles and aims of doctors and researchers, are fundamentally different.

When subjects hear that the research will be conducted in accordance with the value of beneficence, and that that value involves consideration for their wellbeing, the therapeutic misconception might cause them to overestimate the extent to which this will be taken into account. Removing these considerations from the principle of beneficence aids in the explanation that this principle is entirely different from therapeutic beneficence, and is not aimed towards enhancing or protecting the subject’s wellbeing. This is supported by Appelbaum’s contention that dispelling the therapeutic misconception is reliant on “subjects understand[ing] the key principles of how the study is being conducted.”  

**Beneficence in the Belmont Report**
I have used the treatment of beneficence in the Declaration of Helsinki to display the problems with an inadequate understanding of the fundamental differences between the role of beneficence in research, and the role of beneficence in medical therapy. I have argued that the approach in this

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295 Appelbaum et al, “False Hopes and Best Data”, p.23.
document does not adequately recognise the specific concerns of research and thus cannot provide appropriate guidance in research ethics. Furthermore, a lack of understanding of these differences risks perpetuating the therapeutic misconception, which can lead to the risk that a patient will consent to research without an appropriate understanding of what it might involve.

The Belmont Report provides a different approach to beneficence which has some advantages over the Declaration of Helsinki. This document, for example, recognises that the various obligations of beneficence involved in research can clash in different circumstances. However, I will argue that the Belmont Report does not go far enough in recognising this conflict. Despite acknowledging this problem, the Belmont Report downplays the extent of the conflict between the different demands of beneficence in research. Furthermore, the means by which this document suggests we should achieve the principle of beneficence risk having concerns for the wellbeing of the individual overwhelmed by the promise of benefit for others. I will argue that the problem of beneficence is still evident in the Belmont Report, and in contemporary research guidelines that follow its principle-based approach to research ethics. I will show that in order to properly recognise the ethical concerns and context of research, we must come up with an alternate schema of ethical principles that more adequately reflects the specific ethical problems that arise in this domain.

Just as the Declaration of Helsinki, due to the context of its creation, displayed significantly different ethical concerns to the Nuremberg Code, the Belmont Report, coming after several significant societal shifts, and produced as a result of several cases of exploitative research during the 60s and 70s, brings different ethical concerns to light than those that form the focus of the Declaration of Helsinki. As we have seen, the Belmont Report takes a very different structure than the Declaration of Helsinki and the Nuremburg Code. Rather than providing a list of rules that ethical research must adhere to, the Belmont Report provides broad principles that ethical research must take into account. There are several reasons why the National
Commission took such an approach. Firstly, these broad principles are able to capture universal moral intuitions about how we should conduct ethical research. They are not tied to a particular ethical tradition, allowing a framework that various people can agree with despite their substantive views. As Tom Beauchamp, one of the authors of the Belmont Report, explains: “every morally sensitive person believes that a moral way of life requires that we respect persons and take into account their well-being in our actions.”

The principle-based approach was also taken so that the Belmont Report could be developed into more specific guidelines in a wide range of areas, and also so it could provide justification for these guidelines. Though broad principles provide a flexible and pragmatic framework for guiding a range of decisions, they can also be ambiguous and create conflict, even within a single principle. One of the most significant ambiguities is within the principle of beneficence; a problem that is explicitly acknowledged in the Belmont Report.

The Belmont Report notes that the “obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research.” This represents an explicit acknowledgment of the different interests that must be taken into account when considering the principle of beneficence in the context of research. Though the Belmont Report takes the requirement of beneficence to necessitate protecting and promoting the wellbeing of research participants, it explicitly claims that the principle of beneficence may sanction risky research that has no foreseeable benefits to the subjects involved, on the grounds that precluding this sort of research “would rule out much research promising great benefit...in the future.”

Though the Belmont Report acknowledges the conflicting demands of the wellbeing of society and the wellbeing of individual research participants that it subsumes under the principle of beneficence in research, it does not provide an idea of how we might use beneficence to take into account the overall

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298 The National Commission, The Belmont Report, Part B: Basic Ethical Principles
299 The National Commission, The Belmont Report, Part B: Basic Ethical Principles
benefits to society that research may produce while still providing adequate safeguards to protect the subject’s wellbeing. The Belmont Report simply notes that “the different claims covered by the principle of beneficence may come into conflict and force difficult choices.” The problem with this approach becomes apparent when we look at the guidance in this document concerning the application of this principle.

Application of the Principle of Beneficence

In addition to providing no indication of how we might weigh the beneficent concerns directed towards the individual research subject against the imperative to produce beneficial research for society, the instructions concerning the application of the principle of beneficence in the Belmont Report look as if they might present a severe problem for protection of the wellbeing of the individual research subject. The Belmont Report contends that the principle of beneficence is applied by an assessment of the risks and benefits of the research. This involves the determination that “risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research.” They do stipulate that the “risks and benefits affecting the immediate research subject will normally carry special weight”, but also indicate that “interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects’ rights have been protected.” Despite this stipulation, there is no clear indication of how this protection is to be achieved, what it involves, and what it means to give the subject special weight in this equation. We have seen, above, that taking all benefits into account in this kind of calculation in research could involve the overall benefit overshadowing concerns of wellbeing for the individual research subject. Without a more developed notion of how these elements are to be weighed against each other in research, the Belmont Report’s endorsement of this utilitarian calculation does not adequately

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300 The National Commission, The Belmont Report, Part B: Basic Ethical Principles
302 I will explore this idea in Chapter 5, providing a conception of what this stipulation could look like.
account for or protect the wellbeing of the individual research subject.

The Belmont Report does place some additional safeguards on this risk-benefit assessment, such as the stipulation that “brutal or inhumane treatment of human subjects is never morally justified”, and the requirement that where “research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject -- or, in some rare cases, to the manifest voluntariness of the participation).”303 304 However, though these might protect against cases in which there is high likelihood of severe harm, cases where there is smaller risk or more moderate harm are not adequately covered. Thus, the risk in these cases, that the wellbeing of the research subject might be sacrificed for the greater good remains. This is affirmed by Beauchamp’s contention that the Belmont Report contains an “all too utilitarian vision of beneficence – one with inadequate internal controls in its moral framework to protect subjects against abuse when there [is] the promise of major benefit for other sick and disabled persons.”305 306

Avoiding the Problem of Beneficence

Though the Belmont Report does not give an adequate means of dealing with the conflicts within the principle of beneficence, we are given a possible indication of some level of recognition that beneficence on its own provides inadequate protection of the wellbeing of individual research subjects. This is suggested by the fact that the principle of respect for persons in the Belmont Report contains some stipulations which are most convincingly read as exhibiting a concern for the wellbeing of the research subject, and for providing means for its protection. These features of the Belmont Report will be explored in detail in Chapter 5. Although I will

304 This, clearly, could be read as going beyond concerns for the wellbeing of the research subject, I will unpack the Belmont Report’s references to interests, rights and voluntariness, and how this relates to wellbeing, in Chapter 5.
306 Though Beauchamp was a chief author of the Belmont Report, he is quite critical of many aspects of its approach, stating that his true views on the ethics of human research can be found in his philosophical work. I will critically appraise Beauchamp's views in Chapters 4 and 5.
conclude that there are problems with these stipulations as they stand, the approach hinted at here strikes me as the most promising way to address the concerns I have explored in this chapter. Rather than expecting a principle of beneficence to take on the entire burden of protecting and promoting the wellbeing of the research subject, we should look to the principle of respect for persons in research, or, more specifically, to its application: informed consent guidelines.

The primary reason for this stems from the frequently stated contention in both the Ad Hoc Advisory Panel’s Report and in Katz’s work – that the most fundamental ethical conflict in research is the interests of the individual versus the interests of society. The way that research ethics documents are structured must bring this issue to the fore, and must provide us with tools to address it. The way that the Belmont Report is structured, highlighting respect for persons (conceived as respect for autonomy and personal dignity) and beneficence as the two major conflicting ethical values, still reflects the concerns of medical therapy better than medical research. As long as the demand to produce benefit to society through research and the demand to display beneficence for research subjects by protecting their wellbeing are subsumed under a single principle of beneficence, the extent of this conflict, and its centrality to research, is not properly acknowledged. We are left with a crippled principle of beneficence which is unable to adequately guide us in the achievement of either of these aims.

Furthermore, if we simply look at what will produce the most benefit, as the application of the principle of beneficence suggests in the Belmont Report, the wellbeing of the individual research subject will frequently be overwhelmed by the benefits that research can produce for others. As long as both of these disparate concerns are contained under a single principle of beneficence, the risk that the wellbeing of the subject will not be adequately protected is likely to remain. As concern for the wellbeing of the research subject provided the primary impetus for the development of research ethics codes in the first place, and as we have seen it continually disregarded in
notorious research cases in more recent history, this should be a cause for concern for research ethicists. We need another, separate means of ensuring that the wellbeing of the individual research subject is taken into account.

I will argue that it is easier to minimise the conflict between, and to simultaneously promote and protect, the various interests of the individual research subject through appropriately formulated informed consent guidelines in research, than it is to balance the conflict between promoting and protecting the wellbeing of the research subject and all those who stand to benefit from research through a principle of beneficence. This is because people, particularly when acting autonomously, generally have a strong interest in protecting and promoting their own wellbeing. Unlike the various concerns encompassed under a principle of beneficence, these aims do not routinely come into conflict.

However, this is not to say that they never come into conflict. It is certainly not guaranteed that people will act to further their wellbeing, even when acting autonomously. Informed consent guidelines that adequately function to protect wellbeing must be carefully and explicitly formulated with this purpose in mind. Developing this simple insight into a viable theory will also require an understanding of the other purposes of informed consent, and an account of how the promotion and protection of wellbeing through informed consent can fit alongside these aims, as well an account of what should be done when inevitable clashes occur. It will require an explanation of how research differs from therapeutic medicine, where promotion and protection of wellbeing is often thought to routinely conflict with autonomy-based informed consent guidelines.

Conclusion
In the Nuremburg Code, where the motives of researchers were taken as untrustworthy, consent functioned as the primary means of providing for the protection of the wellbeing of research participants. In subsequent guidelines, the doctor’s requirement to act in a beneficent manner began to take over the job of protecting wellbeing, while informed consent became
more focused on promoting autonomy. However, due to the nature of beneficence in research, that is, the conflicting requirements it must take on to assure that the good of others is also promoted, it is not well placed, on its own, to provide sufficient protection for the wellbeing of individual research participants. Even if we can trust researchers to act beneficently, it is not clear that beneficence in research will demand that the wellbeing of the individual research subject is prioritised in all instances. Furthermore, given the concerns of research, it is not clear that we would want it to; attempting to institute this demand will risk substantially reducing overall benefit.

It is clear that the demands of beneficence in a research context differ substantially from the demands of beneficence in medical therapy, and that the problem of balancing the concern for the wellbeing (and other interests) of individual research subjects against the overall benefit that research can generate represents the most fundamental ethical tension in research. I have argued that the Declaration of Helsinki’s attempts to incorporate the obligations of doctors in a therapeutic context into research ethics do not give us the appropriate means of approaching the problems that arise from the conflicting requirements of beneficence in research ethics. Though the Belmont Report represents progress in explicitly recognising this ethical tension, the choice of principles still represents the influence of therapeutic medical ethics, and underemphasises the extent to which the different claims made by beneficence in research can conflict. We need to take a different approach if we are to adequately address the most significant ethical concerns in research. I have suggested that rather than attempting to address this fundamental problem within a single principle of beneficence which attempts to weigh up all disparate concerns, we might be better off devising informed consent guidelines which are designed to protect and promote all of the interests of the individual research subject (including wellbeing), thus emphasising the distinction, in research ethics, between individual interests and societal interests. As consent has been used, at various points in history, to protect both the wellbeing and the autonomy of the research subject, we may be able to protect both of these individual interests in this way. Once I have scrutinised the autonomy/respect for persons related functions of
informed consent in Chapter 4, I will turn, in Chapter 5, to the argument that informed consent guidelines can indeed provide a good means of protecting individual wellbeing, and they can do this without significantly interfering with their role in making sure research is conducted in a manner that shows respect for persons.
Chapter 4: Respect for Persons, Autonomy and Informed Consent in Research

Introduction

Before I attempt to explicitly incorporate protection of wellbeing into informed consent procedures, and argue that this is a suitable approach in research ethics, we must turn to the primary purpose of informed consent in contemporary guidelines; ensuring that respect for persons is achieved through respect for their capacity for autonomy. We have seen that the principle of respect for persons in the Belmont Report is largely concerned with respecting their autonomy, and that this is achieved through informed consent procedures. Informed consent procedures, in the Belmont Report, allow us to discern whether a decision is really autonomous, and treat it accordingly. Honouring these autonomous decisions, according to this document, gives us the means of showing appropriate respect for persons. The approach in the Declaration of Helsinki is more difficult to identify, because, though informed consent requirements are central to the document, there is little indication of the purpose of these requirements. In order to discern the purpose of informed consent requirements in the Declaration of Helsinki, I will look at the content of the informed consent guidelines in this document, linking them to philosophical ideas about autonomy and respect for persons to draw out the tacit purpose of these requirements. I will argue that as in the Belmont Report, informed consent guidelines in the Declaration of Helsinki function primarily as a means to achieving respect for autonomy.

Before we are able to link the informed consent in the Declaration of Helsinki to autonomy, and to explore the connections between informed consent, autonomy and respect for persons in the Belmont Report, however, we must first come to an understanding of the complicated concept of autonomy. This chapter will thus first turn to scrutiny of ideas about autonomy in philosophical work, drawing out the various ways in which they relate to the concept of respect for persons, and how these notions link to informed consent in research ethics. An understanding of these ideas will allow us to discern how various notions of autonomy are made use of in
informed consent guidelines in research ethics. We will see that throughout
philosophical history, the notion of autonomy has been used in a range of
diverse ways. It is only with an understanding of the different notions that
have been linked with the concept of autonomy that we can begin to piece
together what might be involved in the use of autonomy in contemporary
research ethics guidelines.

When we turn, with an understanding of the different notions of autonomy,
to the use of autonomy in the most recent ethical research guidelines, a
serious problem is revealed. This stems from the fact that there are two
distinct notions of autonomy in contemporary philosophical work. One,
which I will refer to as the philosophical model, envisions autonomy as
intimately linked to selfhood. The other, which I will refer to as the
biomedical model, ignores the links to selfhood and focuses instead on
choices being intentional, understood and not controlled. Each notion of
autonomy has a significant strength, and a significant drawback. The
philosophical model of autonomy is grounded in a notion of personhood.
Autonomous actions, under this conception of autonomy, are those that have
some sort of important relation with the self. We can refer to this as the
condition of authenticity; actions qualify as autonomous when they form an
expression of one’s true or authentic self. Though the specific requirements
that actions must meet to qualify as authentic and thus autonomous can
dramatically differ between various philosophical theories, some sort of
authenticity criterion is generally the most central requirement of
philosophical models of autonomy. Because this notion of autonomy is
linked to a notion of the self, it provides an ideal means of achieving the
value of respect for persons. Respecting one’s capacity for autonomy
means respecting the actions that flow from, or constitute a reflection of, the
deepest self. If we value respect for persons, there is a clear imperative to
respect persons’ autonomous actions as defined by the philosophical model.

However, ideas of autonomy that fall under the philosophical model
typically run into problems when attempts are made to utilise them in a
practical context. Though the authenticity condition can be formulated in
various ways, Ruth Faden and Tom Beauchamp convincingly argue that even the most permissive authenticity criteria are too restrictive to allow us to include a sufficiently wide range of decisions as autonomous. There are many decisions which are deliberate, and which we would wish to allow people to make, Faden and Beauchamp contend, that cannot qualify as authentic. Faden and Beauchamp are concerned that if we subscribe to the philosophical model, these kinds of decisions will not be accorded the respect and value that comes with designating a choice as autonomous. They therefore formulate an alternative conception of autonomy, which I refer to as the ‘biomedical model’. This model focuses on capturing a wide enough range of decisions; the kinds of decisions that we would wish to promote, protect, honour and respect within a therapeutic medical or research context. It rejects any sort of authenticity criterion as too narrow, instead suggesting that decisions should be designated autonomous if they are intentional, substantially understood, and free of control, to a sufficient degree.

However authenticity is conceived, it seems as though this condition will be too restrictive to include the wide range of decisions that we would wish to have weight in this context. This is a particular problem for research ethics, as the documents seem to specify that decisions must be autonomous (in the case of the Belmont Report) or must meet the standards of informed consent (in the Declaration of Helsinki, which, as I will argue, is tacitly linked to ideas about autonomy) to qualify as worthy of respect or consideration. Faden and Beauchamp’s desire to provide an alternative, more permissive model of autonomy makes sense in this practical context. However, in rejecting a condition of authenticity, Faden and Beauchamp create a significant problem for their model of autonomy, leaving it unable to achieve its purpose in research ethics guidelines. By excluding an authenticity criterion from their conception of autonomy, they rid their

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320 This is not the case with a decision to refuse to participate in research; most documents explicitly state that the subject should be able to refuse to participate in research for any reason. However, any decision to participate in research must meet this standard.
model of autonomy of any ties to the notion of respect for persons. As we have seen above, the authenticity condition provides the links between autonomous actions and the self. Under the philosophical model, autonomous actions bear a special relation to the self, and respecting these actions therefore gives us a means of upholding the value of respect for persons. In excluding an authenticity criterion, Faden and Beauchamp lose any sense of the significant and special nature of autonomous actions; as well as any imperative to respect them. Faden and Beauchamp do not provide an alternate theoretical means of linking their autonomous actions to a deeper value; resultantly, the criteria that they specify for an action to qualify as autonomous seem arbitrary. That is, there seems to be no reason that the actions that their theory designate as autonomous should be worthy of special consideration (or conversely, that the actions that do not qualify as autonomous under their theory are not worthy of the same consideration).

It is also evident that these two models of autonomy are fundamentally incompatible. The philosophical model makes authenticity its most central criterion, while the biomedical model excludes any notion of authenticity as a criterion. This poses a problem for the Belmont Report, which seems to draw elements from both the philosophical and biomedical models of autonomy in their explication of the value. The criteria for informed consent in the Belmont Report closely resemble Faden and Beauchamp’s criteria for an autonomous decision, and make no mention of a condition of authenticity. However, the Belmont Report’s general description of autonomy and its explanation of why it is to be valued use language that

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321 I focus on Faden and Beauchamp’s model of autonomy here as an example of the “biomedical model” as it is so influential, well-theorised, and has clear links to the approach in the Declaration of Helsinki and the Belmont Report. However, the notion that autonomy should not include an authenticity condition is ubiquitous in models of autonomy and informed consent developed for biomedical contexts (see N. Arpaly, “Responsibility, Applied Ethics, and Complex Autonomy Theories” in J. Taylor (ed.), Personal Autonomy: New Essays on Personal Autonomy and Its Role in Contemporary Moral Philosophy, Cambridge University Press, Cambridge, 2005, p. 174; O. O’Neill, Autonomy and Trust in Bioethics, Cambridge University Press, Cambridge, 2002, pp.37-8 and A. Stigglebout et al. “Ideals of patient autonomy in clinical decision making: a study on the development of a scale to assess patients’ and physicians’ views” in the Journal of Medical Ethics, Vol. 30, No. 3, 2004, p.268. In this specific respect then, upon which much of my discussion is focused, this can be taken as a comparison of trends in biomedical and philosophical models of autonomy in general, and not just Faden and Beauchamp’s approach.
invokes an authenticity-based, philosophical model of autonomy. It also states that autonomy is the means to achieving the primary value of respect for persons, but as we have seen, there is only reason to believe that autonomy functions in this manner if it is an authenticity-based model of autonomy. This presents a dilemma for the Belmont Report; if we take it to be suggesting that autonomy must involve a condition of authenticity, its informed consent guidelines (in lacking an authenticity criterion) are not achieving their stated aim of ensuring that decisions are autonomous. Conversely, if, as suggested through its informed consent guidelines, it is taking Faden and Beauchamp’s route of excluding an authenticity condition from their concept of autonomy, there is no reason to think that their notion of respect for autonomy is achieving its stated aim of guaranteeing respect for persons.

The Declaration of Helsinki makes no mention of autonomy or respect for autonomy in its guidelines. However, like the Belmont Report, its informed consent criteria bear very close resemblance to Faden and Beauchamp’s conditions for the biomedical model of autonomy, namely, intentionality, understanding and noncontrol. This leaves this document in the same situation as Faden and Beauchamp’s theory; there seems to be no particular reason behind their choice of informed consent guidelines. The criteria for an informed consent that they settle upon seem arbitrary; there seems to be no reason to regard the decisions that meet these criteria as particularly worthy of respect (or conversely, decisions that don’t meet the criteria as unworthy of consideration). The other contemporary guidelines that are ostensibly based upon the Declaration of Helsinki generally explicitly invoke autonomy as the basis of their informed consent guidelines, but with no theoretical basis or condition of authenticity, this does nothing to solve this problem.

Both the philosophical and biomedical models of autonomy offer important insights; however, they each contain fatal flaws in the context of research.

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322 I will return to a discussion of these criteria in Faden and Beauchamp’s work as well as in the Declaration of Helsinki and the Belmont Report later in this chapter.
ethics, and a hybrid approach cannot be taken because these two models are fundamentally incompatible. I will argue that to resolve the inconsistencies between these two models of autonomy, while making use of the essential insights that both models have to offer, the only solution is to move away from autonomy as a basis for informed consent guidelines in research ethics. We need a new theory that provides theoretical links between respect for persons and informed consent, but is not unduly restrictive. I suggest that, due to the exclusion of the central authenticity criterion of autonomy, it is confusing and misguided to refer to Faden and Beauchamp’s theory as a theory of autonomy. Faden and Beauchamp’s theory is clearly insufficient to link informed consent to respect for persons. In giving up the theoretical core of autonomy, the very means by which autonomy links decisions to the value of respect for persons and makes them worthy of consideration and respect, Faden and Beauchamp’s theory loses what it is hoping to retain by retaining the word “autonomy”, that is, the special reason that these decisions should be taken into account.

In Chapter 5, I will present a theoretical basis for informed consent that is far less reliant on authenticity-based autonomy as a means of linking decisions to the value of respect for persons. This theory will achieve Faden and Beauchamp’s goal of providing a more permissive set of criteria for informed consent, but it will also provide a theoretical basis for designating these decisions as worthy of consideration due to their links to the notion of respect for persons. By providing a theoretical link to respect for persons, we can ensure that informed consent guidelines will achieve what we wish them to achieve; a means of expressing respect for persons. A theoretical basis will allow us to devise criteria for informed consent which provide a clear means to achieving the goal of showing respect for persons in research.

323 Their urge to label their theory as a theory of autonomy is driven by two related concerns. First, they accept the consensus that informed consent is based on respect for autonomy. Second, they believe that designating a decision as autonomous leads to it being seen as particularly worthy of respect. Although they are right about the latter claim, I will challenge the notions that informed consent should be based upon autonomy, and that we should focus on autonomous decisions when we evaluate which decisions are worthy of respect, in Chapter 5.
Autonomy: The Philosophical Model

Autonomy is a central and much discussed philosophical concept. However, upon inspection, it is apparent that the notion has historically been associated with a very diverse range of ideas, some of which bear little relation to each other. Though there is more convergence in some fundamental aspects of most contemporary accounts of autonomy in philosophical theory, there is still much variation in many aspects of these theories. Because, as I will show, the concept of autonomy defies a clear definition, and there are different ideas associated with the concept that link to the notions of respect of persons, freedom of choice, etc. in different ways, it is important to come to an understanding of some of the main themes, and discern how they are, or can be, made use of in research ethics. Certain elements of this large body of work on autonomy are drawn upon in research ethics, but little to no connection is given to the philosophical work from which they derive. In order to understand how the concept of autonomy is made use of in research ethics, it is necessary to trace some of the most significant formulations of the concept of autonomy in philosophical history, culminating with the contemporary treatment of this idea. This will allow us to link various ideas that have been associated with autonomy in the theoretical, philosophical sense, to the concerns reflected in the Belmont Report and the Declaration of Helsinki. I will also be able to use certain of these ideas to reveal what is valuable about autonomy in the context of research ethics, along with the closely associated concept of respect for persons. I will draw upon elements of these theories to formulate a philosophical basis for research ethics which is responsive to the practical ethical concerns that arise in this context, but that is also grounded in philosophical ideas about the value of autonomy and respect for persons.

I will, in exploring the historical roots of contemporary autonomy, point out the ways in which this theoretical work has influenced ethical discourse concerning human research. In looking at more recent accounts of theoretical autonomy, I will note the point at which contemporary theories of autonomy predominantly converge, to discern the basis of the
philosophical notion of autonomy as it is currently understood.\(^{324}\) We have come across the notion of autonomy, in Chapter 2, in the context of medical and research ethics, as concerned with the right to “choose independently from among all options.”\(^{325}\) In the majority of contemporary theoretical philosophical discourse, however, autonomy is taken to mean more than freedom of choice. I will show that the majority of philosophical accounts of autonomy subscribe to a conception of autonomy as self-governance; that is, “to be directed by considerations, desires, conditions, and characteristics that are not simply imposed externally upon one, but are part of what can somehow be considered one’s authentic self.”\(^{326}\) The notion of being directed in one’s decisions by one’s authentic self forms the core of the contemporary philosophical notion of autonomy, though what constitutes this specifically differs between theories. I will thus refer to the accounts that make authenticity central to their conception of autonomy as fitting the “philosophical model” of autonomy. I will contrast this with what I refer to as the “biomedical model” of autonomy, an account devised by Faden and Beauchamp that departs from philosophical consensus in its exclusion of an authenticity criterion from its model of autonomy. Before we are able to understand the reasoning behind the contemporary models of autonomy, however, we must trace the notion back to its philosophical roots. In addition to giving us a better understanding of what contemporary accounts of autonomy within the philosophical model wish to invoke, I will draw on some of the insights in the historical material on autonomy in my own account of how we express the value of respect for persons in research in

\(^{324}\) This section will not be concerned with providing an extended account of the various contemporary models of autonomy; to document this would require volumes of work, see, for example J. Christman, (ed.) The Inner Citadel: Essays on Individual Autonomy, Oxford University Press, Oxford, 1989 and J. Taylor (ed.) Personal Autonomy: New Essays on Personal Autonomy and Its Role in Contemporary Moral Philosophy, Cambridge University Press, Cambridge, 2005. This section is concerned instead with tracing the most general ideas behind the notion of autonomy, which will be sufficient for my subsequent analysis of the situation in research ethics as it currently stands, and the underlying theory for research ethics which I will provide in the next chapter.


Chapter 5. With these goals in mind, we turn first to Kant’s seminal account of autonomy.\(^{327}\)

**Kantian Autonomy**

Immanuel Kant was the first theorist to make the concept of autonomy central to morality;\(^{328}\) a position which it still enjoys today, especially in the context of research and medical ethics. However, it is essential to understand that the concept that Kant was speaking of differs drastically from the notion of autonomy as it is understood today.\(^{329}\) Writing in the late eighteenth century, Kant’s concern with autonomy came from the idea that the then popular conception of morality as obedience to authority was not able to properly accommodate an appreciation of human dignity which he believed was demanded by the teachings of Christianity.\(^{330}\) To answer this concern, Kant aimed to construct a basis for morality which was not reliant on outside authority. He held that all (normal) persons have a capacity for autonomy, which allows them use rationality to “legislate their own [moral] norms of conduct”,\(^{331}\) independent of outside authority.

Kant’s preoccupation with rationality as the basis for morality can also be seen as a reaction to Humean ideas about reason and morality, namely, Hume’s famous idea that “reason is, and ought only to be the slave of the passions”.\(^{332}\) For Hume, only desire can motivate us to action, and morality must thus be constrained by desire-based motivation.\(^{333}\) For Kant, to relegate reason to an instrumental role in achieving our desires, and to

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327 Though it may seem odd to begin with a Kantian notion of autonomy, as it is so very different from that often invoked in medical and research ethics, I will argue, in Chapter 5, that some insights that stem broadly from the Kantian notions of autonomy and respect for persons play a crucial role in allowing us to make sense of the demands of respect for persons in the context of research.


330 Schneewind, *The Invention of Autonomy*, p.3.

331 Beauchamp and Childress, *Principles of Biomedical Ethics* (5th ed.), p.61.


content that our ends should be fixed by anything external (including desires), was to undermine the notion of human freedom and dignity.\textsuperscript{334}

Autonomy then, for Kant, is the capacity to rationally determine one’s own fundamental moral principles. However, he does not hold that we are free to simply choose whatever principles we like. The key to understanding Kant’s notion of autonomy is to understand the restrictions that he placed on the concept. Kant argues that it is only rational to adopt moral principles that could be chosen and acted upon by all moral agents; nothing can be a moral principle that could not be a principle for all.\textsuperscript{335} Our capacity for autonomy thus leads us to a universal set of moral principles, created by and for all moral agents. Rather than the capacity to choose whatever principles one prefers, Kant’s notion of autonomy is better understood as the ability to see what morality demands, and to act accordingly.\textsuperscript{336} This clearly differs starkly from more recent accounts of autonomy, which give a more individualistic account of the concept,\textsuperscript{337} focusing on independent action.\textsuperscript{338} An individualistic conception of autonomy is not able to provide the sort of basis for morality that Kant has in mind. Autonomy as we understand it in contemporary philosophy, that is, as the ability of persons to govern their own lives with some degree of independence from external strictures\textsuperscript{339} is compatible with selfish and non-universalisable behaviour that “may undercut rather than manifest morality [in Kant’s sense]”.\textsuperscript{340} This is brought out in my subsequent discussion of Mill.

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\textsuperscript{335} I. Kant, \textit{Grounding for the Metaphysics of Morals} (3\textsuperscript{rd} ed.) J. Ellington (trans.), Hackett Publishing, USA, 1993, p.44.
\textsuperscript{336} Schneewind, \textit{The Invention of Autonomy}, p.4.
\textsuperscript{339} And also some sorts of internal strictures, as we will see below.
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Though Kant’s idea of autonomy clearly differs vastly from what we regard as autonomy today, certain aspects of his work endure in our current conception of autonomy, and are relevant to discussion of this value in research ethics. Kant’s work on autonomy provides us with the close links between the capacity for autonomy and personhood, which endure in much contemporary philosophical work on autonomy. For Kant, respect for the dignity of persons necessitates recognising that persons^341 are autonomous beings who are able to legislate their own norms of conduct. To ignore this ability is to ignore an important aspect of what it means to be human, and denies the equality of all human beings.\(^{342}\) This aspect of Kant’s autonomy has also been highly influential in research ethics, as reflected, for example, by the Belmont Report’s contention that respecting autonomy is a necessary and chief component of respecting the inherent dignity of individuals.

**Millian Autonomy**

Mill’s conception of autonomy provides a counterpoint to Kant; while autonomous actions according to Kant’s conception are restricted to those that conform with the universal law, Mill’s notion of autonomy is focused on individual liberty of action and thought. Though Mill does not actually use the term autonomy in this context, his ethical theory has had a clear influence on later accounts of autonomy, bearing much closer resemblance to the notion as used in contemporary accounts than Kant’s theory. Mill takes a very different view to Kant about what autonomy involves and its place in moral theory; however, like Kant, his concept of autonomy is central to his moral philosophy.

As with Kant, the key to understanding Mill’s notion of autonomy is to understand the concerns which motivate his philosophy. Mill aims to discern the “the nature and limits of the power which can be legitimately

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^341 Kant uses the term “rational beings”, but, as we can see from Schneewind’s historical exegesis of Kant, he means for this term to refer to all ordinary people, whom he sees as all equally able (in virtue of their God-given abilities) to see what morality demands and to act accordingly, i.e. to qualify as rational beings. See Schneewind pp.3-7; pp.488-90.

exercised by society over the individual.” He is concerned that, while the question of the “struggle between Liberty and Authority” has been debated in the past, not enough attention has been given to this important question in a democratic society, because democracy is conceived of as “self-government”, thus, the same questions about what power it is legitimate for some people to exercise over others are not perceived to arise. Mill contends, however, that this is a mistake. Even in a democratic society, Mill holds, “the ‘self-government’ spoken of, is not the government of each by himself, but of each by all the rest.” This can lead to a “tyranny of the majority”; the will of the “most numerous or the most active part of the people” can be used to oppress the minority. Mill is concerned with providing safeguards against this phenomenon, holding that there is a limit to the legitimate extent to which collective opinion can interfere with individual independence. He thus aims to devise a principle which will prevent such illegitimate exercises of power. This political discussion provides that background for Mill’s discussion of autonomy in the sense with which I will be concerned with it.

Mill’s principle is that “the sole end for which mankind are warranted, individually or collectively in interfering with the liberty of action of any of their number, is self-protection...In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign.” He holds that people should be free to carry out their desired course of action “without hindrance, either physical or moral, from their fellow-men, so long as it is at their own risk and peril.” Mill does not see this as an abstract, intrinsic right; he advocates this principle on the basis that following it will maximise utility; the ultimate basis of all his ethical arguments. There are two primary reasons why he advocates such liberty of action based upon utility. The first is that

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the ability to live out one’s life in a manner of one’s own choosing is an essential ingredient of human happiness. Mill contends that humans have different types of characters, and that one mode of living, however suitable it might be for one type of person, will not be appropriate for all people. Recognising the differences between people necessitates recognising that different ways of life will be the best means of allowing people to achieve happiness and wellbeing.

Mill also sees liberty of action as being “the chief ingredient of individual and social progress.” It is only through allowing people to live their lives in different ways, Mill contends, that we are able to “test which customs are worth retaining and which should be rejected”. Blind adherence to custom, for Mill, is a hindrance to human advancement. The only way to make social progress is to allow different modes of life to coexist alongside each other. This allows people to compare their own way of living to other, different possibilities, and to see the superiority of other ways, or even to combine the advantages of both ways, “producing something better than either.”

Though Mill talks about liberty of action, his theory is richer than this, and contains the seeds of our contemporary, individualistic conception of autonomy. Mill cannot be taken as advocating that people should simply act upon their strongest desires. He specifies that his doctrine of liberty “is meant to apply only to human beings in the maturity of their faculties...Those who are still in a state to require being taken care of by others, must be protected against their own actions as well as against external injury.” Mill argues that his arguments for liberty can only

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350 The parallels between Mill’s line of argument and the contentions of early 19th century physicians John Gregory and Benjamin Rush concerning consent are clear – see pp.45-7.
351 Mill, On Liberty, Chapter 3.
352 This is a further indication that we should not take autonomy and wellbeing to be routinely opposed. This contention will form part of the basis for my argument in Chapter 5.
353 Mill, On Liberty, Chapter 3.
354 Mill, On Liberty, Chapter 3.
operate if people are appropriately trained in their youth, “to know and benefit by the ascertained results of human experience.” Once they have reached the maturity of their faculties, however, they must be free to interpret this experience in their own way, subscribing to or rejecting it as they see fit.

Mill does not see the value of liberty as coming from people’s ability to act on their “vague and transient desires”. Mill sees strong impulses and desires as an essential part of one’s character, but argues that these strong impulses must be “under the government of a strong will” to have a fully developed character. The aim of giving such scope to liberty of action is, for Mill, what allows “the best and highest in me to have fair play, and enable it to grow and thrive.” His principle of liberty is closely linked with self-development; the ability to develop one’s individual talents and proclivities “to a complete and consistent whole.” This theme of self-development is essential to Mill’s work, and is closely related, as we shall see, to the contemporary idea of autonomy as the development of one’s life as a whole in accordance with one’s authentic self. Mill argues that the cultivation of individuality is essential to producing “well-developed human beings”, going so far as to claim that “Individuality is the same thing with development”. The only way for human beings to develop the very faculties that make them human, Mill argues, is to exercise their decision-making capabilities. A person who simply follows what is customary exercises only the “ape-like [faculty] of imitation”, whereas a person who plans for himself exercises all his human faculties. Though Mill concedes that one may “be guided in some good path, and kept out of harm’s way” by simply following others, he ties the exercise of individual decision-making to human dignity, asking “what will be [such a person’s] comparative worth

357 We can see a similar idea in operation in the Belmont Report’s contention that respect for persons involves respecting the autonomy of the autonomous, and protecting those with diminished autonomy. I will evaluate this idea, and use a similar contention to define the limits of free action in my theory in Chapter 5.
358 Mill, On Liberty, Chapter 3.
359 Mill, On Liberty, Chapter 3.
360 Mill, On Liberty, Chapter 3.
361 Mill, On Liberty, Chapter 3.
as a human being? Mill, like Kant, argues that it is more consistent with Christian faith to exercise and cultivate the development of God-given human faculties, rather than to subordinate them to obedience to authority.

Mill, then, takes a different view to Kant on what autonomy demands, but, like Kant, he makes the recognition and exercise of this capacity essential to one’s value as a person. Mill is able to embrace a more individualistic conception of autonomy because autonomy, for him, does not provide the basis for morality. This means that Mill is not restricted by Kant’s idea that anything that is autonomously willed is universalisable; Mill’s theory allows and even encourages people to recognise that their individual proclivities may make them suited to a different way of life to others. Mill’s suspicion of government control means that his theory reflects similar concerns that led to the rise of the value of autonomy in the 1960s and 70s, as we saw in Chapter 2. Mill’s strong emphasis on individual liberty, and the links between this and self-determination and development, have had, as we will now see, a profound influence on more recent accounts of autonomy.

Autonomy in the 20th Century

Despite the differences between these two theories, we can begin to see common themes emerging that have formed the basis of the concept in more recent work. Both theorists emphasise respecting and recognising a person’s decision-making capabilities as a necessary part of respecting the person. More recent models have taken up this theme, through developing theories of which decisions should be taken as reflective of personhood, and thus as autonomous. During the 70s and 80s, around the time that respect for autonomy achieved increasing prominence in medical

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362 Mill, On Liberty, Chapter 3.
363 Mill, On Liberty, Chapter 3.
ethics and in society generally, the concept of autonomy also enjoyed renewed attention in philosophical discourse. The theories of this time focused on separating actions that were simply free from actions that were reflective of autonomy, that is, actions that have some sort of special relation to the self. They generally did this through distinguishing between desires about what action one wants to take, and desires which receive, or could receive, endorsement from further desires concerning what desires one wants to have. These developments allow the theory of autonomy to be used in applied ethics, because we can then determine which decisions should be respected and protected when we wish to uphold the value of respect for persons. A crucial development in this direction came from Gerald Dworkin’s extremely influential account of autonomy, from the 1980s.366

Dworkin examines the concept of autonomy due to the ubiquity of the notion in philosophical discussions on liberty and equality. Despite the fact that the notion of autonomy played a central role in much normative philosophical work, Dworkin maintained, it had “not received careful and comprehensive philosophical examination.”367 He also points out that, by this stage, all discussions of informed consent invoked the notion of autonomy, so analysis of this concept is likely to have implications beyond theoretical philosophy.368 Dworkin maintains that many disparate ideas are grouped together under discussion of autonomy, and attempts to find unifying factors. He notes that a common theme in all accounts of autonomy “is a notion of the self which is to be respected, left unmanipulated, and which is, in certain ways, independent and self-determining.”369 This is indicated by the etymology of the term: “autos (self) and nomos (rule or law).”370

366 Dworkin’s work on autonomy closely resembles Harry Frankfurt’s earlier work on personhood, which I discuss below. I open with Dworkin’s account because he explicitly frames these ideas in terms of autonomy.
368 Dworkin, The Theory and Practice of Autonomy, p.5.
369 Dworkin, The Theory and Practice of Autonomy, pp.11-12.
Autonomous decisions, then, are decisions which stem in some way from the self, free of influence from external factors. But this basic definition leaves many questions unanswered, and generates some difficult problems. The nature of the “self” that makes the decisions is left undefined. Further, Dworkin argues that for autonomy to be a useful concept, it has to be something that is realistically achievable. This means that we cannot settle upon an overly stringent definition of self-determination. If we require that the autonomous individual is free of all constraint or influence, we arrive at an impossible notion of autonomy. For, as he notes, “all individuals have a history. They develop socially and psychologically in a given environment with a set of biological endowments. They mature slowly and are, therefore, heavily influenced by parents, peers and culture.”

We also want autonomy to be compatible with some measure of dependence on others, and some degree of connectedness to other people. A strong definition of autonomy as self-determination also risks precluding subscribing to standards of correctness or rationality. Dworkin wishes to avoid these difficulties, while retaining the central meaning of autonomy as self-determination.

In order to arrive at his concept of autonomy, Dworkin first considers the relationship between liberty and autonomy. He argues that these two concepts are distinct notions. If we focus only on liberty, that is, freedom from interference, Dworkin suggests, “we miss an important dimension of a person’s actions.”

Dworkin illustrates this with an example:

Consider the classic case of Odysseus. Not wanting to be lured onto the rocks by the sirens, he commands his men to tie him to the mast and refuse all later orders he will give to be set free. He wants to have his freedom limited so he can survive. Although his behavior at the time he hears the sirens may not be voluntary – he struggles against his bonds and orders his men to free him – there is another dimension of his conduct that must be understood.

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This case provides an example of where liberty and autonomy come apart; in limiting Odysseus’ liberty, his men promote his attempts to steer his life overall. This, Dworkin believes, provides us with the key to the basis of autonomy. Odysseus’ conduct cannot be understood by just looking at his desires at any given time, but hinges on the fact that he “has a preference about his preferences, a desire not to have or not to act upon various desires. He views the desire to move his ship closer to the sirens as something that is no part of him, but alien to him.”

The ability to reflect upon and form preferences about one’s desires, wishes or intentions, is, to Dworkin, “a crucial feature of persons” which is ignored when we simply look at interference with liberty, that is, interference with what Dworkin refers to as one’s “first-order desires.” Persons are capable of having a desire, but, at the same time, of wishing that they did not have this desire. Dworkin calls these desires about one’s desires “second-order desires.” Dworkin was not the first to single out this feature as characteristic of persons. Harry Frankfurt’s 1970s theory of personhood similarly suggests that these desires are essential to understanding what it is to be a person. Frankfurt was aiming to analyse the concept of personhood; the question of what defined a person was, he believed, a pertinent yet neglected philosophical problem. He argued that many accepted theories of personhood did not do a good job at distinguishing persons from other creatures.

Frankfurt argued that one thing that does differentiate between persons and other species involves “the structure of a person’s will.” Other species have desires, motives, and the capacity to make choices, he suggests, but

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374 Dworkin, The Theory and Practice of Autonomy, p.15.
375 Dworkin, The Theory and Practice of Autonomy, p.15.
377 Frankfurt does not hold that persons are necessarily coextensive with humans; rather, he wishes his theory to capture the “attributes which are the subject of our most humane concerns with ourselves and the source of what we regard as most important and most problematical in our lives.” This does not preclude a member of another species qualifying as a person, or indeed, does not suggest that all humans will qualify as persons. See Frankfurt, “Freedom of the Will and the Concept of a Person”, p.6.
what seems to be particularly characteristic of persons is that they are able to form second-order desires. Frankfurt argues that in addition to “wanting and choosing and being moved to do this or that, men may also want to have (or not to have) certain desires and motives. They are capable of wanting to be different, in their preferences and purposes, from what they are”.379 The ability to reflect on one’s desires, and evaluate them according to what kind of person one wants to be, Frankfurt suggests, appears to be something that is specific to humans.

Frankfurt is interested in a particular category of second-order desires, which he refers to as “second-order volitions”. He contends that someone can want to have a desire, that is, have a (second-order) desire to have a certain (first-order) desire, without wanting that desire to actually move him to action. For example, someone may want to know what it feels like to crave cigarettes. They may have the desire to have the desire to smoke, just to experience what cigarette cravings feel like, without actually wanting to smoke a cigarette. Conversely, we have second order desires that we want to translate into action. An addict who is trying to quit smoking, for example, might want to not want to smoke. He might possess two first order desires, the desire to smoke, and the desire to refrain from smoking. If this person acts on their desire to refrain from smoking, what he wants to desire at that time is what he does desire. His second order desire, and his first order desire that moves him to action (what Frankfurt refers to as an effective desire) are in line with each other. It is this latter type of second order desire that Frankfurt refers to as a second-order volition, and it is these, and not second-order desires generally, that he regards as essential to being a person.380

Dworkin concurs with this analysis, stating that the “idea of autonomy is not merely an evaluative or reflective notion, but includes some ability both to alter one’s preferences and to make them effective in one’s actions and, indeed, to make them effective because one has reflected upon them and

adopted them as one’s own.” Autonomy, for Dworkin, must involve not only the ability both to scrutinise and reflect upon one’s preferences (that is, to form second order preferences), but also to change one’s desires and actions in light of this reflection (through forming second order volitions).

We see then, a strong trend emerging in both work on autonomy and personhood that singles out certain of our desires as linked in some important way to personhood. These theories of autonomy developed the notion in a useful direction by enabling us to distinguish decisions that reflect the self in some important way. According to Frankfurt and Dworkin, decisions have an important connection to personhood, or qualify as autonomous, when we endorse them through a second order desire, and want these desires to be the ones that we act on. Frankfurt and Dworkin don’t suggest that this needs to be a fully explicit, articulated process; Frankfurt notes that the correspondence between a person’s will and their higher order volitions may, for some people, be a thoughtless and spontaneous process, while Dworkin suggests that persons may unconsciously shape and mold their life in a way that is in accordance with their reflective procedures. The crucial requirement for Dworkin and Frankfurt is conformity between second order desires and the desires that move us to action, however this is achieved.

This means of theorising autonomy has several attendant advantages. These theories do not limit the content of autonomous desires, or specify the source of them; all that is required is that one is able to reflect upon desires, and endorse or reject them. This means that autonomy is compatible with multiple conceptions of what is good and valuable. This is essential to Mill’s ideas about the value of liberty, and, as Dworkin notes, enables the concept of autonomy to be of value for different ideological outlooks. This also avoids problems generated by the fact that every individual has a given history; self-determination under these theories is not taken to be akin

382 Frankfurt, “Freedom of the Will and the Concept of a Person”, p.17
383 Dworkin, The Theory and Practice of Autonomy, p.17
to self-creation. It is not the source of one’s desires and values that matters, but only whether one is able to reflect upon and change these desires.

These theories also provide us with a means of seeing the relationship between autonomy and liberty. As Dworkin argues, autonomy and liberty must be understood as separate notions, though they are related “in both contingent and noncontingent ways.”\(^\text{385}\) Because people generally wish to act freely, restricting liberty may also interfere with the ways that a person wants to be motivated, and thus the kind of person he wants to be; thus, restricting liberty will generally restrict autonomy. However, if a person wishes and chooses to be restricted in certain ways, such as through entering a monastery or the army, this can increase his autonomy, through providing him with the means of bringing his first order desires (at least the effective ones) in line with his second order volitions. Generally, Dworkin argues, liberty, power, and control over various aspects of one’s life, though not the same as autonomy, are “necessary conditions for individuals to develop their own aims and interests to make the values effective in the living of their lives.”\(^\text{386}\) This clearly resembles Mill’s contention that liberty is a necessary condition for self-development. Finally and most importantly, these theories give us a good account of why only certain of our desires should be thought of as autonomous, by linking these desires to a crucial aspect of personhood. As Frankfurt suggests, the capacity to form second-order volitions seems to be a defining feature of persons. Likewise, Dworkin contends that “we fail to capture something important about human agents”\(^\text{387}\) if we take only first-order desires into account. By singling out the decisions which make us persons, Dworkin and Frankfurt connect certain of our decisions to personhood.

**Autonomy in Contemporary Philosophy**

More recently, the concept of autonomy has become central to moral philosophy, and the basic notion as posited by Frankfurt and Dworkin has


been developed in many diverse and sophisticated ways. These various theories of autonomy differ in many particulars, but, as James Taylor notes in his influential anthology on the concept, “most contemporary analyses of autonomy require that a person’s...desires must originate in some way from her ‘self’ for her to be autonomous with respect to them, with this ‘self’ often being given a distinctly Lockean gloss.” Though Taylor uses the term originate, it is fair to imagine that he simply means that they are linked to this notion of the self in some way. As Dworkin notes, “If the notion of self-determination is given a very strong definition – the unchosen chooser, the uninfluenced influencer – then it seems as if autonomy is impossible.” All individuals develop in a given environment, and with a given biological makeup. Thus, if we want the notion of autonomy to be useful, we must aim not for desires that originate within the self, but which bear some sort of important relation to the self.

Through Frankfurt and Dworkin’s theories, we have seen an indication of one way that this might be achieved. Desires are autonomous in virtue of being in line with the higher order desires; our desires about our desires, that reflect the kind of person we are and want to be. Frankfurt and Dworkin, however, say little about the source of these higher-order desires. Though they stress that possessing and acting upon higher-order desires are a distinctive part of being a person, they do not tell us what about these desires makes them particularly reflective of the self, and what gives them the authority to constitute a special reflection of the self. Contemporary analyses of autonomy generally tend to circumvent this problem by basing their theories of autonomy on a broadly Lockean conception of the self. That is, desires qualify as autonomous in virtue of having some sort of special relationship with the (Lockean) self. In order to understand the core

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389 Taylor, “Introduction”, p.17. I will discuss this Lockean notion of autonomy in detail below.
391 For more about this and other problems with hierarchical analyses of autonomy, and the ways in which contemporary theories of autonomy have responded to these problems, see Taylor, “Introduction”, pp.1-29.
of the majority of contemporary theories of autonomy, therefore, we must outline the Lockean conception of personhood.

For our purposes, we just need to understand the general idea behind the theory of autonomy; the idea that it links to the self, and the conception of the self that is thought to underlie this concept. I will therefore turn to an explanation of Locke’s theory of personhood, before providing a couple of sketches of how this theory has been used to form the basis of the concept of autonomy in contemporary philosophy. We will use this theory of personhood as the basis for autonomy in Chapter 5 to single out the decisions that are related to personhood in the context of research ethics. This will give us means of assessing when this criterion is relevant in practical circumstances, and I will use it to argue that autonomy, as conceived of in this way, is related to a smaller subset of decisions made by the research subject than is often assumed, though it is still an essential tool when it comes to capturing what is valuable about these decisions.

**Locke’s Theory of Personal Identity**

Locke’s theory of personal identity, or of what constitutes the self, forms part of his work on establishing the continuity of identity for all things, that is, what makes something the same thing over time. Substances, or inanimate objects, he argues, remain the same over time in virtue of being made up of the same constituent parts over time. However, this will clearly not apply to living things, which can change all their constituent parts over time but still remain the same thing. Locke gives the example of an acorn turning into an oak; though all the constituent parts change, we would still want to say that it is the same thing. Locke argues that the sameness of identity for living things inheres instead in the continuing function of its constituent parts towards the continuation of the same life. Though the parts change over time, they are geared towards continuing the same life. This is true for any living thing, whether it be an oak or a horse. As a man is a type
of animal, Locke contends that his identity can be understood in the same way.\(^{392}\)

However, Locke distinguishes between the identity of a man, and the identity of a person. The identity of a person, for Locke, inheres in the sameness of consciousness. While consciousness is not continuous (for example, there are breaks when we sleep), we can draw on the same memories to show that we are the same person over time. In order to argue that the identity of the person cannot inhere in the body, Locke argues that if a prince and a cobbler were to swap consciousness and memories, we would want to say that the identity of the person goes with the consciousness, and doesn’t remain with the body. That is, the prince-bodied individual with the consciousness of the cobbler is the cobbler and vice versa.\(^{393}\) Though this is an intuitively pleasing view of personhood, it is not entirely clear what ‘sameness of consciousness’ amounts to for Locke. As he refers frequently to memory, it is natural to assume he is referring here to autobiographical memory. That is, the ability to remember a person’s past experiences makes you that person. This is bolstered by the fact that Locke suggests that people cannot be held responsible for what they do not remember (are not conscious of having done) because where there is no sameness of consciousness, you cannot attribute the acts to the same person.\(^{394}\)

However, there are several problems with this account, which have led to some subsequent theorists further developing this notion of the self. There are three primary problems with Locke’s theory of personal identity. Firstly, it is unable to account for false memories. It seems to imply that if someone has a memory of leading the troops at Waterloo, that makes him Napoleon.\(^{395}\) Secondly, it seems to privilege memory above other


psychological elements, such as beliefs, desires and values, which seem equally important to identity. Thirdly, there is a problem concerning requiring ‘sameness of consciousness’; brought out by Thomas Reid’s challenge to Locke’s view, commonly referred to as the ‘Brave Officer Paradox’. Reid presents the paradox thus:

Suppose a brave officer to have been flogged when a boy at school for robbing an orchard, to have taken a standard from the enemy in his first campaign, and to have been made a general in advanced life; suppose, also, which must be admitted to be possible, that, when he took the standard, he was conscious of his having been flogged at school, and that, when made a general, he was conscious of his taking the standard but had absolutely lost consciousness of the flogging.

This presents a problem for Locke’s theory; he must hold that the school boy was the same person as the officer and that the officer was the same person as the general in virtue of their shared memory. However, as the general has forgotten the memory of the school boy, they cannot possibly, on Locke’s account, be the same person.

In response to these concerns, several more contemporary philosophers have suggested amendments to a theory of personhood based upon psychological continuity. Rather than requiring a sameness of consciousness, it has been suggested that sameness of self should be based upon overlapping chains of psychological connections, including memories, beliefs, desires and values. It is also argued that these psychological elements must be appropriately caused. This solves the problem presented by the Brave Officer paradox by removing the need for direct connections to establish sameness of self. In addition, these revisions allow us to take a variety of psychological elements into account, and, by requiring that these elements

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are appropriately caused, removes the problem of false memories. The Lockean ‘self’ that Taylor refers to, if interpreted along the lines of these updated Lockean accounts, posits that the self consists of overlapping, appropriately caused psychological connections. This is what I will be referring to in future references to the Lockean self. Autonomous action, then, as construed by the vast majority of philosophical theories on autonomy, must bear a special relation to the bundle of psychological connections that constitute the self.

The Lockean Self in Contemporary Theories of Autonomy

Contemporary theories of autonomy tend to broadly take this conception of the self as central, though the way they construe the connection that autonomous actions must have to the self differs. We will briefly survey some of the more significant contemporary alternatives here, however, the most important element to keep in mind here is that the vast majority of contemporary theories of autonomy rely on a self of this sort that underlies any autonomous decisions, and autonomous decisions are evaluated as such if they bear some relation to this self. This is often referred to as the condition of ‘authenticity’; the requirement that the desires are somehow authentic to the agent, or in other words that they are a real reflection of her self. Rather than committing to a particular way of theorising how decisions must relate to the Lockean self when I utilise the idea in Chapter 5 for my own philosophical theory of research ethics, I will just use the general idea of an underlying Lockean self to evaluate the role and value of autonomous decision-making in research ethics. However, it is useful to have some sort of conception of how contemporary theorists utilise the Lockean theory of personhood in their accounts of autonomy in order to understand how the concept works. With this in mind, I briefly turn to two contemporary, Lockean-based accounts of autonomy.

Michael Bratman draws explicitly from a Lockean conception of the self as constituted by a continuing set of psychological connections to support his

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401 Schechtman, “Personal Identity”.
theory of autonomy. Bratman bases his evaluation of whether desires are autonomous on whether they are compatible with an agent’s plans over time. In addition, the agent must not be alienated from these long term plans, or, as Bratman refers to them, these “self-governing policies”. The agent must instead be satisfied with these plans. This avoids a problem that is often raised in the context of Frankfurt and Dworkin’s hierarchical theories. To take the example of the unwilling smoker above, the smoker, instead of achieving autonomy by repudiating the first order desire to smoke, might alter his second order desire to not want to want to smoke, as the continuing struggle against the cravings is too difficult. This would be compatible with autonomy according to Frankfurt’s model sketched above. By requiring that the agent is satisfied with his self-governing policies, Bratman avoids classifying the grudging smoker as autonomous. In addition, Bratman provides a basis by which these long term plans can be said to have a special role in determining whether desires are autonomous. Because, in accordance with a Lockean conception of the self, these long term plans are constitutive of the self, they are able to provide a reference by which we can assess whether a certain desire is autonomous or not. This means that we are only able to assess whether a desire is autonomous, as Dworkin suggests, by looking at the agent over time. This notion of autonomy as something that is able to be assessed only by looking at extended periods of the agent’s life is an important feature of autonomy that we will be returning to in the subsequent chapter.

Laura Waddell Ekstrom’s model of autonomy focuses on similar concerns to the 20th century models of autonomy we have looked at thus far. She begins with the insight that led Frankfurt, Dworkin and Bratman to develop their theories; that a person is autonomous with respect to the desires and preferences that move them to act when these flow from her self. Ekstrom posits that a preference becomes autonomous when an individual critically

403 Bratman, “Planning Agency, Autonomous Agency”, p.44.
reflects upon, and endorses it, where this critical reflection is based upon “one’s conception of the good”. However, Ekstrom also places a second condition on autonomy, and it is upon examination of this condition that the links to a Lockean theory of personhood become apparent. Ekstrom holds that in order to qualify as autonomous, a preference must cohere with the other reflectively accepted preferences held by the agent. Though Ekstrom acknowledges that we have conflicting desires to some extent, she posits that our cohering motivations are more central to whom we are, and constitute our real self. Ekstrom holds that these cohering preferences are an attractive candidate for the self, as these preferences are well supported by each other; they form “an interweaving structure of mutual support”. As a result, these preferences are likely to be “abiding, relatively stable through time”, and Ekstrom contends that “we tend to view the more enduring aspects of a person’s psychology as central rather than peripheral.” This clearly links to the Lockean conception of the self as constituted by psychological continuity through time. Furthermore, as in Bratman’s theory, because these preferences are constitutive of the self, they provide an appropriate means of assessing whether a desire is autonomous or not. Whereas in a Frankfurtian hierarchical theory one might ask why second-order preferences have a special role in determining whether a desire is reflective of the self, and whether higher levels of preferences might need to be invoked to justify these second order preferences, Ekstrom’s theory locates the self in these cohering preferences, providing this set of preferences with the authority to determine which preferences are autonomous.

Many contemporary theories of autonomy take a similar route, providing structural conditions under which an agent’s desires might be said to qualify as autonomous. Generally, these theorists focus purely on the internal

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structure of the agent's desires and preferences. However, there are a minority of theorists that suggest that this internal focus is insufficient, contending that we must introduce an additional, external criterion for autonomy. I will return to theories of this sort in Chapter 5, where I argue that a weak external criterion can be used to constitute some restrictions on the exercise of free choice, and defend my account against claims that a strong external criterion may be required.

**Autonomy: The Biomedical Model**

The previous section has focused on the primary elements of autonomy in philosophical theory. However, at the same time, autonomy has a central role in debates about issues in applied philosophy. As we have seen, autonomy is given a central place in research ethics codes. But it is important to understand that the notion of autonomy utilised in most practical debates differs starkly from the notions that we have discussed above; so much so, in fact, that it makes little sense to refer to such a notion as autonomy. To illustrate this, and to get a handle on what is being aimed at in the informed consent guidelines in research ethics that purport to protect autonomy, I will now present the influential, practically focused model of autonomy developed by Ruth Faden and Tom Beauchamp in their book *A History and Theory of Informed Consent*.

Faden and Beauchamp were writing at a time following a huge growth in the importance of autonomy in medical ethics. As we have seen in the second chapter, prior to the 1960s, medical practice was focused almost exclusively on the wellbeing of the patient. Medicine had, as a result, been characterised by widespread paternalism; doctors acting in the best interests of the patient, often without consulting the patient on treatment options. However, an increased focus on individualism in Western countries in the 1960s and 70s led to a concern with limiting the authority of the doctor in order to allow the patient to exercise his capacity for self-determination.\(^{412}\) The concurrent development of informed consent guidelines reflected this

burgeoning concern for the autonomy of patients. Informed consent also acquired the legal function of protecting the doctor/researcher from liability. Faden and Beauchamp wished to provide a detailed theory that grounds informed consent in a moral concern for respecting agents’ autonomy, rather than legal concerns of protecting against liability, which they believe often come to dominate or confuse the discussion of informed consent.

Faden and Beauchamp’s concern with the historical factors that led to the rise of the moral value of autonomy in a practical, medical and research context results in a model that, while placing emphasis on autonomy, differs in focus from the contemporary theoretical discussions of autonomy. While, as we have seen, contemporary models of autonomy are primarily concentrated upon theorising what makes an action authentically the agent’s, Faden and Beauchamp are more concerned with protecting the agent’s freedom of choice and action against “controlling constraints imposed by others”.

We have seen, in Chapter 2, that the value of autonomy in the context of medical ethics during its rise as a reaction to paternalism was basically construed as “the right of the patient to choose independently from among all options.” A similar emphasis on freedom from external constraints leads Faden and Beauchamp to attempt to protect a wide range of decisions from interference through designating them as autonomous. This results in a substantial departure from the contemporary theoretical work in autonomy; the rejection of the authenticity criterion.

Rejection of Authenticity

Faden and Beauchamp examine and reject authenticity as a condition of autonomy, though they do acknowledge the importance of the point about ownership of values that is raised by the discussion of authenticity. By emphasising reflection upon values, and incorporation of these values into a coherent personality structure, authenticity-based models of autonomy

capture something important about what it is to make values ‘one’s own’. We have seen above how this type of condition is often linked to a Lockean theory of personhood, and thus how the links between autonomous (authentic) action and the self can be established in this manner. However, Faden and Beauchamp are concerned about this authenticity-based notion of autonomy for two main reasons.

Firstly, due to their concern with providing a theoretical basis for informed consent, they want their model of autonomy to present criteria for what it is for an individual action to qualify as autonomous. They point out that in an authenticity-based theory of autonomy, autonomy is seen as involving “a kind of agent”, namely, the kind of agent whose “life has a consistency that derives from a coherent set of beliefs, values and principles, by which his actions are governed...[that] he has made his own.”417 The autonomous agent’s “life as a whole expresses self-directedness.” This idea of autonomy is more focused on autonomous persons. The only way in which it is possible to evaluate whether one’s decision is autonomous under a Lockean authenticity-based theory, for example, is with reference to the stable, enduring values that constitute the self. Faden and Beauchamp are concerned that this leads to a focus on whether agents possess the capacity for autonomy (i.e. whether they have the kind of stable or coherent personality from which autonomous decisions can flow), where they wish to focus more on individual actions. They want to emphasise that making an autonomous decision in a certain case does not necessarily follow from being a generally autonomous person. For example, if a person with the capacity for autonomy signs a consent form based on a mistaken idea about its content, this particular decision is not autonomous.418 I will return to this idea in Chapter 5.

Primarily, however, they “reject authenticity...because [they] believe it is too demanding as a condition of autonomous action”.419 Faden and Beauchamp

417 Faden and Beauchamp, A History and Theory of Informed Consent, p.236.
are concerned that the inclusion of a standard of authenticity will designate very few choices, and choosers, as autonomous. Many deliberate actions that are understood and carefully thought out will fail to meet the condition of authenticity. Actions that in every ordinary and conventional sense would qualify as one’s own actions, they argue, need not meet this condition of authenticity. Where authenticity is conceived of as reflective acceptance of a desire (along the lines of Frankfurt and Dworkin’s theories), for example, Faden and Beauchamp argue that everyday actions that may not meet this criterion include “stopping at red lights, praying before meals, standing up when the national anthem is played, ordering sandwiches on whole wheat rather than white bread and the like.” Though one may well have reflected upon these types of actions, and endorsed them based upon this reflection, it seems equally likely that one would just engage in these actions due to societal conditioning, without ever reflectively considering or identifying with them.

Faden and Beauchamp are concerned by the exclusion of these types of actions from a conception of autonomy because they believe that these actions are worthy of being respected as autonomous. They do not mean to suggest by this that only autonomous actions should be regarded as worthy of respect. However, they believe that a satisfactory model of autonomy should incorporate these deliberately chosen actions because they think that the special protections that come with having a decision designated as autonomous should apply in these cases. This can be explained by the special moral role that they assume autonomy to have. They postulate that autonomy is a central, prima facie principle in medical and research ethics, and that having a decision regarded as autonomous “gives us respect, moral

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420 What Faden and Beauchamp take to be Dworkin’s conception of autonomy, though in conceiving of this as requiring “conscious, reflective identification with one’s preferences” (p.264) they construe this condition somewhat more stringently than Dworkin (or Frankfurt) intended, as we have seen above.


422 They don’t give an indication of how non-autonomous decisions should be respected, however, focusing only on the respect that is accorded to decisions that are designated autonomous.

entitlement, and protection against the invasions of others.” 424 This is not to say, Faden and Beauchamp specify, that autonomous decisions and actions trump all other moral considerations, but they suggest that an autonomous decision may only be overridden with sufficient moral justification, and that the “burden of moral proof will generally be on those who seek to intervene in another’s [autonomous] choice.” 425 They also take for granted that “informed consent is rooted in concerns about protecting and enabling self-determining 426 choice by patients and subjects.” 427 It follows from this that choices that do not qualify as autonomous will not be entitled to the protection and promotion through informed consent requirements. These factors account for Faden and Beauchamp’s push to have actions that we would intuitively regard as worthy of protection from outside interference classified as autonomous.

Faden and Beauchamp consider several formulations of the authenticity criterion, rejecting them all as unduly restrictive, or otherwise inappropriate for a practically-focused account of autonomy. The first, as we have seen above, is the notion of authenticity as reflective acceptance; the idea that actions can be seen as authentic if they are accepted, upon reflection, by the agent. 428 Though they concede that this notion of autonomy captures something important about agents, they contend that the exclusion of a great deal of deliberately chosen actions renders this criterion too demanding to be useful for practical purposes. If we accept this notion of authenticity as essential to autonomy, Faden and Beauchamp argue, “many familiar acts of consenting and refusing would fail to qualify as autonomous and thus would not qualify for protection from interference by a principle of respect for autonomy.” 429

I have already noted, however, that both Frankfurt and Dworkin were themselves concerned with this type of problem when formulating their

426 Which they use as equivalent to autonomous in their sense, which I will detail below.
428 Faden and Beauchamp, A History and Theory of Informed Consent, p.263.
theories of autonomy. They, too, are concerned that requiring that every autonomous decision must be approved after explicit reflection is too demanding, and shows a bias towards those who are academically inclined. They allow that correspondence between the desires that move someone to action and their higher order volitions might come about spontaneously or through unconscious processes – they both suggest that it is the correspondence that matters, rather than a specific process of reflection. To translate this to a Lockean condition of authenticity (where stable values and other psychological elements take the place of second order desires), we should perhaps simply require that actions correspond with the stable and enduring values that constitute the Lockean self. According to this more permissive condition, autonomous actions should be reflective of the self, but need not be reflected upon in terms of the self.

Faden and Beauchamp consider this less demanding formulation of the authenticity condition – requiring that the values underlying a choice are stable and consistent (and thus count as elements that constitute the self in Lockean terms). However, they reject this revised authenticity condition, contending that it still excludes actions we would wish to respect as autonomous. They maintain that agents should be free to deliberately choose an action which is out of character, and that these decisions should be respected as autonomous. This conception of authenticity also poses problems in contexts where the agent faces a decision in “new and unfamiliar circumstances”. Decisions made in these situations may generate actions that seem to be out of character, “simply because the surrounding events are unprecedented in the actor’s experience.” Faden and Beauchamp contend that these situations are particularly likely to arise in situations where informed consent is sought or required, and that it would be morally inappropriate to refuse to protect these decisions under the principle of respect for autonomy.

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As well as being unduly restrictive, Faden and Beauchamp maintain that incorporating either of these two criteria into their concept of autonomy would result in the moral concept of respect for autonomy becoming less useful, as its ability to function as a guiding principle in everyday situations would be reduced. In singling out authenticity, as construed as involving reflective acceptance or correspondence with stable and abiding values, a standard for assessing decisions is created that is likely to simply be irrelevant to many everyday situations or decisions. Many everyday decisions, such as what to have for lunch, or what type of washing powder to buy, can simply not be assessed with these criteria; reflective acceptance or cohesion with one’s stable values might not present a useful framework for evaluating these types of decisions, because the overlapping psychological connections that constitute the self may not point to a decision one way or another. The key elements of the self may well be indifferent regarding many everyday decisions. A low-stakes decision to participate in research could constitute a decision of this sort. When it comes to many everyday decisions, including decisions to participate in research, a theory that only focuses on authenticity as the important and legitimating basis for making a decision will not be able to capture what is meaningful about them, and to recognise the relevant ethical reasons for and against honouring, considering or promoting these decisions. I will return to this contention in Chapter 5, where I argue that the role of authenticity-based autonomy in assessing the decisions of research subjects should be far more circumscribed than is currently assumed, and where I advance a theory which captures what is valuable about these everyday decisions, as well as what might cause us to overrule them.

After rejecting these two formulations of the authenticity condition as too restrictive, Faden and Beauchamp consider one final formulation, which they believe shows the most promise due to the fact that it is the most permissive; the requirement that actions are not repudiated by the agent. According to this criterion, all actions should count as autonomous unless the agent, upon reflection, repudiates them. Actions that have not been

reflected upon automatically count as autonomous.\footnote{This presumes that the agent has a reflective capacity, but doesn’t require that he use it.} This formulation is clearly not vulnerable to objections of over-demandingness, and there is something quite intuitive about the idea that a repudiated desire or action is experienced as alien to oneself, and thus should not count as autonomous. Actions that might fall into this category include acts that stem from weakness of the will, such as smoking or infidelity, where the person repudiates the desire that drives him, but acts upon it anyway.

Despite the advantages of this kind of condition of authenticity, Faden and Beauchamp believe that nonrepudiation is ultimately unsuitable as a condition of autonomy. The reasons for this are twofold. Firstly, there are some actions that, although repudiated by the agent, seem as though they should be regarded as autonomous. Take, for example, a corporate executive who repudiates her greed and struggles to change her life to make herself less materialistic, but continues to succumb to her greed and be motivated by the high salary she wants, but wishes she did not want.\footnote{Faden and Beauchamp, \textit{A History and Theory of Informed Consent}, p.268.} Faden and Beauchamp suggest that the deliberate and repeated nature of this behaviour suggests that it should qualify as autonomous, despite the fact that it is repudiated by the agent. Secondly, it seems strange to allow that an agent’s desires and actions are authentic unless repudiated; an action could be entirely autonomous as long as the agent does not reflect on it, but as soon as he does (and rejects it) it no longer qualifies as autonomous. It is odd to contend, for example, that a drug addict’s desire for drugs is autonomous until he considers and repudiates it. This notion of autonomy has the counterintuitive consequence that more reflection is likely to make an agent less autonomous; as a decision will automatically be counted as autonomous unless it is reflected upon (and rejected), someone who never exercises her reflective capacity will automatically qualify as perfectly autonomous. Faden and Beauchamp argue that this criterion is both too restrictive in places, and too permissive in places, and thus cannot be used as a suitable means of incorporating authenticity into their model. Having considered and rejected each of these alternative formulations of an
authenticity condition, Faden and Beauchamp conclude that authenticity cannot be incorporated into a practically-focused model of autonomy. In order to produce a practical, intuitively viable account of informed consent, Faden and Beauchamp thus exclude any notion of authenticity from their informed consent requirements.

**Faden and Beauchamp’s Conditions for Autonomous Action**

Having rejected authenticity as a necessary condition of autonomy, Faden and Beauchamp proceed to outline what they see as three necessary conditions of autonomous action:\(^438\)

\[
\text{X acts autonomously only if X acts}
\]
\[
1. \text{ intentionally,}
\]
\[
2. \text{ with understanding, and}
\]
\[
3. \text{ without controlling influences.}
\]

They take these conditions to each be necessary (though not necessarily jointly sufficient)\(^439\) conditions of autonomous action. The two latter conditions, they postulate, are a matter of degree, hence autonomy is a matter of degree. The level of autonomy that should be aimed at in informed consent requirements, they suggest, is not full but *substantial* autonomy, consisting of intentionality, substantial understanding and substantial noncontrol. They offer explications of each of the conditions. In what follows, I will briefly explore these requirements. This will help us to link this work to autonomy and informed consent in the research ethics guidelines in the next section, and will allow me to draw upon (and criticise) some of these ideas in my own theory in the next chapter.

**Intentionality**

Intentionality is here a relatively straightforward condition. For an act to be intentional, it must correspond with the actor’s conception of the act. This

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\(^{439}\) Mainly because sufficiency is more difficult to establish (p.238) and because it is difficult to talk about some sorts of psychiatric disorders within the scope of these three principles alone (p.268-9). Though a condition of authenticity is better placed to deal with these sorts of issues, Faden and Beauchamp suggest that the costs of incorporating such a condition outweigh the benefits.
requires that the act is planned, however, this does not mean that the planned outcome must result from the action. Because an intentional action may have unintended (and perhaps unforeseeable) consequences that we would not hold the actor responsible for, and because we might wish to hold people responsible for an unintentional act (someone who unintentionally crashes their car, for example, might still be responsible for this act), Faden and Beauchamp stress that intentionality (and thus autonomy) and responsibility are distinct notions. Faden and Beauchamp also posit that, unlike the other two conditions of autonomous action, intentionality is not a matter of degree; either an action is intentional, or it isn’t.

Understanding

Faden and Beauchamp’s selection of a condition of understanding recognises that simply disclosing information to a potential research subject is not sufficient to ensure that they understand the relevant aspects of a proposed action. This condition therefore attempts to outline what is necessary to ensure that an action is understood. After noting the various limitations that must be placed upon the concept of understanding in order for it to remain realistic and relevant, Faden and Beauchamp suggest that in order to have a “full or complete” understanding of an action, an agent must have “a fully adequate apprehension of all the relevant propositions or statements (those that contribute in any way to obtaining an appreciation of the situation) that correctly describe (1) the nature of the action and (2) the foreseeable consequences and possible outcomes that might follow as a result of performing or not performing the action.”

By requiring only that the foreseeable consequences are apprehended, Faden and Beauchamp avoid a requirement of omniscience. Furthermore, they require that only that substantial understanding is present for an act to be substantially autonomous, believing that a condition of full understanding is too oppressive, and unnecessary in an everyday context.

443 Faden and Beauchamp, A History and Theory of Informed Consent, p.252.
444 Where foreseeable is taken to mean foreseeable by a normal, rational person.
Both the relevance and the adequacy of understanding are emphasised by Faden and Beauchamp. In their discussion of the notion of relevance they note that some “act-descriptions are irrelevant, trivial, and others vital.”\textsuperscript{445} For the threshold of “substantial” understanding that they take to be requisite for the appropriate level of autonomy they require only that the agent apprehends all of the “important descriptions – but not all of the relevant (and certainly not all the possible) descriptions.”\textsuperscript{446} They take the idea of importance to be a subjective concept, and not necessarily causally effective. Rather, an agent values his understanding of an important act description, and would be unhappy to discover after undertaking the action that he had acted in ignorance of it, whether or not the act description would have caused him to act differently.\textsuperscript{447} They are also concerned with the adequacy of an agent’s understanding, stressing, for example, that though an agent may understand that an operation may result in postoperative pain, they may not understand the real nature of the pain, what it is likely to be like to experience it.

Faden and Beauchamp also note a difficulty in establishing whether something is true or false, or even in achieving intersubjective agreement on the truth or falsity of a description. As a result of this, they advocate asking not if a belief is true or false, but whether the agent is justified in believing it is true. Though this solution just pushes the problem back further, as we must then ask what criteria determine the justifiability of beliefs,\textsuperscript{448} this conception captures something about the common sense notion of reasonable belief. By not linking belief directly to truth, there is also room for the agent to be surprised by the outcome of an autonomous action. As we would not wish to say that any action that did not turn out as expected cannot be autonomous, this is a crucial requirement.

\textsuperscript{445} Faden and Beauchamp, \textit{A History and Theory of Informed Consent}, p.252.
\textsuperscript{446} Faden and Beauchamp, \textit{A History and Theory of Informed Consent}, p.302.
\textsuperscript{447} Though they note that this must be supplemented by an ‘extrasubjective’ component in some cases to ensure adequate understanding, see pp.309-10
\textsuperscript{448} Determining whether beliefs are reasonable or justifiable is a huge potential problem for autonomy and informed consent in research ethics; I will be dealing with these issues in Chapter 5.
Noncontrol

The condition of noncontrol is not the same as the condition of noninterference. This is because, as Faden and Beauchamp note, not all interference is controlling. Though someone may be subject to manipulation, for example, this influence may not have a completely controlling effect on their ability to act freely; the option may remain open to the agent to accept or reject this influence. Similarly, some influences, like persuasion, Faden and Beauchamp suggest, are not at all controlling, and (when it has an appropriate character) can rather facilitate free choice. Influences can be seen to fall along a continuum, from completely controlling (coercion) through to completely noncontrolling (persuasion). Manipulation falls in between these two extremes, and can have a widely varying degree of controlling influence. Some manipulation may have no effect at all, while other instances may have a coercive effect. Faden and Beauchamp recognise that the “role constraints” may lead to authoritarian behaviour on the part of the doctor or researcher (and passive behaviour on the patient or subject) that might be controlling to a degree. They contend that for an action to be substantially autonomous, it must be substantially noncontrolled. Faden and Beauchamp stress that an adequate account of noncontrol would include internal as well as external controlling influences, such as those deriving from mental disorders. However, due to the difficulty of formulating a condition of this sort, they do not explore this issue in detail.

449 Faden and Beauchamp, A History and Theory of Informed Consent, p.256.
452 This is particularly important in a model of autonomy that has no condition of authenticity, as it cannot use a condition of authenticity to exclude internally arising yet alien desires (such as the desires that might stem from certain types of mental illness like obsessive compulsive disorder, anorexia or depression). This is possibly the most significant problem with Faden and Beauchamp’s theory. I will attempt to provide a means of dealing with these types of cases in my theory in Chapter 5.
453 Faden and Beauchamp, A History and Theory of Informed Consent, p.316.
Autonomy and Informed Consent in Research Ethics Guidelines

Faden and Beauchamp’s discussion of the authenticity condition has revealed a fundamental weakness in the philosophical model of autonomy, if it is to function as a realistic, intuitively viable basis for informed consent guidelines. They convincingly argue that a condition of authenticity is unable to capture the wide range of decisions that we would wish to see promoted and protected by informed consent in medical and research ethics.454 They have responded to this contention by providing an alternative, authenticity-free model of autonomy, which they feel is better able to capture a sufficiently wide range of decisions to provide a practically viable, intuitively appealing basis for informed consent. In this section, I will look at the approaches to autonomy and informed consent utilised in the Declaration of Helsinki and the Belmont Report, in light of this discussion. I will first turn to the Declaration of Helsinki, arguing that the strong resemblance between the content of the informed consent guidelines in this document and Faden and Beauchamp’s conditions of autonomy suggest that informed consent guidelines here are motivated by considerations of autonomy, as understood under the biomedical model. After I have drawn out this connection, I will reveal the problems with this approach, showing that Faden and Beauchamp’s biomedical model of autonomy is also significantly flawed.

Next, I will turn to the treatment of autonomy, respect for persons and informed consent in the Belmont Report, contending that this document draws elements from both the philosophical and biomedical models of autonomy, presumably to avoid the shortcomings of each approach. However, I will show that this approach is also fatally flawed, and is not able to produce a coherent, theoretically cogent basis that is also able to function as a practical action guide for decisions relating to autonomy and respect for persons in the context of research ethics. By the end of this chapter, I will have revealed the shortcomings of both the models of

454 Or, when it is reformulated to be more permissive, generates some strange and counterintuitive consequences, and doesn’t capture what is valuable about decisions, as we have seen.
autonomy outlined above, and shown the impossibility of combining these two approaches. This will establish the need for a new approach to informed consent, autonomy and respect for persons in research ethics, which is able to capture the strengths of both approaches to autonomy while avoiding the weaknesses. In Chapter 5, I will provide such an alternative approach, arguing that the only way to avoid the problems in both of these models of autonomy, to avoid confusion and obfuscation, and to reveal what is really ethically at stake when we are evaluating people’s decisions in research ethics, is to reject the assumption that informed consent is based upon a principle of autonomy.

The two theoretical models of autonomy outlined above provide us with the means to explore and critically analyse the theoretical basis for informed consent guidelines in the Declaration of Helsinki and the Belmont Report. We are now able to draw out the implicit theoretical approaches in these documents, and to reveal inconsistencies and problems that result from the approach to autonomy and informed consent in both of these sets of guidelines. The reason for the focus on these two documents is, as I have shown in Chapter 2, that the approaches therein have heavily influenced a wide range of the most prominent contemporary international and national research guidelines. The problems with the approach to these issues in these documents are also present in the prominent contemporary guidelines outlined in Chapter 2. In addition, these documents still operate as significant contemporary research ethics documents in their own right (the contemporary version of the Declaration of Helsinki is still regarded as the cornerstone of modern research ethics,455 and the Belmont Report still operates as the ethical foundation for federal research guidelines in the United States). I have already discussed the wellbeing-based function of consent in the Nuremberg Code in Chapters 2 and 3, and will return to the document in Chapter 5, where I will argue for my suggestion, raised in Chapter 3, that this approach to informed consent, though neglected in philosophical discussion, still has contemporary value and may operate

tacitly within the Declaration of Helsinki and the Belmont Report. The remainder of this chapter, however, will continue to focus on informed consent and autonomy, beginning with an analysis of the informed consent guidelines in the Declaration of Helsinki.

Informed Consent and Autonomy in the Declaration of Helsinki: limitations of the biomedical model.

I have already briefly outlined the content of the 2013 Declaration of Helsinki in Chapter 2. Now, with an understanding of the philosophical background on the concept of autonomy, and the overwhelming contemporary agreement about its purported role as the basis of and motivation behind informed consent guidelines in bioethics and theoretical philosophy, we can delve into an analysis of its informed consent guidelines. As I have mentioned in Chapter 2, the Declaration of Helsinki differs in approach from the Belmont Report. While the Belmont Report explicitly states the broad ethical principles that motivate its informed consent procedures, the Declaration of Helsinki does not contain broader principles, consisting instead of 37 more specific edicts. Thus, while the Belmont Report frames informed consent as the expression of its principle of respect for persons, the Declaration of Helsinki does not provide any indication of the reason for inclusion of its informed consent guidelines, forcing us to rely on contextual and historical clues to discern the deep philosophical principles that motivate its informed consent requirements.

The first thing that can be noted about the Declaration of Helsinki’s approach to informed consent is that discussion of these requirements forms a substantial portion of the document. Of the 37 principles, 8 principles (25-

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456 We have seen the prevalence of this assumption in Chapter 2, and have also seen how Faden and Beauchamp rely on this idea above. For further examples see; Feinberg, *Harm to Self;* Appelbaum, Lidz and Meisel, *Informed Consent: Legal Theory and Clinical Practice;* Dworkin, *The Theory and Practice of Autonomy* and Beauchamp and Childress, *Principles of Biomedical Ethics.*

457 These are commonly referred to as principles, but they are not broad ethical principles in the same sense as in the Belmont Report; they contain specific pronouncements that must be adhered to. I will use, following from the wording in the Declaration of Helsinki, the word principles in the following discussion, but these should not be taken to constitute principles in the sense that I use elsewhere.
32) are concerned with outlining the ethical requirements for informed consent. The number of principles dedicated to this subheading is substantially greater than on any other specific topic. This is consistent with the importance given to informed consent requirements since the rise of autonomy in the 1970s. The stringency of the requirements also reflect this; all individuals capable of giving informed consent must give it for the experiment to proceed, and all informed consent must be documented or witnessed.\textsuperscript{458} Principles 25-7 outline general requirements for informed consent (for those who are capable of giving it). Principles 28-30 cover cases involving subjects who are incapable of providing consent. Principle 31 is concerned with physicians who are both treating and researching on their patients/subjects, and principle 32 outlines consent requirements for human material or data. We will focus here on principles 25-7 and 31; the principles outlining what constitutes informed consent. We will return to the treatment of research subjects who are deemed incapable of consent in Chapter 5. For now, it is sufficient to note that these requirements are similar to what is contained in the Belmont Report, with an emphasis on restricting this type of research where unnecessary, and ensuring that research in these circumstances “entails only minimal risk and minimal burden.”\textsuperscript{459}

The principles outlining the requirements of informed consent clearly resemble Faden and Beauchamp’s concerns in their model of autonomy. Principle 25 states that participation “must be voluntary...no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.”\textsuperscript{460} Principle 26 requires that each subject capable of giving informed consent “must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study,” as well as their

“right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal.” It stresses that the information provided should take the “specific information needs” of the subject into account. It stipulates that the physician must ensure that “the potential subject has understood the information”, before obtaining their “freely-given informed consent.”

Principle 27 focuses on ensuring that the subject is not subject to coercive influence, demanding caution and independent third-party authorisation where the potential research subject is “in a dependent relationship with the physician or may consent under duress.” Principle 31 deals with similar concerns, requiring that a decision to withdraw from a research study never “adversely affect the patient-physician relationship.” This principle also requires that in therapeutic research, patients must be informed of “which aspects of their care are related to the research.”

The requirement of voluntariness is similar to Faden and Beauchamp’s condition of intentionality. The focus on information and understanding in Principle 26 clearly bears very close resemblance to their condition of understanding. The language that Faden and Beauchamp use to describe their condition of full understanding; an “adequate apprehension of all the relevant propositions or statements” is remarkably similar to the Declaration of Helsinki’s requirement that the subject must be “adequately informed [about the] relevant aspects of the study.” The features of the research listed by the Declaration as necessary information for research subjects describe the nature (aims, sources of funding, institutional affiliations) and foreseeable consequences (anticipated risks and benefits, possible discomfort, post-study provisions) of the decision to participate in research, just as Faden and Beauchamp suggest. The Declaration of Helsinki accommodates Faden and Beauchamp’s contention that the information that is important to the subject may differ from person to person.

with the requirement that the “specific information needs”\(^{466}\) of each individual subject be taken into account. It recognises, as do Faden and Beauchamp, that simply providing information is not sufficient, emphasising that information must also be understood for informed consent to be possible.

We also see, throughout all four principles outlined above, concerns and requirements that are analogous to the concerns raised in Faden and Beauchamp’s third requirement of noncontrol. Faden and Beauchamp’s principle of noncontrol focuses, as we have seen, on freedom from controlling influences. The Declaration of Helsinki’s repeated references to requirements that the agent “freely agrees” or provides a “freely-given informed consent”\(^{467}\) reflect this focus. Requirements that agents should be free to choose not to participate in research “without reprisal”\(^{468}\) or adverse effects,\(^{469}\) as well as calls for caution and more stringent guidelines when there is reason to think that subjects “may consent under duress” or when they are “in a dependent relationship with the physician”\(^{470}\) are geared towards ensuring that agents are free of controlling influences. The latter concern also recognises the potential for the dynamics of the physician-patient relationship to generate controlling influences, a concern that, as we have seen, Faden and Beauchamp share. The incredibly close conformity between Faden and Beauchamp’s requirements for autonomy and the Declaration of Helsinki’s requirements for informed consent provides a strong indication that the informed consent guidelines in the Declaration of Helsinki are geared towards protection and promotion of autonomous decisions, as understood under the biomedical model. This is bolstered by the fact that the rise in the prominence and stringency of the informed consent in the Declaration of Helsinki corresponds, as we have seen, to the rise of the value and importance of autonomy in medical ethics. The almost

universal consensus that informed consent requirements are based upon the notion of autonomy in bioethics makes this conclusion very plausible.

The Declaration of Helsinki’s informed consent requirements correspond to Faden and Beauchamp’s biomedical model of autonomy in one further, crucial way. There is no explicit mention of any sort of condition of authenticity; no idea of actions being one’s own somehow, no matter how this is conceived. I used Faden and Beauchamp’s explication of their biomedical model of autonomy to reveal the shortcomings in the authenticity-based philosophical model of autonomy. Now that I have established the practical influence of the biomedical model in research ethics, I will point out a significant problem with this theory, which, as we can now see, will undermine not just Faden and Beauchamp’s theory, but also the basis for informed consent in the Declaration of Helsinki.

The biomedical model of autonomy, as we have seen, caters well to practical concerns about the inclusiveness of the standard of autonomy. Faden and Beauchamp have made an important observation in noting the disconnect between the theoretical, authenticity-based models of autonomy and what we expect from the practical informed consent guidelines which purport to be based upon respect for autonomy. However, in excluding an authenticity criterion from their account of autonomy, Faden and Beauchamp’s biomedical model generates a significant theoretical problem. We have seen that the chief strength of the philosophical model of autonomy is its ability, through the condition of authenticity, to provide a basis for connecting certain of our actions to the value of respect for persons. By respecting the actions that have some sort of special relation to the self, we show respect for persons. In excluding a condition of authenticity from their model of autonomy, Faden and Beauchamp have severed their notion of autonomy from the impetus to respect these actions. This makes it difficult to see what is particularly valuable about the actions that Faden and Beauchamp designate as autonomous. In outlining their conditions for autonomous action, Faden and Beauchamp fail to connect their chosen actions to a deeper value. In the context of research ethics, it is unclear why respecting
these particular decisions forms an appropriate means of striving towards any particular ethical value. They purport to exclude authenticity chiefly as a means of widening the range of decisions that are respected as autonomous, but if the impetus behind this model is simply to include more decisions under the category of those that should be respected as autonomous, why is it necessary to place restrictions on this category at all? Faden and Beauchamp give us no indication of why the decisions they single out should be particularly worthy of respect. The criteria that these choices must meet to qualify as autonomous thus begin to seem arbitrary. Without a coherent theory providing a basis for their guidelines, Faden and Beauchamp are unable to tell us why we should respect the actions they have singled out, and, also importantly, why actions that do not fall into this category are not worthy of the same respect.  

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**Informed Consent and Autonomy in the Belmont Report: Problems with a hybrid approach**

In the Belmont Report, unlike the Declaration of Helsinki, informed consent requirements are explicitly linked to the ethical principles of respect for autonomy and respect for persons. It will be useful to begin the discussion on autonomy and informed consent in the Belmont Report by briefly revisiting the role of autonomy, and its connection to informed consent, in this document. Respect for autonomy is not, on its own, one of the fundamental principles in the Belmont Report. Rather, respect for autonomy is seen as a necessary (and primary) part of the fundamental principle of respect for persons. Respect for the capacity for autonomy is seen as the chief means by which we are able to show appropriate respect for persons. As we have touched upon in previous chapters, the principle of respect for persons, as formulated in the Belmont Report “incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are

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471 One might say that wide agreement concerning the requirements, without appeal to any deeper principle, is sufficient, but in linking the criteria for informed consent to the value of respect for persons by some theoretical means, we are able to ensure that informed consent is a means of expressing this value, and justify the choice of our criteria by invoking this theoretical basis.
entitled to protection.”\textsuperscript{472} As with the Declaration of Helsinki, we will defer
the discussion of those who do not qualify as autonomous to the next
chapter, focusing here on the requirements for autonomous action. The
former part of this requirement, then, is achieved through assuring that
“subjects, to the degree that they are capable, be given the opportunity to
choose what shall or shall not happen to them. This opportunity is provided
when adequate standards for informed consent are satisfied.”\textsuperscript{473}

As we can see, unlike the Declaration of Helsinki, the Belmont Report
explicitly links the notions of respect for persons, autonomy, and informed
consent. Respect for persons is achieved through respect for their
autonomy, which itself is achieved through informed consent procedures.
The way that these concepts are linked strongly suggests that this document
is invoking the philosophical, rather than the biomedical model of
autonomy. As we have seen, it is only through inclusion of an authenticity
criterion that respect for a person’s autonomous decisions forms a means of
expressing the value of respect for persons; authenticity-based accounts of
autonomy focus on those actions that can be said to be a true expression or
reflection of the self, so respecting these actions provides a clear means to
respecting the self. In making respect for autonomy the primary means of
respect for persons, the Belmont Report invokes an understanding of
autonomy as authenticity-based. This contention is supported by the
language that the Belmont Report uses when describing autonomy: The
Belmont Report uses language in its description of autonomous agents that
seems to directly reference an authenticity-based notion of autonomy. It
refers to autonomous individuals as agents who are “capable of deliberation
about personal goals and of acting under the direction of such deliberation”
and as individuals capable of forming and acting upon “considered
judgments”. They also describe autonomy as a “capacity for self-
determination”. \textsuperscript{474}

\textsuperscript{472} The National Commission, \textit{The Belmont Report}, Part B: Basic Ethical Principles.
\textsuperscript{473} The National Commission, \textit{The Belmont Report}, Part C: Applications.
\textsuperscript{474} The National Commission, \textit{The Belmont Report}, Part B: Basic Ethical Principles.
However, in its explication of the criteria required for informed consent, the practical means of securing respect for autonomy, the Belmont Report, like the Declaration of Helsinki, closely resembles Faden and Beauchamp’s biomedical model of autonomy. The Belmont Report suggests that “information, comprehension and voluntariness”\(^{475}\) are the necessary elements for informed consent. This closely resembles Faden and Beauchamp’s conditions of intentionality, understanding and noncontrol. The conditions of information and comprehension correspond to Faden and Beauchamp’s condition of understanding, and the condition of voluntariness requires that decisions are made in “conditions free of coercion and undue influence” (where undue influence includes manipulation).\(^{476}\) The condition of intentionality is tacit in the definition of informed consent as allowing subjects the “opportunity to choose what shall or shall not happen to them”.\(^{477}\) Crucially, the Belmont Report’s informed consent guidelines do not contain a condition of authenticity, despite the apparent references to authenticity in the language used to describe autonomy.

The close resemblance between the informed consent guidelines in the Belmont Report and Faden and Beauchamp’s model of autonomy is no coincidence; Tom Beauchamp was one of the primary authors of the Belmont Report. However, it would be a mistake to make too much of this connection. Beauchamp has distanced himself from the work in the Belmont Report, stressing that he had and continues to have “major substantive disagreements”\(^{478}\) with the content. He notes that he was limited in his analysis by the expectations of the National Commission, and that his deepest philosophical convictions about ethical principles can be found in his other work.\(^{479}\) The disconnect between Beauchamp’s other work and the Belmont Report is also noted by another author of the Belmont Report, Albert Jonsen, who contends that although Beauchamp’s work on

\(^{479}\) Chapter 5 will include a critical appraisal of Beauchamp’s theoretical work, and will draw out other inconsistencies between his views and the content of the Belmont Report.
the Belmont Report and the academic work on principles in bioethics that he was undertaking at the same time had a mutual influence on each other, they are only “superficially similar”.\textsuperscript{480,481}

This explains why references to an authenticity-based notion of autonomy are present in the Belmont Report though the notion of authenticity is explicitly eschewed by Faden and Beauchamp. The disconnect between the explication of the Belmont Report’s principle of autonomy and its application, which has been noted elsewhere (albeit for somewhat different reasons)\textsuperscript{482} is likely to result from the circumstances under which the document was created, synthesizing a range of ideas from various sources. Harold Vanderpool notes that the Belmont Report, despite its clear schema, “is not easily understood or fathomed” due to the fact that it “contains the multilayered features of a document comprised by a committee with many agendas.”\textsuperscript{483} Inclusion of a variety of ideas under this single principle reflects the process by which this document was formulated.\textsuperscript{484}

However, from our examination of the two models of autonomy in this chapter, we can recognise that excluding an authenticity criterion from its informed consent guidelines, while espousing ideas about autonomy that are seemingly authenticity-based, generates a serious problem for the Belmont Report. That is, these two notions of autonomy are fundamentally incompatible. One idea makes authenticity central to autonomy, while the other argues that authenticity cannot function as a criterion for autonomy. There are two possible ways we could read the Belmont Report as providing

\textsuperscript{480} A. Jonsen, \textit{The Birth of Bioethics}, Oxford University Press, USA, 2003, p.120.
\textsuperscript{483} Vanderpool, “Unfulfilled Promise”.
\textsuperscript{484} For more on the collaborative process through which the Belmont Report was developed, including the synthesis of various ideas, see Jonsen, \textit{The Birth of Bioethics}, pp.102-4; Beauchamp, “The Origins and Evolution of the Belmont Report”; and Churchill, “Toward a More Robust Autonomy”, pp.116-17.
a coherent line on autonomy, and both options generate serious problems. If we take the Belmont Report to be suggesting that autonomy involves a condition of authenticity, its informed consent guidelines, due to their lack of an authenticity criterion, are not appropriately formulated to ensure that decisions are autonomous (and thus provide a good means of showing respect for persons). The strong links between autonomy and respect for persons that, as we have seen, are provided by an authenticity-based notion of autonomy, are retained under this reading of the Belmont Report, but the link between the informed consent guidelines and autonomy is severed. As we have seen, however, the Belmont Report explicitly contends that its informed consent guidelines are aimed towards ensuring that the value of respect for autonomy is achieved in research.

We might then, on this basis and in virtue of its authenticity-free informed consent guidelines, instead read the Belmont Report as suggesting that authenticity is not a necessary condition of autonomy. If this is the case, however, we are left in the same position as with the Declaration of Helsinki, and Faden and Beauchamp’s authenticity-free model of autonomy. That is, as I have argued above, there is no reason to think that this notion of autonomy provides a good means of achieving the value of respect for persons. Under this reading, the link between autonomy and informed consent is retained, but, as in the biomedical model, the link between autonomy and respect for persons is severed. This is also problematic, because the Belmont Report contends that respect for persons is achieved, in part, through respect for autonomy. Their use of language that invokes the authenticity-based model of autonomy seems to subscribe to the view that it is the authenticity criterion that provides this link.

By utilising language that seems to invoke the philosophical model of autonomy, while omitting an authenticity criterion from their informed consent guidelines, the Belmont Report obscures the real capabilities of its notion of autonomy, and its informed consent guidelines. The Belmont Report is attempting to utilise both the philosophical and the biomedical model of autonomy, in order to provide clear links between respect for
persons, respect for autonomy, and (practically viable) informed consent guidelines. Because these models are fundamentally incompatible, however, there is no way to reconcile these two models. We cannot produce a coherent reading of the Belmont Report that allows it to retain the theoretical links between respect for persons and respect for autonomy, as well as the links between autonomy and its chosen informed consent guidelines.

Moving away from Autonomy

This fundamental dissonance that is generated by the Belmont Report’s explication of autonomy is not immediately apparent. Because both notions utilised are accepted uses of the term autonomy, it is easy to miss, at first glance, the fact that the Belmont Report is drawing upon two different and incompatible ideas in its discussion and use of the notion of autonomy. To avoid this confusion, and to prevent the obfuscation that results from the Belmont Report’s idea of autonomy, we need to make a clear distinction between these two models. I propose that we do this by abandoning the idea that Faden and Beauchamp’s biomedical model, or any notion of autonomy that does not involve an authenticity condition, is autonomy. Though Faden and Beauchamp have good reason for advocating the exclusion of the authenticity criterion from autonomy for practical purposes, I do not believe it is possible to refer to Faden and Beauchamp’s theory as a theory of autonomy without generating substantial confusion. In order to defend the idea that the biomedical model should not be called autonomy, I will examine and reject the reasons why they prefer to use this term. Faden and Beauchamp favour calling their theory a theory of autonomy for three reasons.

Firstly, though Faden and Beauchamp note a strong tradition of authenticity-based accounts of autonomy, they maintain that there is no widespread agreement regarding the characteristics of an autonomous person or action. Though they were correct at the time of writing, and though there is still little agreement on how autonomy should be theorised in detail, since they wrote, theoretical accounts of autonomy have begun to converge in several
important aspects. Most notably, as we have seen, a concern with (a broadly
Lockean notion of) authenticity has become a mainstay in almost all
theoretical accounts of autonomy.\textsuperscript{485} Authenticity is now central to
theoretical accounts of autonomy, and by omitting this criterion Faden and
Beauchamp deviate too far from the core of contemporary theories of
autonomy to fall into the same category. Continuing to call this theory a
theory of autonomy despite this contemporary agreement generates
confusion. In addition, due to the contemporary dominance of authenticity-
based accounts of autonomy, when the term “autonomy” is used, special
theoretical links to the value of respect for persons are automatically
assumed. With Faden and Beauchamp’s biomedical model, however, as we
have seen, there is not necessarily a basis for this assumption. The
theoretical links between the value of respect for persons and autonomy
come from the authenticity condition, and when this is lacking, we cannot
assume that the links exist. Referring only to authenticity-based theories as
autonomy forces us to explain why other theories provide a good means of
showing respect for persons, and thus form a good means of linking this
value to informed consent guidelines.

Secondly, Faden and Beauchamp contend that the decisions that their model
captures are the types of decisions which we ought to respect as
autonomous, which are also the types of decisions that informed consent
ought to protect, as we have seen above. I have maintained throughout this
chapter that Faden and Beauchamp are right in endeavouring to expand the
range of choices that are protected and promoted through informed consent
guidelines beyond those that count as authentic. If we are to accept this
idea, while contending that only authentic decisions should count as
autonomous, this means we need to reject the (as we have seen,
overwhelmingly popular) idea that informed consent is grounded in the
ethical value of respect for autonomy. I will argue in the next chapter that
rejecting the idea that autonomy is the basis for informed consent is the key
to producing a model of informed consent that is able to incorporate the

\textsuperscript{485} Taylor, “Introduction”, p.17.
strengths of both the philosophical and biomedical models. I will contend that decisions that may not qualify as authentic can be linked to the value of respect for persons in a philosophically cogent manner, and in a way that allows us to take the wide range of decisions that Faden and Beauchamp advocate into account.  

Rejecting the assumption that informed consent is an expression of respect for autonomy will better allow us to see what is really valuable about the decisions that we wish to protect through informed consent procedures.

Thirdly, as we have seen above, Faden and Beauchamp maintain that because authenticity cannot capture a wide enough range of decisions, “no further conditions beyond intentionality, understanding, and noncontrol are needed” in the analysis of autonomy and informed consent. It does not follow from the contention that authenticity cannot capture (or provide a good tool for evaluating) all decisions we wish to see protected through informed consent, that reference to authenticity is never required to ethically evaluate decisions for the purposes of acquiring an informed consent. In the next chapter, I will argue that Faden and Beauchamp are correct in their contention that authenticity-based autonomy does not provide a good means of evaluating the majority of the decisions that we would wish to see protected and promoted by informed consent procedures in the context of research ethics. However, there is still a small subset of decisions whose value can only be adequately captured, appreciated and appropriately responded to through the use of authenticity-based autonomy. Thus, it is not possible to do away with the concept entirely. My theory will utilise both an authenticity-free standard and (to a lesser extent) authenticity-based autonomy as part of the philosophical means of achieving the value of respect for persons. To distinguish between these two different ideas, it will be useful to move away from the term “autonomy” to refer to decisions that deviate from the contemporary philosophical notion (i.e. those that are not authenticity-based).

486 Perhaps even, as I will argue in the next chapter, a wider range of decisions.
So, to avoid confusion, to uncover a new philosophical means of linking respect for persons with informed consent, and to retain the notion of authenticity-based autonomy due to its value in some situations, I will refrain, in my theory, from using the term “autonomy” to refer to any part of my theory that does not contain a condition of authenticity. I have referred, in this chapter, to Faden and Beauchamp’s theory as a theory of autonomy, both in line with their usage of the term, and to bring out the contrast between their ideas and other philosophical ideas associated with the notion. In what follows, whenever I use the term “autonomy” in Faden and Beauchamp’s authenticity-free sense, I will ensure that this specialised usage of the term is clear. This may simply seem like a semantic issue, but I believe that the idea that autonomy need not contain authenticity has led to guidelines with no theoretical justification or link to any deeper ethical value (the Declaration of Helsinki) and confused guidelines that contain an incoherent and inconsistent notion of autonomy (the Belmont Report). It is imperative, in order to get to the ethical issues at the heart of the value of respect for persons in the context of research, to distance ourselves from the practices that have involved confusion and lack of reflection.

**Conclusion**

In exploring philosophical accounts of the notion of autonomy, I have identified two distinct and fundamentally incompatible models of autonomy in philosophical thought. While the philosophical model of autonomy makes authenticity the central condition for autonomous action, the biomedical model of autonomy rejects any notion of authenticity, preferring to focus on capturing a wider or more intuitive range of decisions. When we attempt to translate these models of autonomy into a basis for informed consent guidelines in research ethics, both approaches are fundamentally flawed. The philosophical model is indeed too restrictive to provide protection for a wide enough range of actions, or, at its most permissive, produces quite counterintuitive consequences. Therefore, it is unable to give us good ethical guidance in many practical situations relating to research ethics. The biomedical model can achieve what the philosophical model cannot, but only at the cost of sacrificing the link between autonomy...
and respect for persons. This model provides us with no theoretical means of showing why its chosen decisions are particularly worthy of respect (and those that do not qualify are not). Rather, because of the use of the term “autonomy” to describe this theory, links to respect for persons are automatically assumed, though no justification is provided for this, or contained in this approach. Because the models are at odds on the issue of whether to include an authenticity criterion, there is no way of combining the two models to consolidate their strengths while combating their respective flaws.

Though the link between informed consent and respect for persons is crucial, giving us a reason to respect these actions and a means of achieving the value of respect for persons, the importance of Faden and Beauchamp’s insight should not be underestimated. Restricting the decisions that are worthy of respect to only authentic/autonomous decisions, while ignoring decisions that people are perfectly capable of making, and that they value, seems to undermine respect. A practically viable yet theoretically cogent basis for informed consent needs to make use of both of these insights. What is needed is a theoretical model that explains what sort of decisions should be respected, protected and promoted, as well as explaining which decisions can be ignored or restricted. It must be able to link this explanation to the value of respect for persons. But it also needs to let a wider range of decisions come into the equation than the philosophical, authenticity-based accounts of autonomy allow. I have shown that there is no way that this can be achieved through either of the prominent contemporary approaches to autonomy (or a combination of both).

I will thus argue, in the next chapter, that in order to generate a theoretical basis for informed consent that achieves both of these aims, we need to abandon the idea that informed consent finds its theoretical basis in respect for autonomy. I will present a theoretical underpinning for informed consent guidelines, still based in large part on finding a means of showing

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488 In particular, worthy of promotion and protection through informed consent procedures in research.
appropriate respect for persons in research, that can combine the strengths of the two models of autonomy, and avoid their weaknesses. I will also incorporate measures for the protection of individual wellbeing into these informed consent guidelines, as suggested as a solution to the problem of beneficence in Chapter 3. I will suggest that a broadly Lockean account of autonomy still has value in assessing some decisions in the context of research ethics, but for many decisions, it will not be a relevant or necessary tool.
Chapter 5: Towards a Choice-Based Theory for Informed Consent

Introduction

In this chapter, I will outline a new approach to the theoretical basis of and goals underlying informed consent guidelines in research ethics. I will suggest that rather than focusing on promoting and protecting autonomous choices, informed consent guidelines should be geared towards protecting and promoting the choices that research subjects have reason to value. I will argue that my choice-based theory will result in the development of informed consent guidelines that better express the value of respect for persons, and that this new approach allows us, at the same time, to ensure that informed consent guidelines are appropriately formulated to function as an adequate means of protecting the wellbeing of individual research subjects. I will argue that though, on the face of it, it may seem strange that informed consent guidelines can fulfil these two functions at once, a choice-based approach to informed consent guidelines will reveal that these two goals need not clash to the extent that we may expect, and can in fact be pursued simultaneously, with the appropriate theoretical underpinning, and appropriately structured informed consent guidelines.

Though I will propose some changes to existing informed consent guidelines, my choice-based theory will not provide a radically different account of what concrete informed consent guidelines should look like. Many of the goals of this theory, I will argue, are implicitly or explicitly included in the Belmont Report’s account of respect for persons, or Faden and Beauchamp’s theory of autonomy and informed consent. My choice-based account, however, will provide a clear means of linking informed consent practices with more abstract ethical goals, namely, the goals of showing respect for persons in research, and of protecting the wellbeing of individual research subjects. This will give us an indication of how these goals are best pursued in the context of research ethics, and allow us to ensure that informed consent practices are appropriately structured to achieve these goals. In addition, a coherent underlying theory will iron out

489 By this, I mean a generic reason that someone has to subjectively value making a choice – I will explore and explain this below.
inconsistencies and ambiguities in current informed consent guidelines.

I will argue, for example, that protecting the research subject’s ability to make low-stakes decisions is a crucial part of showing respect for persons in research, though there is a risk that current approaches to informed consent will neglect and ignore these decisions.\textsuperscript{490} By outlining why protection of these decisions is an important part of showing respect for persons in research, and by showing how informed consent guidelines can be structured in a way that ensures that these decisions are taken into account to a greater extent, we can better ensure that the value of respect for persons in research is adequately upheld through informed consent guidelines. Similarly, I will contend that informed consent provides a good means of protecting the wellbeing of research subjects, and that it is often implicitly assumed that informed consent guidelines will play this role to a certain extent.\textsuperscript{491} However, we can only rely on informed consent guidelines to play this role if we make this function explicit, and structure them appropriately; in their current form, there is no guarantee that informed consent guidelines provide adequate protection for individual wellbeing, which makes this implicit assumption potentially dangerous.

The structure of this chapter will be as follows: I will first contend that the value of respect for persons in research needs to involve more than taking choices that qualify as autonomous in an authenticity-based sense into account. My choice-based theory suggests that respect for persons in research is better conceived as involving the facilitation and promotion of the choices that people have reason to value. This goal will form the basis, in my theory, of informed consent guidelines. That is, I will suggest that the purpose of informed consent guidelines in research should be to ensure that we are conducting research in a way that reflects the value of respect for persons, and that this can be achieved by ensuring that informed consent guidelines protect the decisions that research subjects have reason to value.

\textsuperscript{490} Particularly depending on how these guidelines are read – a clear theoretical basis can clear up ambiguities.

\textsuperscript{491} A view that I have alluded to in Chapter 3.
I will next suggest that some restrictions on the types of choices that we should promote and protect in research ethics are justified, on both the same respect-based grounds that suggest that we should protect certain choices in the first place, and on the basis of concern for the wellbeing of the individual research subject. If these restrictions are put in place, I will then argue, there is good reason to think that informed consent guidelines can also function as a good means of protecting the wellbeing of the individual research subject.

This choice-based approach to respect for persons and informed consent in research ethics contains several advantages over the existing approaches documented in the previous chapters, which I will highlight; it allows us to avoid the problems with autonomy and beneficence that I have outlined in the previous two chapters, and provides a consistent and clear respect-based justification for taking a wide range of decisions into account. It will also provide an approach that is geared towards the distinctive concerns of research ethics, emphasising the difference between research ethics and medical ethics, which, as I have argued throughout the thesis, is crucial. I will then address a potential problem with my choice-based approach: there is a risk that it will sanction undue restrictions on high risk conduct. I will argue that an authenticity-based theory of autonomy can be invoked in these cases to provide additional assurance that concern for the wellbeing of the individual research subject does not collapse into problematic paternalism.

**Scope of the Theory**

Before I begin, it will be useful to address the proposed scope of this theory. A significant part of the argument in this chapter will surround the contention that informed consent in research should be geared towards the protection and promotion of choices that people have reason to value, which forms a crucial part of upholding the value of respect for persons. This,

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492 A feature that, as I have argued in the previous chapter, is both highly useful, and that is missing from Faden and Beauchamp’s theory. This chapter will display why it is so useful.
however, is not to say that protecting and promoting the choices that research subjects have reason to value is the only necessary means of showing respect for persons. My theory will suggest that the value of respect for persons is best achieved, in some cases, by relaxing the requirements for consent, so that the wishes of some subjects that are traditionally regarded as unable to consent should be honoured in some cases. Due to my focus on consent requirements, however, I will not be dealing with cases in which the subject is entirely unable to consent, due to the fact, for example, that they are incapacitated. I do not mean this to suggest that these types of research subjects should not qualify as able to participate in research under any circumstances, or that there are not other appropriate means of showing respect for these research subjects. Similarly, I do not mean to suggest that these informed consent guidelines necessarily constitute a complete means of showing respect for subjects who can consent. Respecting the choices that research subjects have reason to value should be regarded as just a component of showing respect for persons.494

A focus on informed consent will also not adequately address the kinds of ethical issues that are central to social science concerning the systematic withholding of information or failure to seek consent from research subjects, through deception, or covert observation.495 Doing justice to these issues requires specialized and in-depth treatment. In the second appendix, however, I will suggest that my choice-based approach shows promise in identifying the ethical issues concerning these practices (something that has been quite difficult with autonomy-based approaches to these issues). I will also not be looking at questions of coercion here – I will take for granted that voluntariness, and a lack of coercion, need to be established before subjects are regarded as being able to consent.496 I will leave questions

494 Australia’s National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research does an admirable job of pointing out that factors beyond autonomy or meeting informed consent requirements must be taken into account when it comes to showing respect for persons in research.

495 Though these issues are of central importance to social science research, where these practices are widespread and central to research methodology, they can, of course, arise in other research contexts.

496 For a detailed treatment of these questions, see Faden and Beauchamp, A History and Theory of Informed Consent.
about whether subjects who are in arguably coercive circumstances, such as prisoners, have the capacity to consent, open.

Finally, I will not provide a concrete answer to the question of how exactly these requirements should be balanced against other concerns in research; for example, beneficent concerns about the overall good that research can generate for society, and concerns about distributive justice. I agree with the contentions in both the Belmont Report, and in Faden and Beauchamp’s work, that it is impossible to stipulate exactly how these values should be balanced against each other in every circumstance; a more promising approach is to outline broad ethical principles, or identify broad ethical concerns, that can be applied to specific circumstances on a case-by-case basis. My choice-based theory will, however, explain what the interests of the individual research subject can generally be thought to be in research ethics, and give us guidance on how we can translate this into informed consent guidelines that represent these interests. Recognising what these interests are, why they are significant, and how they can be achieved, is a crucial first step towards approaching the question of how these interests can be balanced against other values. In the first appendix, I will provide an indication of what these suggestions might suggest in terms of revisions for a particular research ethics document, namely the Belmont Report. This will help to reveal how my theory contributes to the general problem of balancing values, especially ensuring that the interests of the individual research subject are given sufficient weight, without purporting to specify exactly what should be done in every situation, or to dissolve the inevitable conflicts between ethical principles.

Recap: Why a choice-based theory?
The next two sections will be dedicated to outlining, respectively, the two elements that I believe that informed consent in research should be focused on protecting and promoting; respect for persons through respect for the choices that they have reason to value, and individual wellbeing. I will

497 By which I mean choices that they value – as we need to come up with a general policy here, I will focus on generic reasons that people have to value making their own
suggest that these two elements should not be regarded as diametrically opposed; that, in fact, we can generally regard an approach which includes both these elements as an assurance that the interests of the research subject are adequately being taken into account, and are not subsumed by what might produce the most benefit for society as a whole. Before I turn to these arguments, however, it will be useful to briefly recap my argument in the previous two chapters, in order to highlight why I contend that a choice-based theory is preferable to existing approaches to informed consent in research ethics. This will help to explain why I take this specific approach.

I have pointed out two major problems with research ethics as it currently stands: firstly, the principle of beneficence does not function as a good means of both protecting the wellbeing of the individual research subject and pursuing benefit for society. These goals will frequently clash, and the tension between them is one of the most significant ethical conflicts in research. I have argued (in Chapter 3) that the current view of beneficence in research ethics is too influenced by therapeutic medical ethics, and does not adequately emphasise the potential conflict between these two beneficence-based imperatives, or provide an appropriate means of balancing these two values. I have suggested that in order to emphasise the conflict between societal and individual good, we might consider promoting and protecting the wellbeing of the individual research subject along with his other interests, through appropriately-structured informed consent guidelines. I have noted that this broad idea is not without precedent; as I explored in Chapter 2, the earliest research ethics guidelines (most notably the Nuremberg Code) used informed consent guidelines as a means of protecting the wellbeing of individual research subjects. In this chapter, I will argue that informed consent is a good means of protecting the wellbeing of research subjects, but only if we add certain conditions – without these additional safeguards, we cannot rely on informed consent to fulfil this function. I will argue that informed consent can then fulfil this role alongside its other functions.

choices. This will become apparent in the discussion below.
Secondly, in Chapter 4, I have criticised the assumptions that respect for autonomy is the appropriate means of achieving the value of respect for persons in research ethics, and that respect for autonomy forms an adequate theoretical foundation for informed consent procedures. I have looked at several different models of autonomy, and suggested that each of them is plagued with problems that prevent them from functioning as a good means of linking informed consent guidelines to the value of respect for persons in the context of research. Authenticity-based models of autonomy are either too restrictive to take a wide range of decisions into account, or, at their most permissive, generate counter-intuitive results and do not seem to capture what is valuable about certain decisions and what makes them worthy of protection and promotion through informed consent procedures. Faden and Beauchamp’s authenticity-free model of autonomy, proposed in response to the problems with authenticity-based theories in practical, medical and research contexts, does seem to capture an intuitively pleasing range of decisions. However, there is no explanation as to why these decisions are worthy of protection and promotion, while decisions that fail to qualify can be ignored or overridden without undermining respect for persons.

I contend that we would benefit from a theory that allows us to discern which decisions we should promote and protect in research ethics in order to uphold the value of respect for persons, as well as providing us with a justification for ignoring or overriding decisions. A theory of this type will allow us to ensure that informed consent guidelines are appropriately structured to achieve the goal of showing respect for persons. Due to the confusion that the ambiguous use of the word autonomy has caused in research ethics, and the problems with each of the models of autonomy considered above in the context of research ethics, I have also suggested that we reject the assumptions that respect for persons is achieved in large part

498 Or whatever concrete means we use of expressing this principle; I will argue that informed consent, if appropriately structured, provides an ideal means of expressing the value of respect for persons in research as I argue it should be conceived.
through respect for their autonomy in research ethics, and that informed consent guidelines are and should be based on the value of respect for autonomy. This will additionally force us to justify why certain decisions are worthy of respect, rather than relying on the term “autonomy” to provide this justification for us (even when there might be no reason to suggest that the decisions we designate as autonomous have some special characteristic that makes them worthy of respect).

Rejecting the assumption that informed consent is based on respect for autonomy allows us to approach the question of how to express the value of respect for persons in research ethics from a different angle. Rather than chiefly involving respect for autonomy, I take respect for persons to be best conceived as involving the promotion and protection of the interests of the individual research subject. This is certainly not to say that respect does not involve any considerations beyond this, but this will be a crucial part of expressing the value of respect for persons in research. It is the protection and promotion of the interests of the individual research subject, I will argue, that should form the basis for informed consent guidelines in research. I will investigate when concern for the interests of the individual research subject supports the facilitation and protection of the choices of the research subject, and when the interests of the research subject are better served by restricting the subject’s decisions. I will contend that in many cases, simply requiring that subjects give informed and voluntary consent in order to participate in research will promote the subject’s two primary interests in research; the opportunity to make valuable choices, and their wellbeing.

I suggest that the interests of the research subject can be best protected in research ethics by focusing on facilitating and protecting the choices that the subject has reason to value. I argue that subjects have reason to value making many choices that do not qualify as autonomous. Requiring that subjects are informed, as I will show, will enhance the value of some of these choices, and will not undermine their value. Informed consent can thus function as a means of facilitating and/or protecting valuable choices. I
will also argue that informed consent is generally a good means of protecting and promoting the wellbeing of research subjects. Research subjects will generally have an interest in protecting their wellbeing. Ensuring that subjects are adequately informed of the risks involved in a given research project will typically enhance their ability to protect their wellbeing. I argue that in the context of research, there are several reasons that informed and voluntary consent is a particularly efficacious means of ensuring that the wellbeing of subjects is promoted and protected. In research, both of these interests can generally be simultaneously promoted and protected through informed consent guidelines.

**Respect for Persons as the Protection and Promotion of Valuable Choices**

In this section, I will outline what I contend should be the basis for informed consent guidelines in research; protecting and promoting the choices that research subjects have reason to value. I will draw here from the work of T. M. Scanlon to highlight the range of choices that we have reason to value, before arguing that taking these decisions into account in research is an important part of showing respect for persons. These choices, I will show, go beyond the autonomous choices that are usually upheld as a significant component of respect for persons. This wide range of choices can function as a realistic partial basis for informed consent guidelines, as long as we constrain it with the other element (wellbeing). Scanlon aims to document, as part of a larger argument about moral responsibility, “the positive reasons that people have for wanting opportunities to make choices that will affect what happens to them”. Scanlon examines three generic reasons that people might have for wanting to make their own decisions:

*Instrumental:* The most obvious reason that people have to value making their own choices is because it increases the likelihood that the resulting outcomes will cohere with their preferences. Scanlon gives the example of wanting to choose what he eats at a restaurant because he is generally most

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likely to know best what he will enjoy. Enjoyment does not have to be the only aim here, it can be anything valued by the chooser. It is also important to note that as this value is entirely contingent on outcome, there can be times where it will support the opposite conclusion, i.e. sometimes having others choose for us will provide the outcome that best matches our preferences. As Scanlon puts it, the instrumental value of choice depends both on the agent’s ability to choose in a way which will best secure future satisfaction of preferences, and on the other available options for selecting outcomes.\textsuperscript{500} Both of these factors are relevant to our discussion in the context of research ethics, as we will see below.

*Representative:* Making a representative choice is valuable because it attaches special meaning to the choice, or allows us to express something about ourselves. Scanlon suggests that it is important to pick out a gift for one’s wife rather than having her pick it out herself (though she would surely be better able to choose what she would like) because the gift will have a special meaning in virtue of the giver choosing it; reflecting his thoughts about his wife. Similarly, we might wish to decorate our own home in order to express something about ourselves.\textsuperscript{501}

*Symbolic:* Symbolic choices are valuable because the ability to make these choices shows that the chooser meets an expected standard of competence, and has the standing normally accorded to an adult member of society. To return to the example of instrumental choice above, imagine denying an adult the choice of what to eat in a restaurant, due to a belief that he, because of advanced age or mental illness perhaps, is not likely to choose in a way that will best satisfy his preferences. Denying someone the ability to make this choice might be keenly felt and regarded as an insult, not because of the consequences of making it, but because of what being granted the ability to make this choice says about the agent. Scanlon provides the example, in societies in which arranged marriage is uncommon, of the desire to choose one’s own spouse. An agent may wish to make this

\textsuperscript{500} Scanlon, *What We Owe to Each Other*, p.252.

\textsuperscript{501} Scanlon, *What We Owe to Each Other*, pp.252-3.
decision not just because he believes that his own choice will be the most satisfactory, or because he wants to express something about himself through making the choice. In addition, he might want to make this decision because having his parents make it for him (for example) would be demeaning, not properly reflecting his status as a competent, independent adult.  

Scanlon notes that these three categories of reasons to value choice are not mutually exclusive – choosing one’s spouse, for example, might be valued for instrumental, representative and symbolic reasons. He also leaves open the possibility that agents may have other reasons for valuing choice. He lists these three, however, because, he contends, they are “significant classes of generic reasons”. The fact that these reasons are likely to be both significant to many people, and shared by many people, he suggests, gives us reasonable grounds for proposing and determining the shape of a general principle that prohibits interference with certain decisions. We can reject interference with certain decisions, he contends, on the grounds that interference

(a) would deprive people of the opportunity to make choices with significant instrumental value, (b) would interfere with choices that have important representative value for people as ways of shaping their lives and expressing their values, or (c) would stigmatize those who are interfered with by labeling them as immature or incompetent.

Scanlon argues that where these three values are significant, and where there is no other strong reason to interfere with choices, then “principles that no one could reasonably reject” will support the protection of these choices from outside intervention. Scanlon looks at reasons to value choice at a very general level – this is because he is interested with devising general moral principles. This goal means he must focus on general conclusions

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502 Scanlon, *What We Owe to Each Other*, p.253.
503 Scanlon, *What We Owe to Each Other*, pp.253-4.
504 Scanlon, *What We Owe to Each Other*, p.254.
505 Scanlon, *What We Owe to Each Other*, p.254; Scanlon’s contention here follows from his broader contractualist approach, but it is not necessary to accept his contractualist views in order to utilise this argument in this context.
about the reasons that people are likely to have in any given situation. Though this technique will not cater perfectly to distinctive situations and personal characteristics, operating on a high level of generality allows Scanlon to produce simple principles that are easier to apply across a wide range of cases. A similar approach will benefit us in research ethics; a focus on generic reasons will both capture what is valuable about making choices for a wide range of people, and allow us to generate a relatively straightforward action guide that can be applied to a wide range of situations in research ethics without too much difficulty.506

One aspect of Scanlon’s account will be particularly useful to my discussion and analysis; he points out that there are reasons to value choice beyond an interest in securing the outcomes we want. Where the instrumental value of choice is focused on outcome, symbolic and representative choices have value that is not contingent on the consequences of making the choice, but rather is based on the meaning of making the choice in itself.507 Goran Otterström refers to these two different types of value as the “outcome-side” and the “process-side” of the value of choice.508 The instrumental value of choice comes from its value in bringing about the outcomes that we want, while the representative and symbolic values stem from the process of making the choice. This distinction tracks the differences between Mill’s and Kant’s conceptions of autonomy surveyed in the previous chapter. For Mill, as we have seen, allowing people to make their own choices is valuable because this is what will generate the greatest utility. Mill provides several arguments to suggest that allowing individuals to make choices will maximise wellbeing. I will turn to a discussion of the instrumental value of choice later in the chapter, after I have introduced considerations of wellbeing; for these two elements will be closely interconnected.

506 This is important to keep in mind in all that follows; a policy that is intended to operate on a general level must rely on generalizations to a certain degree, and there may, as a result, be certain special cases that provide exceptions to the general rules I outline below. I will endeavour to point out some of these possible exceptions in what follows.
507 Scanlon, What We Owe to Each Other, p.253.
The representative and particularly the symbolic values of choice, on the other hand, closely resemble elements of Kant’s conception of autonomy. Stephen Darwall illustrates this in an example in which the instrumental value and the symbolic value of choice come apart. While it may be appropriate for parents to push a child to eat her broccoli, he argues, it would be inappropriate for the parents to take the same action concerning their adult child. This remains true even if eating the broccoli is the best way for her to achieve her own preferences (she might, for example, have a concern for her own health, and the parents know better than she does that eating broccoli is a good means to achieving this outcome). The problem with this course of action stems from the fact that the parents fail to recognise the daughter’s will as having intrinsic value. They fail to show her appropriate respect, by failing “to recognize the authority that persons have to demand, within certain limits, that they be allowed to make their own choices for themselves.”509 Darwall holds that this kind of value is linked to the core notion of autonomy in the Kantian sense; the idea that, independent of instrumental considerations, respecting a person’s authority to make her own decisions is an essential component of recognising the fundamental dignity of the human being. This idea, though it forms the basis for Kant’s moral autonomy (the idea, as explored in Chapter 4, that the capacity to act autonomously forms the basis for morality), can clearly come apart from it.510

This idea is important to a notion of respect for persons in research ethics; it suggests that, regardless of the content of choices, and regardless of their instrumental value, allowing people to make their own choices is fundamental to the notion of respect. This interpretation also produces quite a wide-ranging obligation of non-interference – choices cannot be ignored just because they do not have significant consequences; what is significant about this type of choice is being granted the ability to make it. This begins to give us an indication of why choices beyond those that qualify as

authentic are still important to the principle of respect for persons. I will now turn to my argument that we should incorporate concern for individual wellbeing into the principle of respect for persons, to determine if pursuit of this value is compatible with the promotion and protection of choices we have reason to value, and if restrictions upon choices can be justified in this context.

**Protection of Wellbeing and Informed Consent**

This section will deal with my second proposed element of informed consent; protection of the wellbeing of the individual research subject. Though a wide range of choices are likely to be valued, especially for symbolic reasons, this does not mean that there is no good reason to restrict some choices. As Scanlon suggests, where there is a “sufficiently strong countervailing”\(^5\) value, inhibiting choice may be justified. I will suggest that considerations of individual wellbeing, in the context of research, can present a justification for curtailing research subjects’ ability to make choices that they have reason to value. I will defend, and outline, the restrictions I think are necessary to ensure that wellbeing is adequately protected. However, I will suggest that these restrictions will not in fact constitute significant interference with choices that agents have reason to value in research ethics. The restrictions on allowing research subjects to make choices which I advocate, I will argue, can also be justified on the same respect-based grounds that lead me to suggest that we should honour the choices of the research subject in the first place. Furthermore, if we can put these minimal restrictions in place, informed consent guidelines, that is, allowing subjects to make their own informed decisions concerning their participation in research, will function in the majority of cases as an appropriate means of protecting (and even promoting) the wellbeing of the individual research subject.

We can bring out my argument here by clarifying an aspect of the instrumental value of choice. Otterström points out that

\(^5\)Scanlon, *What we Owe to Each Other*, p.254.
there are two different relevant ways in which a person might make mistaken choices. More controversially, she might fail to choose what she ought to choose according to the preferences that she ought to have.\footnote{512} She might also fail to choose what she ought to choose according to her actually held preferences.\footnote{513}

In suggesting that the instrumental value of choice comes from the subject’s ability to bring outcomes into line with his preferences, whatever they are, I am essentially suggesting that only the latter type of objection is a valid basis for intervening in someone’s choices.\footnote{514} Though the efficacy of a given choice as a means of achieving one’s preferences can be questioned, the preferences themselves are placed out of reach of scrutiny. I contend there is one instance, however, where restricting agents’ actions based on their preferences is justifiable in the context of research ethics: when they do not have sufficient regard for their own wellbeing. If research subjects do not give their wellbeing sufficient weight, if it does not count among one of their chief concerns when they are making a decision about whether to participate in research, then this provides sufficient reason to override the subject’s desire to participate in research (for reasons that I will detail below).

The kind of cases I have in mind here are exemplified by anorexic research subjects. Anorexic research subjects are an example of individuals who can qualify as autonomous in a theoretical sense, but are likely to display a tendency to be overly submissive, cooperative, obedient, and self-sacrificing.\footnote{515} \footnote{516} Spencer and Cheryl Eth and Harold Edgar suggest that

\begin{itemize}
\item \footnote{512} That is, one might wish to argue, for example, that a person ought to have preferences that will best or better secure her wellbeing (in an objective, or intersubjective sense). For example, one might criticise another agent’s preference to smoke, as it does not involve sufficient regard for her wellbeing. One might argue in this case that the agent in question should hold a preference to not smoke, as this preference will better serve her interests (not subjectively understood).
\item \footnote{513} Otterström, “Freedom of Will and the Value of Choice”, p.266.
\item \footnote{514} We will return to this below.
\item \footnote{516} For more on this, see R. Bachner-Melman, “The relevance of pathological altruism to eating disorders” in B. Oakley et al (eds.), Pathological Altruism, Oxford University Press, Oxford, 2012 and E. Bachar et al, “Depressive tendencies and lower levels of
anorexic research subjects are often too eager to consent to dangerous and painful research. This, they believe, “greatly increases the likelihood of a variety of self-destructive behaviors.” 517 They go so far as to argue that presenting an anorexic research subject with the opportunity to be involved in a dangerous and self-sacrificing activity (such as painful or dangerous research) will compel the subject to participate.518

However, anorexic research subjects also typically retain their intellectual capacities. For this reason, the sort of behaviour displayed by the anorexic research subject is completely compatible with the models of autonomy we have surveyed in the previous chapter. Indeed, anorexics could be viewed as paragons of autonomy (in the theoretical, authenticity-based sense) due to their extreme self-control. They could also qualify as autonomous under Faden and Beauchamp’s theory; self-destructive or self-sacrificing behaviour is fully compatible with intentionality, sufficient understanding and sufficient noncontrol.519 Anorexics would qualify as able to give informed consent according to the requirements contained in the Belmont Report and the Declaration of Helsinki; they may be fully informed, completely understand the information, and not be coerced or manipulated in any way, yet still be drawn to the self-destructive action. Even the consent guidelines in the Nuremberg Code, explicitly and deliberately formulated as a means of protecting the wellbeing of research subjects, would not restrict a self-sacrificing research subject from consenting to dangerous research.520

There are several reasons why we might wish to restrict subjects that display these sorts of tendencies from participating in research. A request to

517 Eth, Eth and Edgar, “Can a Research Subject be too Eager to Consent?”, p.20.
518 Eth, Eth and Edgar, “Can a Research Subject be too Eager to Consent?”, p.20.
519 Unless noncontrol could be formulated to exclude people suffering from mental illnesses (encompassing internal as well as external sources of control), but as previously mentioned, this is a difficult task that Faden and Beauchamp have not attempted.
520 We will return in detail to several of these types of cases below, scrutinising the extent to which interference in the actions of research subjects that display these tendencies can be justified.
participate in research due to a tendency to behave in a self-destructive, self-sacrificing manner amounts to a request for the researcher to facilitate this behaviour. Even if one does hold a strong, Humean view about one’s ends being out of reach of rational scrutiny,\(^\text{521}\) it is not incompatible to hold that though people should be free to pursue their self-destructive preferences in some areas of life, others do not have an obligation to help them to achieve these ends. This is particularly the case where the facilitator in question might be thought to have special obligations towards the people in question. Researchers have a responsibility towards their research subjects that goes beyond the obligations that we would typically suggest people generally have towards one another. This plausibly involves a special obligation to not allow subjects to sacrifice their own interests through involvement in research.\(^\text{522}\)

Similarly, throughout the history of research ethics, as we have seen in Chapter 2, there has been significant preoccupation with minimising the risk of harm in research, for good reason. The many historical examples that show how easy it is for research to cause harm to subjects necessitate stringent requirements to minimise this possibility wherever it may be ethically questionable. Because the enterprise of research can potentially lead to great risk of harm, and to the interests and wellbeing of the individual being sacrificed for the good of others, we must be particularly careful in this domain to ensure that the individual is adequately protected. Where people do not have sufficient regard for their own wellbeing, additional protective measures may be required. Exposing such people to harm in research without adequate safeguards in place also risks damaging society’s view of the research enterprise in general.

Scanlon also suggests a similar means of justifying additional safeguards on wellbeing in situations in which a social goal justifies the creation of risk.


\(^{522}\) I have explored this argument in more detail in L. White, “Understanding the Relationship Between Autonomy and Informed Consent: A Response to Taylor”, in the *Journal of Value Inquiry*, Vol. 47, No. 4, Dec 2013, pp.483-91.
Scanlon asks: where we determine that a social goal is of sufficient importance that it justifies the creation of risk to certain members of society, what obligations do we have to ensure that this risk is mitigated? Scanlon makes a general argument here, but the scenario he describes clearly resembles the situation in research; as I have argued throughout the thesis, the central ethical tension in research is working out how to pursue significant societal benefits without sacrificing the interests of certain individuals (or to at least come to an understanding of how we might represent each of these important interests, and ensure that one does not subsume the other). Thus, his discussion can aid us in determining what kinds of obligations we might be thought to have to research subjects, specifically regarding protection of individual wellbeing.

Scanlon argues that the arguments against putting people at risk for some good reason lose their strength if we introduce a requirement that people are informed (within reason) of possible danger. Generally, he argues, a significant reason that people have to value choice stems from the fact that it gives them the ability to avoid harm. If we inform people of a possible danger, we give them the opportunity to avoid this danger. Ordinarily, if we wish to pursue a social goal that may put people at risk of harm, informing those that may be affected of this risk and allowing them the opportunity to avoid it will constitute an adequate safeguard against the risk of harm created by this activity. In this way, Scanlon argues, we can fulfil our obligations to protect people against the risk of harm that we create.

However, informing an individual will only function as a safeguard against wellbeing if she is already motivated to avoid risk. If someone does not value her wellbeing, informing them about risk will not reduce the risk of harm (or in fact, in the case of the anorexic research subject, could even increase it). This strategy for protection of wellbeing is contingent on the research subject having an incentive to avoid harm, and to protect their wellbeing. If we wish to put adequate safeguards in place to protect the wellbeing of all research subjects, this will require additional measures. Scanlon suggests that if we wish to put people at risk in order to pursue a
societal good, we must ensure that there are adequate measures in place to protect all people from harm, to ensure that agents have no cause for complaint if they are in fact harmed.\textsuperscript{523} This will clearly require a different approach for people that do not value their wellbeing sufficiently to be motivated to avoid harm.

Scanlon’s contentions here invoke the key reason that I wish to incorporate the promotion and protection of wellbeing into informed consent guidelines, and that I wish to restrict people from participating in research due to an insufficient regard for their own wellbeing. If we can ensure that additional safeguards are in place to assure that people adequately value their wellbeing (I will return to how this might be done below), we can protect and promote the wellbeing of research subjects by ensuring that they are informed, and that they have the opportunity to choose. As Scanlon points out, people will typically have an interest in protecting their wellbeing, and providing them with information about a proposed course of action (particularly the risks involved), and ensuring that it is understood, will increase the ability of research subjects to protect themselves against risk. Informed consent guidelines can function as a good means to protecting the wellbeing of research subjects, as long as we can ensure that the people that have the opportunity to choose to be involved in research are motivated to protect their own wellbeing. In addition, there are good arguments to suggest that allowing people to protect their wellbeing in this way is particularly appropriate to research. I will now outline the arguments for this contention, before turning to the various advantages of using informed consent guidelines in research both to protect valuable choices and to protect and promote the wellbeing of research subjects.

\textit{Informed Consent and Protection of Wellbeing in Research}

We have already been introduced to a general argument suggesting that people are in the best position to protect and promote their wellbeing through choosing for themselves. This argument, explored in Chapter 4,

\textsuperscript{523} Scanlon, \textit{What we Owe to Each Other}, pp.253-4.
was forcefully advocated by Mill. As we have seen in Chapter 4, Mill puts forward two main arguments suggesting that individual wellbeing is best pursued by allowing people to make their own decisions. He argues, firstly, that individuals have diverse characters, and what will secure the wellbeing of one person thus may not secure the wellbeing of another.  

Because individuals have a privileged knowledge of their own tastes, they have privileged insight into what will best benefit themselves. Furthermore, Mill suggests that exercising liberty is an intrinsic part of wellbeing; that being able to choose for oneself is in itself a principle ingredient of human happiness. It is for this reason that Mill’s theory, though utilitarian at its absolute basis, makes liberty such an essential component; liberty is not intrinsically valuable in itself, but it is an intrinsic part of what, for Mill, does have intrinsic value; happiness or wellbeing. We have seen similar arguments applied to therapeutic medicine in Chapter 2, during the early 19th century. As we have explored, it was argued during this time that maintaining a state of liberty is essential to health and wellbeing, and that the beneficent obligations of the physician thus demanded informing patients, and letting them make their own decisions. A strong advocate of a Millian approach might go so far as to argue that that paternalism is self-defeating, as the importance of liberty for wellbeing will undermine the goal of paternalistic intervention; better securing the wellbeing of another person.

However, this contention could well be undermined in therapeutic medical contexts by the fact that the doctor, in virtue of her special knowledge about medicine, will typically have an enhanced ability to assess complex information related to various treatments, probable outcomes, etc. A lack of access to or understanding of relevant information will clearly inhibit the patient’s ability to unilaterally make a decision that has the best (or even an

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528 This is certainly not the view that was held by the physicians that advocated informing patients during the 19th century however – as we have seen, this was highly contingent on circumstance.
adequate) chance of securing her goals, including wellbeing. As Scanlon notes, the instrumental value of making decisions is contingent on the other available means of deciding, and on the agent’s ability to decide. In this case, the doctor’s enhanced ability to make a choice based on available evidence, and the difficulties that patients are likely encounter in processing the complicated information to determine what will best satisfy their interests (specifically, in this case, their wellbeing) suggest that the instrumental value of choice, and thus the patient’s ability to protect and promote her own wellbeing through making her own decisions, is diminished. This of course does not completely override the fact that patients have special knowledge about their own interests, and may get, as Mill suggests, utility simply through choosing for themselves. But it does suggest that in this case, the doctor may well be able to make a decision that will better secure the patient’s wellbeing than the patient herself.

However, even if we do recognize that the doctor may be better placed to make judgments concerning the patient’s wellbeing in a therapeutic medical context, there are two reasons to suggest that this does not apply so well to research. The first, as we have seen in Chapter 2, underlies the motivation for making consent an important means of protecting wellbeing in the Nuremburg Code. As we have reviewed at length in Chapter 3, an essential difference between the ethics of research and the ethics of medical therapy, that must be acknowledged in order to adequately approach the specific ethical problems in research, concerns the different motivations of the therapeutic physician and researcher, and the different demands of beneficence in these two domains. Whereas the ethics of medical therapy stipulate that the physician’s primary motivation should be beneficent concern for the individual patient, the driving motivation in research is the production of benefit for society. This means that the researcher is not motivated in the same way to promote and protect the wellbeing of the research subject above all else (in fact, as we have seen in Chapter 3, attempts to incorporate this goal into research may actually undermine the ability to do research). The therapeutic physician, due to his motivation and his specialized knowledge, could be argued to be in a better position to
promote and protect the wellbeing of the patient. The researcher, however, may have the same specialized knowledge, but does not have the same motivation to prioritize the wellbeing of the subject, and to always act in a manner that is consistent with this motivation. The argument that I have outlined above suggesting that informing a subject, and giving them the ability to choose may provide a good means of allowing the subject to protect his own wellbeing is contingent on having the motivation to pursue his wellbeing. Generally, we can expect the subject to value his own wellbeing to the extent that he will be motivated to pursue it. Where we cannot hold that expectation, I have argued that research subjects should be precluded from participating in research. The researcher, however, can simply not be expected to have this same motivation.

It is a suspicion about the motivations of the researcher that drives the Nuremberg Code to make informed consent a central and essential wellbeing-protecting mechanism. As we have seen in Chapter 2, the Nuremberg Code reflects concerns that the motives of the researcher may not be beneficent in any sense, but indeed nefarious. However, as my arguments in Chapter 3 have shown, even if we can trust researchers to act in a beneficent manner, this will not guarantee that the wellbeing of the individual research subject is protected and promoted. Whether the researcher is motivated by beneficent concern or not, the subject can be better trusted than the researcher to have an interest in the promotion and protection of her own wellbeing, if we take steps to exclude those unusual cases in which the research subject does not sufficiently value her own wellbeing. While the researcher, like the therapeutic physician, may be in a better position to see what might benefit the subject, the subject is in a better position to protect and promote her own interests, because we know, at least, that this will be of importance to her.

There is a second reason that the objection to the Millian arguments concerning wellbeing do not apply so well to research: the types of decisions that the research subject makes in the context of research are often quite different to the types of decisions the patient makes concerning
medical therapy. The choices that the research subject can make in this domain are far more circumscribed. Where the patient may have to choose between many possible treatment options with an eye to many competing preferences and values, the research subject will typically have an option of choosing one thing; whether or not to participate in a research project. Furthermore, the patient will often not be able to simply opt out of treatment without facing consequences, while the research subject does not have this concern when refusing to participate in research. Though research will still be likely to involve complicated and esoteric medical or scientific concepts, it may well be easier to furnish the subject with the important information relevant to making this particular decision.

In addition, a clear expression of the fact that the motivations and expectations of the researcher differ from those of the therapeutic physician provides the means of overcoming the prevalent and troubling therapeutic misconception, which, as we have seen in Chapter 3, constitutes a pervasive threat to the wellbeing of the research subject. It also reduces the chance of the recurrence of a case similar to the Jewish Chronic Hospital Disease Case discussed in Chapter 2, which again arose from a mistaken ascription of the motives of therapeutic physicians to researchers, and confusion on the part of the researchers about what their obligations of beneficence entailed.

In summary, informed consent is better as a wellbeing-promoting measure in a research context than in a therapeutic context, as we can add all the traditional arguments about making one’s own decisions being best for one’s wellbeing to arguments about subjects being better placed to protect their own wellbeing in the context of research. Together, these arguments make a more compelling case than they do in medical therapy. If we can treat wellbeing as something that patients have an interest in pursuing (which, as I have argued, we can do if we make it a condition of

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529 This is certainly not to say that there may not be cases in which a researcher is better placed to promote the subject’s wellbeing, even if the subject is appropriately motivated and sufficiently informed. I believe these considerations, however, are sufficient to remark on the general situation in research, and to form the basis for policy proposals which, as I have noted above, must operate on a general level.
participation in research), informed consent provides a good means of protecting wellbeing in the context of research. Additionally and crucially, it means we can treat pursuit of wellbeing as one instrumental value of choice among others, which means that we can protect wellbeing (in the majority of cases) along with other valuable choices. The next section will expand on this benefit of a choice-based approach, while also outlining further advantages.

**Advantages of a Choice-Based Approach**

In the previous section, I have argued that there is a case for curtailing the actions of research subjects based on a paternalistic concern for their wellbeing. I have suggested that this can justify excluding research subjects from participating in research if they do not sufficiently value their wellbeing.\(^{530}\) If we do place this initial constraint on the choices of subjects, I have suggested that we can then use informed consent guidelines to protect wellbeing. I have also suggested that informed consent in research should be aimed towards protecting the choices that research subjects have reason to value. This section will be dedicated, firstly, to outlining how we can consolidate these two aims in a single set of informed consent requirements. Allowing people freedom of choice, and protecting their wellbeing are typically regarded as antithetical. However, I will show that we can typically (if we put my suggested restrictions in place) use informed consent guidelines to promote and protect both wellbeing and the choices that research subjects have reason to value at the same time. Once we have ruled out subjects who do not have sufficient interest (subjectively understood) in protecting their own wellbeing, we can treat wellbeing as another interest/preference of the subject, which they will be motivated to achieve along with their other interests. Pursuit of wellbeing thus becomes another value which subjects are motivated to pursue, and another reason to value choice instrumentally. This means we can pursue and protect wellbeing and respect for valuable choice simultaneously, and through the same mechanisms. That is, we can put mechanisms in place to ensure that

\(^{530}\) I will return to exactly what I contend this to mean, and how it can be assessed without undermining the ability to choose, in the next section.
wellbeing is protected that also, in the vast majority of cases, do not involve interference with choices that people have reason to value, and that can even, in some cases, enhance their value.

This highlights a fact that I have alluded to throughout the thesis; in research, regarding wellbeing and autonomy (or freedom of action) as fundamentally opposed is a mistake. Not only are these values typically not opposed in research, but they can typically both be promoted through informed consent. The idea that autonomy (freedom of choice) and wellbeing are deeply conflicting principles arose, as we have seen in Chapter 2, in the 60s and 70s in the struggle against the then-dominant ethos of paternalism in therapeutic medical ethics and then found their way into research ethics. We have received further clues concerning why this is such a deeply entrenched idea in the arguments against a Millian approach to wellbeing in therapeutic medical ethics in the previous section. Because a doctor will typically have specialized knowledge about medical treatments, and because they have a professional obligation to prioritise the wellbeing of the individual research subject, they may well be in the best position to determine what is in the best interests of the patient (though of course this may be undermined somewhat by the fact that the patient has special knowledge about his own tastes, interests and preferences). Furthermore, the doctor’s imperative to pursue the wellbeing of the research subject, post-1970s, is typically balanced with the value of requiring that patients are given at least some degree of freedom of choice over their medical care. This leads to a situation in which autonomy (freedom of choice) and promotion and protection of wellbeing are regarded as opposing values. The considerations outlined in the previous section (as well as in Chapter 3 in particular), however, highlight the differences between medical therapy and research, and thus a need for a different approach to the protection of the research subject’s wellbeing in the two fields. In research, we can promote and protect wellbeing and freedom of choice simultaneously (generally) and we can protect and promote wellbeing without paternalism (for the most part).
Secondly, I will outline another advantage of incorporating wellbeing into informed consent guidelines, which also allows us to increase the number of decisions that we honour in research ethics: when we acknowledge that wellbeing is the reason that we have to restrict actions, we can avoid restricting actions when there is no reason to do so. This is especially true of choices that are on the low end of the spectrum of risk, but, as we have seen, that people may well have reason to value for symbolic reasons, and thus should be taken seriously as a component of showing respect for persons. I will show that this approach has advantages over both Faden and Beauchamp’s proposals concerning informed consent, and the informed consent guidelines in the Belmont Report. Though informed consent’s function as an adequate means of protecting wellbeing relies on an initial paternalistic restriction on certain actions this approach actually allows us, in the two ways just described, to minimise paternalism and the restriction of valuable choices overall. Finally, I will show that this means of approaching informed consent guidelines allows us to make sense of mentions of ‘protection’ in the Belmont Report, and to provide a way of meeting some of the stated goals of this document – which are difficult to make sense of, and determine how to apply to research, without a theory of this type.

_Informed Consent Protects and Promotes all Interests of Research Subject_

We should first establish that ensuring that a subject is informed, and that he understands the consequences of his actions (to an appropriate degree – we will return to what this means in the final section) does not constitute paternalism. We can find support for this idea in Joel Feinberg’s _Harm to Self_.531 Feinberg draws a distinction between what he refers to as ‘hard’ and ‘soft’ paternalism. Hard paternalism involves interfering with an agent's voluntary, self-regarding conduct for her own good. Soft paternalism involves only interfering when the action is nonvoluntary, or in order to ascertain that the action is indeed voluntary. Feinberg draws on Mill’s famous bridge-crossing example in order to illustrate this difference. If a

policeman sees a man approaching a bridge which the policeman knows
cannot hold his weight and will collapse into the river if he attempts to cross
it, he is obliged to call out a warning to the man, making sure he is aware
that his action is truly voluntary – i.e. that the man means to fall into the
river. If there is no time to warn the man, he is warranted in grabbing the
man and dragging him back from the bridge, due to a presumption that the
man does not mean to take a needless risk. Once he has established that the
man is indeed apprised of the relevant facts and wishes to continue anyway,
if we do not wish to resort to hard paternalism, he must be allowed to
proceed, no matter how foolish or dangerous we may think his subsequent
conduct is. While hard paternalism encompasses what we would generally
think of as paternalism, Feinberg regards soft paternalism as “really no kind
of paternalism at all”.

This is reminiscent of a point made by Otterström, mentioned in the
previous section. Otterström suggested that we might wish to claim that
someone’s choices are mistaken (on instrumental grounds) because they are
mistaken about what choices will in fact provide a good means of securing
their preferences. Informing agents about the consequences of their
choices enhances their instrumental value, by giving agents information that
allows them to better determine what the likely consequences of their
proposed courses of action will be, and by allowing them to better determine
which actions are likely to allow them to secure their preferences. If
protection of wellbeing is one of the subject’s goals, informing her will
enhance her ability to do this, just as it will enhance her ability to pursue her
other preferences. In this way, we can see that informing agents enhances
both wellbeing and the (other) instrumental value of actions. And, if we
accept Feinberg’s argument about soft paternalism, it is a means of
achieving this without paternalistic interference.

In using informed consent as a primary means of protecting wellbeing, we
also insulate choices that the subject has reason to value for representative

532 Feinberg, *Harm to Self*, p.16.
or symbolic reasons from paternalistic interference. Informing will not enhance the value of these choices; as we have seen, it is not the consequences of these choices that constitute a reason to value them, but rather, being granted the ability to make choices in itself is what is of value. Relying on informed consent as the chief mechanism through which wellbeing is protected can protect these choices to a greater degree by increasing the number of choices that research subjects are free to make without paternalistic interference. The means by which this is achieved is through recognizing that, in many cases, we can entrust the subject with the responsibility of protecting and promoting her own wellbeing. In research, as I have argued, the subject is generally well placed to protect and promote her own interests, which will generally include an interest in protecting wellbeing. Deficiencies that the subject might have in the ability see what her preferences demand in terms of action can be reduced by informing the subject and ensuring that she understands the consequences of her actions; a non-paternalistic means of increasing the likelihood that she is able to choose in a way that best secures her preferences. This means that we do not need to interfere with these choices on paternalistic grounds, therefore preserving symbolic (and representative) value through preserving the subject’s ability to make these decisions.

Relaxing Restrictions on Low-Risk Decisions

This approach goes beyond just preserving the ability to make choices with symbolic or representative value however; it allows us to protect and honour

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534 This will certainly require restrictions on what the subject needs to be informed about, cf. policies requiring that a woman wishing to have an abortion is exposed to graphic pictures of a foetus. This is outside the scope of what I can cover here, however.

535 I have also advocated another measure which goes beyond informing, but that also constitutes a non-paternalistic means of increasing the likelihood that the subject will be able to see what her preferences demand. This is the clear delineation between research ethics and therapeutic medical ethics. As we have seen in Chapter 3, the lack of a clear delineation between these two areas is a significant contributing factor to the prevalence of the therapeutic misconception. I have shown that simply informing patients about the differences between research and therapy does not do much to dispel the misconception. However, this comes to the same thing – distancing research ethics from therapeutic medical ethics, and making clear that these two domains involve very different ethical standards governing conduct, increases the ability of the agent to secure her preferences by reducing the likelihood that she holds mistaken ideas about what leads to them. It does this without paternalistic interference in the decisions of the agent.
more choices, particularly those that may be valued by the research subject for these reasons. We can achieve this through recognizing that concern for wellbeing constitutes the reason we have to restrict the decisions of the research subject. This guides us in discerning what is required from the subject in different circumstances, and assures us that we are not restricting actions when there is no justification for doing so. I propose that when a decision involves little to no risk of harm, we should require less from the research subject in order for them to give their consent to a procedure. In this way, we can remove arbitrary standards prohibiting people from making certain decisions where there is simply no reason to prohibit them.

Faden and Beauchamp’s theory of autonomy, discussed at length in Chapter 4, was devised due to a desire to make the standards for informed consent more inclusive. They were concerned that a focus on authenticity in existing accounts of autonomy risked excluding many perfectly deliberate decisions that they regarded as worthy of respect from promotion and protection in medical and research ethics. Through my account of the choices that people have reason to value, I have come to a similar conclusion; focusing only on authenticity-based autonomy neglects many other choices that people have reason to value. I have even argued, with particular reference to the symbolic value of choice, that this kind of choice can be linked to Kantian ideas about autonomy, but have shown that the value of a choice in the symbolic sense has nothing to do with the content of the choice. This includes whether it, for example, corresponds with the agent’s deeply held values. There is reason, stemming from the earliest notion of autonomy, and concerning its links to human dignity and the respect that is due to persons, to advocate taking choices into account beyond those that qualify as autonomous in the contemporary, authenticity-based sense.

In suggesting that concern for individual wellbeing provides the reason to restrict decisions, my theory is better able to achieve Faden and Beauchamp’s goal of devising an inclusive standard than their own theory. In providing a theoretical basis for informed consent requirements, we have
a means of looking at the value and relevance of certain requirements in different situations, and relaxing or increasing the stringency of the standard as the context requires. Let us take Faden and Beauchamp’s condition of understanding as an example. In order to meet the conditions for substantial understanding (a condition of substantial autonomy and thus a requirement for informed consent) Faden and Beauchamp suggest that the subject must be informed of, and understand, a certain set of core propositions. Faden and Beauchamp are aiming to ensure that the subject is informed about, and understands, information that she would find important concerning her decision to participate in research, stipulating that what the subject might find important is “entirely subjective”. The best way of ensuring this, they suggest, is to require that the subject understands the facts that most subjects generally consider important when deciding whether to participate in research, as well as the facts that the researcher believes are important to participation in research. These facts will involve descriptions of “the foreseeable consequences and possible outcomes” that may result from participation in research (not all of them, just those that subjects are likely to find important, and that the researcher finds – or should find – important).

Under my theory, there are two different functions involved in informing a research subject; giving them a means of protecting their wellbeing, and enhancing the instrumental value of their choices. If we are to imagine a situation in which the research subject wishes to be involved in a research procedure which involves no risk of harm, there is no wellbeing-based reason to require that the agent understand the risks of the situation. Informing the subject will still be a valuable means of enhancing the

536 Where important means that the subject would be upset, after the fact, if she found out she had consented in ignorance of that proposition; it does not require that knowledge of this fact would change the subject’s decision.
540 I have suggested, through Scanlon’s arguments, that we have an obligation to protect the wellbeing of research subjects, and that this obligation can be discharged in research through informed consent (and additional restrictions on those that do not value wellbeing). I will turn specifically to what our obligations to research subjects are (particularly concerning what information we – or the researcher and institution conducting research - are obligated to furnish them with) and why in the final section of this chapter.
instrumental value of the choice. But perhaps the subject is not trying to satisfy a preference through making the choice to participate in research; rather, they adamantly contend that it should be their decision whether or not to participate. Perhaps it is an elderly patient, hospital-bound, who has very limited means of exercising her freedom of choice in other areas of her life. In this case, it seems as though the value of making this choice for the subject is symbolic, and there is good reason for the subject to imbue this choice with symbolic value, as she has limited opportunity to make choices imbued with this symbolic value in other areas of her life. Though the subject should still be informed (as this can only enhance the value of choice), and it should be ascertained that she does not hold any mistaken beliefs about the instrumental value of participation, there seems to be no further justification for restricting a choice that she has reason to value.²⁴¹

In providing an explanation of the purpose of informed consent, my theory gives us a means of determining why informing is valuable (and thus when, why, and what type of information a subject may require, with reference to her specific circumstances), and also when lack of understanding warrants restricting an action. These two things can come apart. While informing a subject can only be beneficial (providing that the subject is not inundated with information that she cannot understand),²⁴² Faden and Beauchamp’s proposed condition of understanding requires not just that she be informed, but that she be excluded from participation in research if she is unable to understand many facts that, in this case, will simply not be important to her decision. Recognizing the value of informing subjects, and the value of restricting decisions, means that we are not precluding subjects from making choices that they have reason to value, without justification.

Faden and Beauchamp’s focus on consequences also neglects the non-outcome-oriented reasons that people have to value choice. Ensuring understanding of what subjects are generally likely to find important about

²⁴¹ We will return to what, specifically, our obligations to inform the research subject might be thought to entail, in the final section.
²⁴² See Manson and O’Neill, Rethinking Informed Consent in Bioethics.
this research, or what the researcher believes is important about the research, simply does not seem necessary in this case. Their approach requires that the subject understand certain possible consequences of the decision when these consequences will be insignificant to the subject, and when the reason that the subject values making the decision is not related to consequences. My account can recognize that there is no reason to prevent the subject from making this decision, and that she has reason to value making it. Faden and Beauchamp themselves suggest that

respect has historically been connected to the idea that some persons possess an intrinsic value independent of special circumstances. As expressed in Kantian philosophy, autonomous persons are ends in themselves…Thus, the burden of moral justification rests on those who would restrict or prevent a person’s exercise of autonomy.\textsuperscript{543}

I have shown that choices that do not qualify as autonomous under Faden and Beauchamp’s framework qualify as worthy of respect on these Kantian grounds. These decisions can be, under Faden and Beauchamp’s theory, overridden without justification. My theory recognizes that overriding these types of decisions requires justification, and should be avoided where possible.

The Declaration of Helsinki’s informed consent guidelines, as we have seen in Chapter 4, are very similar to Faden and Beauchamp’s requirements for autonomy, but rather than endorsing Faden and Beauchamp’s standard of ‘substantial’ autonomy as a threshold for informed consent, their requirements for informed consent more closely resemble Faden and Beauchamp’s notion of ‘full’ or ‘complete’ autonomy (that is, the act must be intentional, all relevant descriptions of the act must be understood, and the actor must be completely free of controlling influences). This document requires that subjects understand “the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, anticipated benefits and potential risks of the study”\textsuperscript{544} before they qualify as able to give informed consent. This standard is similarly needlessly

\textsuperscript{543} Faden and Beauchamp, \textit{A History and Theory of Informed Consent}, p.8.

restrictive, and risks precluding subjects from making choices that they have reason to value, and there is no reason to restrict. 545

**Responsiveness to Risk in the Belmont Report**

I mentioned briefly in Chapter 3 that it seemed as though the Belmont Report might contain a hint of acknowledgement of the fact that its principle of beneficence is an inadequate means of protecting the wellbeing of individual research subjects. This is indicated by the fact that they suggest that the principle of respect for persons might also have a role in protecting individual wellbeing. We are now in a position to explore and evaluate these claims. I will argue that it is difficult to make sense of these claims in the Belmont Report as it currently stands, but that my underlying theory enables us to make sense of these demands and to resolve the confusions and inconsistencies concerning this aspect of the Belmont Report. The central ambiguity in this document has come from this quote stressing two central requirements of the principle of respect for persons in research:

“first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.” 546 As we have seen, Beauchamp criticised the wording of this statement. He states that the “purpose of consent provisions is not protection from risk...but the protection of autonomy and personal dignity, including the personal dignity of incompetent persons incapable of acting autonomously, for whose involvement a duly authorized third party must consent.” 547 Beauchamp explains that each principle is designed to apply to a separate “zone of moral concern” 548. The principles to which he refers are heavily influenced by the context of biomedicine. The principle of beneficence, then, is designed to cover all ethical issues to do with wellbeing, while the principle of respect

545 This is not to say that people might not need information for representative or symbolic reasons – perhaps the research is being conducted by a group that the subject would rather not associate with, for example. We will return to how much information we should provide research subjects with below. My point here is that the variety of information that the Declaration of Helsinki requires a research subject understand to give informed consent may well not be relevant to the subject, and these high requirements may well undermine people’s ability to make a choice which is valuable to them where there is no reason to do so.


for persons is geared solely towards the protection and promotion of autonomy and personal dignity.

I have argued at length that we are mistaken in bringing the therapeutic medical idea that autonomy (or freedom of choice) and beneficence are separate zones of moral concern into research ethics. Part of the reason for this, as argued in Chapter 3, is that the principle of beneficence in the Belmont Report does not provide adequate protection for the wellbeing of individual research subjects, something that Beauchamp himself admits. However, there is additional reason to repudiate the claim that respect for persons in the Belmont Report should not be read as including concern for individual wellbeing. It is difficult to make sense of some of the stipulations concerning protection under the principle of respect for persons unless it is read as involving concern for wellbeing.

The following passage in the Belmont Report, included under the principle of respect for persons, gives us an indication of what protection is thought to involve:

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks

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550 Beauchamp believes that we are better off clearly distinguishing between a principle of beneficence and a principle of nonmaleficence; see T. Beauchamp and J. Childress, Principles of Biomedical Ethics (7th ed.), Oxford University, Oxford, 2013. This is certainly a good move in ensuring that concerns for the protection of the wellbeing of the research subject are conceptually separated from benefit to the majority in research ethics. However, we are still not given much of an indication of how these principles are to be balanced against each other. My approach allows us to see that the autonomy (freedom of choice) and beneficent concern of the research subject do not clash as much as generally believed in this domain, and, through incorporating concerns for wellbeing into the principle of respect for persons, allows us to devise a flexible standard that is more inclusive than authenticity-based autonomy and that can be geared more towards the specific needs of the individual research subject; a stated goal of his theory of autonomy in A History and Theory of Informed Consent. It is only upon recognizing that autonomy and beneficence are not easily separable into two different zones of moral concern in research that we can achieve the benefits that I have described in this chapter.
autonomy should be periodically reevaluated and will vary in different situations.\textsuperscript{551}

The explicit claim that protection will involve protection from harm is difficult to read as a concern with protection of autonomy and personal dignity, divorced from considerations of wellbeing. The suggestion that the extent of protection should depend on risk of harm is something that is not achieved by the informed consent guidelines in the Belmont Report (intended to ensure that the value of respect for persons is upheld); as we have seen in Chapter 4, they present uniform guidelines which bear close resemblance to Faden and Beauchamp’s criteria for autonomy, which have no provisions for relaxing or increasing stringency in relation to risk of harm. My theory, in explicitly acknowledging that we may be justified in restricting the decisions of research subjects out of concern for wellbeing, provides a means of formulating informed consent guidelines that can achieve this goal, allowing us to see the factors that justify relaxing standards of informed consent in order to take the valuable choices of the research subject into account to a greater degree.

A particularly interesting feature of this passage is the claim that some persons “require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence.”\textsuperscript{552} This could be read in two ways. It could be intended to mean that autonomous individuals, in virtue of their capacity for autonomy, will act to protect themselves from the risks involved in research. As we have seen with reference to anorexic research subjects, this assumption is sometimes mistaken. Although my theory relies on the fact that people will generally have an interest in protecting their wellbeing, and they will generally use information about the possible consequences of their actions to pursue this goal, this is not always the case. Anorexic research subjects could well qualify as autonomous according to the authenticity-based notions of autonomy surveyed in Chapter 4, and according to Faden and Beauchamp’s criteria for autonomous action. There is nothing in the way that autonomy is

\textsuperscript{551} The National Commission, \textit{The Belmont Report}, Part B: Basic Ethical Principles.

\textsuperscript{552} The National Commission, \textit{The Belmont Report}, Part B: Basic Ethical Principles.
defined in the Belmont Report to preclude autonomous subjects from acting in a self-destructive manner. If the Belmont Report allows for this, this presents a dangerous gap concerning the provisions that are made for the protection of the research subject.553

The other way that this statement could be read is as suggesting that honouring autonomous actions is sufficiently important as to override considerations of wellbeing; that autonomous research subjects should be free to act in a risky manner, and that paternalistic interference with autonomous action would be worse than allowing this free exercise of autonomy. I will return to this possibility in the subsequent section of this chapter, where I will deal with concerns of authenticity-based autonomy.

**High-Risk Decisions and Authenticity-Based Autonomy**

In the previous section, I have argued that a significant benefit of my choice-based approach to informed consent is its ability to provide us with a standard that can better accommodate low-risk decisions in research. I have also suggested that individual wellbeing and the ability to make valuable choices are more intertwined in research than we might think. However, my approach hinges on limiting the research subject’s ability to make decisions in research based on an insufficient concern for his own wellbeing. As the potential risk of research climbs, a potential problem for my theory becomes more apparent. How can we ensure that a subject is free to make decisions, especially those that may entail higher risk, while simultaneously ensuring that his wellbeing is adequately protected? How do we ensure that we do not overstep the mark when it comes to restricting decisions, thus interfering with respect for persons in research, while also ensuring that we have sufficient protections in place for individual wellbeing?

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553 This is not to say that we should necessarily argue that an autonomous research subject cannot consent to research due to self-destructive tendencies (I will argue in my final section on authenticity-based autonomy that there are in fact grounds for excluding subjects for research on these grounds, even when their decision is autonomous in the strong, authenticity-based sense), but the precise aim here should be clarified, in order to mitigate the risk that a tacit assumption that autonomous subjects will protect their wellbeing lead to the inadvertent harm of a subject.
In incorporating a condition that people value their wellbeing as an initial restriction on the ability to consent, we must be careful to avoid putting forward a standard that collapses into paternalism. We need to make sure that we do not construe this requirement too strongly – we need to allow for the idea that an agent can choose something that is not in her best interests.\footnote{I will address how this is to be understood in this section.} In this section, I will defend the idea that incorporating protection of wellbeing into informed consent guidelines need not collapse into paternalism. I will contend that the restrictions that I have outlined on honouring the choices that research subjects have reason to value can be justified on the same grounds that lead us to link freedom of choice to the value of respect for persons in the first place. I will argue that we can use a Lockean account of authenticity-based autonomy to guide us in establishing the limits of warranted restriction of the actions of research subjects, especially as the risk involved in research grows.

\textit{Respect and Restriction of Choices}

Darwall’s discussion of the symbolic value of choice, and its links to a Kantian notion of respect for persons, highlights why paternalism is typically seen as the antithesis to respect for persons, as we have seen earlier in the chapter. Interference with a person’s self-regarding actions, even when it is motivated by concern for their wellbeing (even construed subjectively, as helping them to achieve their own preferences),\footnote{I discuss the differences between subjective and objective wellbeing in White, “Understanding the Relationship Between Autonomy and Informed Consent: A Response to Taylor”.} involves a failure to recognise the intrinsic value of a person’s will, and their authority to make their own self-regarding decisions. However, Darwall suggests that these very same respect-based grounds can justify ignoring or overriding certain types of decisions. Certain types of decisions, he contends, undermine the Kantian notion of dignity, by failing to show oneself an appropriate amount of respect. Darwall suggests that being too deferential to others can constitute a failure to respect oneself. If an agent’s actions show a lack of respect for herself, we could be justified in refusing, for respect-based reasons, to endorse or support these actions.
Darwall claims that we can fail to respect ourselves in these ways no less than we can others. Giving little weight to one’s own wishes and values, by being inappropriately deferential to those of others, can be no less a failure to respect oneself.  

Where individuals do not give sufficient weight to their own interests, where they act, in other words, in a deferential or subservient manner, they are not treating themselves with the dignity that respecting the ability of agents to make their own decisions is an attempt to display. Thomas E. Hill Jr. explores this problem in his paper “Servility and Self-Respect”. He suggests that the failure to respect oneself here is not about acting against one’s best interests, but rather, is acting as though “one’s rights were non-existent or insignificant”. Such conduct, Hill argues, violates the Kantian maxim that everyone, in virtue of being a person, is imbued with equal dignity.

The types of actions that, according to Darwall and Hill, undermine a Kantian notion of dignity, are the same types of actions that I advocated we override in order to allow informed consent to function as a means of protecting wellbeing. The anorexic research subject that I invoked to illustrate this point displays the same behaviour; as Eth and colleagues argue, “A prominent personality feature of the anorectic woman is submissiveness…The manifest need to be cooperative, even obedient, propels anorectics into perpetual self-sacrifice.” Ensuring that a research subject adequately values her own interests, in addition to allowing informed consent to function as a good means to protecting wellbeing, can also be justified (or even demanded) on respect-based grounds.

558 We can see the reason for this when we reflect on Kant’s motivations for constructing a theory of autonomy in Chapter 4; his goal, as outlined there, is to argue that our God-given human dignity necessitates constructing one’s own moral law, rather than living in obedience to the church.
559 Eth, Eth and Edgar, “Can a Research Subject be too Eager to Consent?”, p.20.
As I have argued, however, these types of actions can qualify as autonomous in the authenticity-based sense, and could also meet the informed consent criteria proposed by Faden and Beauchamp, the Declaration of Helsinki, and the Belmont Report. Paul Benson explores the problems that such cases pose to autonomy – and outlines a solution to this problem. Benson is concerned with feminist claims that “oppressive modes of gender socialization can impair...autonomy”. He considers a subservient housewife who puts the interests of her family ahead of her own in all circumstances. Though she has the appropriately structured personality from which her desires flow in appropriate ways (as we have seen in Chapter 4), and though she has the ability to reflect on the content of her desires, and reject those that do not have the appropriate relation to herself, her entire personality and thus the means by which she accepts and rejects desires is influenced by her deeply ingrained and internalised subservient attitude.

Benson contends that it would be misguided to, as some suggest, avoid this problem by placing strong restrictions on the content of the desires that qualify as autonomous. This, he argues, is too restrictive, leaving autonomy unable to achieve many of the valuable functions that it can when the content is not restricted. Rather than directly excluding some desires, based on their content, from qualifying as autonomous, Benson argues that we can take a middle ground. We can incorporate, he suggests, some normative content into a theory of autonomy without directly constraining the content of the desires which qualify as autonomous. The key to this, he contends, is to incorporate the “weakly” substantive condition that that autonomous agents have a sense of their own competence and worth as decisionmaking agents. This approach could be thought to receive support from Hill’s

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561 Benson, “Feminist Intuitions and the Normative Substance of Autonomy”, p.136

562 Again, I do not want to categorically rule out the possibility that an agent could hold submissive or self-sacrificing values and have an appropriate sense of their own competence and worth. At the general policy level upon which my theory is meant to operate, however, there is a strong argument for excluding all those who wish to
following characterization of the problem: “To be servile is not simply to hold empirical beliefs but to have a certain attitude concerning one’s rightful place in the moral community.”\textsuperscript{563} In order to exercise autonomy, one must have the appropriate attitude about oneself.\textsuperscript{564} These theorists begin to give us an indication of the kinds of restrictions we might place on freedom of choice that are compatible with the value of respect for persons. An agent cannot be criticised based upon the contention that there is something wrong with her desires in themselves; but she can be excluded from acting in a certain manner on the grounds that she does not have sufficient regard for herself, a condition of acting in a manner which is congruent with a notion of herself as worthy of respect.\textsuperscript{565} \textsuperscript{566}

\textit{Strongly Substantive Autonomy}

It is worth saying a bit more about why I have utilised a weakly substantive theory of autonomy, rather than relying on a strongly substantive theory. As I have noted above, strong substantive theories of autonomy place direct restrictions upon the \textit{content} of the decisions that can count as autonomous. Natalie Stoljar, for example, holds that decisions that result from oppressive modes of gender socialization are not nonautonomous because there is something wrong with the reasoning process, but rather because the norms that form the basis of the decision-making are \textit{false}.\textsuperscript{567} How might we be determine whether values and norms are false? Susan Wolf, in her account of freedom and moral responsibility,\textsuperscript{568} suggests that the best way we have participate in research based on these values. This could be seen as akin to the argument that we are justified in banning prostitution although it is possible to work as a prostitute autonomously, because many people lack autonomy in these situations and it is impossible to adequately distinguish between the autonomous and the non-autonomous (thanks to Steven Weimer for this suggestion).\textsuperscript{563} Hill, “Servility and Self-Respect”, p.90.

\textsuperscript{564} The anorexic research subject, examined earlier in the chapter, constitutes a case of a person who fails to qualify as autonomous on these grounds.

\textsuperscript{565} This resembles Rousseau and Mill’s arguments prohibiting persons from selling themselves into slavery; see Mill, \textit{On Liberty} and J. Rousseau, \textit{The Social Contract and other political writings}, Cambridge University Press, New York, 1997.


\textsuperscript{568} Part of the reason that Wolf endorses such strong requirements comes from her concern with providing an account of the necessary conditions for moral responsibility, which need not be coextensive with autonomy (see Arpaly, “Responsibility, Applied Ethics,
of discerning true from false beliefs, or, as she puts it, “the minimally sufficient ability to recognize and appreciate the world for what it is” is through “widespread intersubjective agreement”.

To include a condition of intersubjective agreement or acceptability in my theory would certainly make it easier for me to consolidate wellbeing and concerns about autonomy, choice and respect for persons into a single standard. However, I feel that such a condition cannot operate as part of my theory. It is important that the decisions of agents are insulated against intersubjective judgments concerning the content of their actions. My theory is aimed towards ensuring that the interests of research subjects are adequately represented. To place intersubjective restrictions on the types of decisions that can be honoured in a research context is to belie the fact that agents have insight into their own preferences and values that allow them to see how their own interests may be best pursued. Establishing that a research subject has sufficient motivation to protect and pursue her own interests, and sufficient information to see how her interests might be pursued can both allow us to affirm that a research subject is in a good position to act upon her interests and allows for a diversity of conceptions about what one’s own interests are. To place a further restriction on the content of one’s self-regarding conduct is to lose the benefits of this approach. When we impose an outside conception of what is in one’s own best interests, our standard risks collapse into paternalism, and we are no longer able to protect valuable choice and wellbeing with a single standard. The approach I have advocated, on the other hand, can both ensure that the


571 Which, as Wolf suggests, seems to be the only way we can regard certain norms or values as false.
research subject’s interests are protected, and can minimise conflict between concerns for wellbeing and allowing maximum scope to promote and protect the choices that the research subject has reason to value.\textsuperscript{572}

\textit{Avoiding Paternalism through Authenticity-Based Autonomy}

Despite my contentions above, a risk remains that my standard for informed consent could collapse into paternalism. In order to ensure that subjects are in a position to adequately protect their own wellbeing, as I have argued throughout this chapter, we need to ensure two things. Firstly, that they have the motivation to protect their own interests, including (and especially, for our purposes) wellbeing. Secondly, that they have sufficient information to protect their interests, including wellbeing. These two factors must be evaluated by a third party, however, and as the risk of the decision grows, there is an increased risk that the subject will not be judged as adequately valuing her wellbeing unless her proposed course of action corresponds with the evaluator’s notion of what is in her best interests. An evaluator might feel that if a subject wishes to undertake a risky or dangerous course of action, she \textit{must} not be adequately valuing her wellbeing, or that she must not have a sufficient understanding of the risks involved in the situation. Making the decision in itself could regarded as indicating a problem, which introduces a tacit, unwanted intersubjective element into my standards for informed consent.\textsuperscript{573}

We need to be particularly careful about these types of cases. If we were to maintain that an agent is only adequately valuing her wellbeing when she prioritises it, particularly according to an outside perspective, this would make the resulting standard unacceptably paternalistic; the agent would effectively be restricted to courses of action that others judge to be in her best interests. In order to avoid paternalism and thus allow this theory to

\textsuperscript{572} I’d like to thank Jeremy Shearmur for many conversations on this topic which have allowed me to clarify my views.

\textsuperscript{573} This already happens with standards of autonomy; when people make a decision that others do not agree with, there is a tendency to assume that there must be a problem with autonomy (or the decision would not have been made). For discussion and examples of this phenomenon, see my forthcoming paper “How Autonomy can Legitimate Beneficial Coercion” in \textit{Beneficial Coercion in Psychiatry? Foundations, Areas of Conflict, Prevention}, Mentis, Münster.
protect and promote the choices that people have reason to value in a meaningful sense, agents must be able to make choices that do not correspond to these strictures. Though Benson’s distinction has given us a means of distinguishing between a problematic general attitude towards oneself, and the content of a particular desire, this risk, particularly in a research context, where a judgment is likely to be made based primarily on this one decision rather than the subject’s behaviour over time, remains. I suggest that in these cases, the special value of authenticity-based autonomy can be brought into the equation to mitigate the possibility of such actions being precluded.

Where decisions are of high risk, and there is suspicion that the patient is exhibiting an inadequate concern for her wellbeing, we can use a theory of authenticity-based autonomy to provide support for the idea that another’s judgment of what constitutes adequate regard for one’s interests is inappropriate. Where it can be demonstrated that a decision is reflective of an agent’s deeply held, enduring values, and is thus an autonomous decision, in the theoretical sense discussed in the previous chapter, this can be used to provide additional assurance that judgments concerning an agent’s wellbeing are not used to preclude an agent from pursuing a course of action that has high value to her, when she does indeed value her wellbeing. Through invoking values that have played an enduring and central part of her life, the agent can claim that she is in a better position to judge what is important than another could be. High risk decisions are likely to have a profound impact on the agent’s future self. Through showing that the values that lead her to reject another’s judgment about what is in her best interests are central to her life over time, the agent shows that a generic judgment of wellbeing may not be applicable, as the pursuing a proposed course of action might be central to the agent’s own sense of self and sources of pleasure and happiness. We can invoke the ties between her present and future self, constituted by her deeply held, enduring values, to assert the agent’s authority over the decisions made on behalf of her future self, putting her in a privileged position when it comes to making these decisions.
This assertion of authority over decisions that will have significant effects on one’s distant future self is supported by a Lockean theory of personal identity. As we have explored at length in the previous chapter, the core of a (broadly) Lockean account of personal identity lies in establishing the sameness of identity of the self over time. As we have seen in the work of Bratman and Ekstrom, this is often translated into contemporary theories of autonomy through an emphasis on the enduring desires of – in our context – the research subject. There are two advantages of taking a similar approach here, to bolster the ability of a research subject to make high-risk decisions without undue outside interference. Firstly, an account of the self that emphasises continuity can be used in order to give the agent authority to make these decisions, and stresses the authority of the agent to make these decisions over the authority of others. The links establishing the sameness of identity over time give us a means of suggesting that the subject is intimately tied to her future self, and will thus have privileged insight over what will best benefit her future self. It suggests that the agent has a special relationship to her future self, which others cannot claim. In invoking desires which have endured over time, the agent can claim that these desires are more likely to persist into the future, and remain central to the pursuit and satisfaction of her interests, than an external judgment of what will best further the interests of the research subject.

Secondly, this gives us something concrete that the research subject can refer to, in articulating why a proposed decision does in fact reflect a sufficient attitude of self-respect and self-worth. In order to discern why an agent wishes to participate in an experiment, and whether they have adequately valued their wellbeing in making the judgment about whether to participate, the individual must be able to explain their reasons for wishing to participate. If they wish to take a risky course of action, they will need to explain the reasons for their proposed course of conduct. They can do this in reference to enduring values where sufficient concern for wellbeing is doubted. This resembles a contention of Benson’s; that agents’ sense of competence and worth as a decisionmaking agent can be displayed through
an ability to “present their reasons for acting and to speak with authority in support of their decisions, should others question them.”

A reference to enduring values can provide further reassurance that a subject is not acting in a manner that shows insufficient regard for wellbeing, but rather reflects a different, yet still valid, conception of one’s own interests from an outsider. Articulation of one’s reasons for a desire to participate in research can also ensure that a potential research subject understands the potential risks in a situation, and that desired participation in research is not contingent on false beliefs about outcomes. Requiring that we carefully discern reasons for participation in this kind of case, with reference to long term goals, can particularly provide a good means of picking up on instances of the therapeutic misconception. High risk cases, with low possibility of direct benefit – that is, cases in which the subject’s desire to participate may not be easily comprehensible to others – are also cases where there is a particular risk that the subject may be operating under the therapeutic misconception. A requirement that the subject articulate his reasons for participating in these cases will increase the chance of picking up on a mistaken belief that the research will help treat his condition, rather than aid in treatment of the condition in general. Questioning the research subject carefully about his goals and what motivates him to participate in this research study increases the possibility that we can dispel this misconception in these cases. Though this kind of careful interrogation may pose problems if applied to all research, it is certainly warranted in cases where the research is likely to pose high risk.

Some examples will illustrate what I have in mind, and the situations in which this appeal to authenticity based autonomy will prove useful. My examples are of cases in which an agent may legitimately make a decision that may not, to an outsider, seem to be in his best interests. However, because it is based on his own particular values and personality it represents

575 Of course, it is difficult to distinguish when an agent is making decisions which indicate an insufficient regard for her own interests – this is similar to the practical problem encountered by Faden and Beauchamp, concerning how best to distinguish when subjects are acting due to internal controlling tendencies arising from, for example, mental illness.
an outcome which he will prefer in the long term. Consider a case in which an athlete wishes to enrol in high risk research, which may allow him to avoid having his gangrenous foot amputated. If the experimental treatment is unsuccessful, there is a good chance that the gangrene will spread. The athlete could defend his decision to enrol in such a study, even when the risk of an optimal outcome is low or unknown, by claiming that the ability to continue competing as an athlete is central to imbuing his life with meaning. This agent may feel that this high risk is worth taking, because of the extreme effect that the loss of a foot will have on the course of his life, and his ability to achieve his long term goals. He may judge that a risk of losing a leg rather than a foot, or even risking death, is mitigated by the chance to continue in a pursuit which he has made central to his life, and is central to his life’s meaning. The agent’s desire to engage in such risk is not motivated by an insufficient regard for his wellbeing, in this case, but rather by the belief that this course of action provides the best means of pursuing what, for him, is a central means of securing his wellbeing and making his life worth living.

We can see a real example of this kind of action in recent research history, where Barry Marshall won the 2005 Nobel Prize in Physiology or Medicine based on his research on peptic stomach ulcers, part of which he had conducted by infecting himself. Rather from coming from a lack of concern for his own wellbeing, this decision seemed to come from the high importance Marshall placed on conducting this research. It is certainly more easily conceivable that researchers will be in the kind of position where this is regarded as not so morally problematic, due to their deep understanding of what is involved in the research project, a drastically reduced risk of coercion, and the clear importance that an ongoing research project is likely to have for them, both in terms of the possible benefits that could be accrued, and because of their scientific interest in the project itself. In addition, it is easier to sanction actions that harm oneself than to sanction

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actions that will potentially harm others. It is presumably for these reasons that the Nuremberg Code specifically stipulated that “No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.”

Nevertheless, it is possible that a subject who is not an experimenter may, due to deeply held values and motivations rather than lack of concern for their wellbeing, wish to pursue a dangerous course of action.

We can imagine similar cases in research in which the subject and experimenter are not one in the same. Take, for example, a middle aged father, who is suffering from a terminal cancer. He may wish to be involved in high risk research on this cancer, due to his deep concern for fighting the disease. In his case, perhaps, there is no hope for a cure, so there is no self-interested reason for his participation in the research. However, due to the profound impact it has had on his life, this subject is highly motivated to contribute in some way to a possible future cure. Perhaps this cancer has a genetic element, and he is motivated to join the effort for a cure out of the hope that his children will not have to undergo the same experience. This, I believe, represents a case in research in which the subject might legitimately prioritise another deeply held value above concern for his own wellbeing.

These examples help to illustrate the kinds of cases in which careful scrutiny of the motives of the subject is required, and where a Lockean-inspired theory of autonomy may help us to discern where the research subject simply does not have an adequate interest in protecting and promoting his own interests, and where he may have reasons that, although difficult to comprehend for an outsider, are still representative of an adequate concern for wellbeing. This provides a means of allowing us a standard that is sufficiently open to allow subjects to pursue their own interests in diverse ways, guarding the standard against a collapse into

patient, while still ensuring that the interests of the research subject are adequately represented.

Where decisions do not have this sort of significant and far-reaching impact, a model which places emphasis upon a “self” that is based upon psychological continuity over time is not necessary or even possible to utilise when evaluating whether a decision is worthy of respect, as I have argued in the previous chapter. Decisions that are not likely to have an enduring impact on the course of one’s life need not, and perhaps cannot, be evaluated in accordance with one’s long term goals. In many cases, one’s enduring desires may not point an agent to any particular momentary decision, and even in cases in which they might, we do not want to use this as a means of preventing an agent from acting out of character. To interrogate whether an agent’s desires display this sort of relation is to ignore the intrinsic value of the agent’s will, for no good reason. It is only when there are serious doubts that an agent is adequately valuing his interests that extra reassurance may become necessary. It is for this reason that autonomy, complete with a condition of authenticity, is useful in some contexts, while the standard outlined in the previous part of this chapter, lacking this emphasis on the self, is useful when assessing whether more everyday, less significant decisions are worthy of respect. A Lockean, authenticity-based theory of autonomy provides a useful tool in discerning the limits of intersubjective judgments of wellbeing in these situations, emphasising the centrality of deeply held enduring values to the self, and providing a means for allowing the agent to assert authority over the decisions which are likely to have a significant impact on the course of his life. This type of theory, in stressing the importance of such values and their deep connection to the self, allows the agent to pursue these values, insulated from intersubjective judgments concerning wellbeing.

**Choice-Based Informed Consent Guidelines**

I have advocated several changes to current approaches to informed consent, especially when the decision to participate in research is a low risk decision. Here, I will outline what obligations the researcher or research institution
should have to inform the subject, and I will also reiterate specifically what should be required from a research subject at different levels of risk.

I have already suggested, drawing from Scanlon, that our obligation to inform research subjects may be grounded in our obligation to put adequate measures in place to protect individuals from harm, when we expose individuals to harm for some social good. To briefly reiterate; I have suggested that research is a situation that fits into Scanlon’s general characterization of a case in which we believe a social benefit is of sufficient importance to expose some people to harm, and that this produces obligations to put measures in place to protect these people from this harm. I have deployed Scanlon’s argument that, most of the time, informing subjects about the harms in a given situation is sufficient to meet our obligations. I have argued that in research, there is good reason to think that providing subjects with information is a good means of allowing them to avoid harm. What must be assured, I suggest, is that subjects have both sufficient information (that they understand and appreciate the significance of) and sufficient motivation to avoid harm (but where, as I have explained, this is compatible with particular individuals wishing to participate nonetheless). Where we suspect that subjects do not have the motivation to avoid harm, or, in other words, to pursue their own interests and to treat them as of central importance, further protective measures are required; that is, subjects may be excluded from participation in research on these grounds.

I have argued that an additional benefit of informing research subjects is that it can enhance the instrumental value of decisions. There is an argument, however, to suggest that we have obligations to inform subjects on the grounds that it will enhance the instrumental value of their choices, independent of considerations of harm. This argument comes, again, from Kantian notions concerning human dignity. As we have seen in Chapter 4, Kant was concerned with devising a moral theory that could properly accommodate an appreciation of human dignity. As well as his work on autonomy, which we have discussed, Kant devised the second formulation
of his famous categorical imperative: “Act in such a way that you treat humanity, whether in your own person or in the person of another, always at the same time as an end and never simply as a means.”

This notion has been given a lot of philosophical attention, but at its most basic level, it suggests that it is inappropriate to make use of people in certain ways. It is in order to avoid this situation that some obligations to inform might be justified. In informing research subjects in a way that facilitates the achievement of their instrumental goals, we show respect and concern for their own ends, and therefore avoid using them purely as a means. As a minimal requirement, we should at least inform them insofar as to ensure that they do not have false beliefs about the instrumental efficacy of participation in research. If we allow research to proceed when they have false beliefs, we do not allow them to take on the ends of the experiment, and show a disregard for their own ends. In this way, we risk using them purely as a means, failing to show them adequate respect.

The representative and symbolic value of decisions may not incur such obligations to inform – as the value of these choices are not related to the consequences of making them. However, I have argued, an attitude of respect for persons requires that we recognize the value of these types of decisions – particularly symbolic decisions – and to give research subjects maximum scope to make these decisions. With these obligations in mind, we can turn to the question of what we should require from the research subject, and the researcher or research institution, in research of different levels of risk. I have argued that what we should expect from research subjects, and how we approach research, should always be tied to the risk of

594 Also note Kant’s acknowledgment of the possibility that one can violate the categorical imperative by treating oneself purely as a means; an idea that we have made use of in this chapter.
596 Though, as I have mentioned above, some information might be relevant to these types of decisions – subjects may not wish to be involved in research commissioned for the benefit of causes they find odious for representative or symbolic reasons, for example. We must, as I note below, make sure we are providing sufficient information to the subject to ensure that we are not making use of them – that they, in other words, can broadly share in the ends of the research, or that their ends are not being ignored.
the proposed research. Now we can look at research of different levels of risk, to see what may be required. Where a proposed research project presents no risk of harm, we should be concerned with informing subjects for respect-based reasons only. This should require gauging whether the research subject has any false beliefs about participation (including whether they are under the therapeutic misconception). In addition, we should make sure that the research subject understands, for representative/symbolic reasons, what the purpose of the research is (the intended use of the data collected). If it can be ascertained that the research subject does not hold any false beliefs about the instrumental value of participation in research, and has no problem with the aims of the proposed study, and thus does not risk being “used” in research in a disrespectful manner, then she should be allowed to proceed, even if she displays limited understanding of further aspects of the research. To restrict the research subject from participating would be to undermine the reasons we have to respect the symbolic and representative reasons that subjects have to value choice, and to do so for no good reason. In these cases, we need only to ascertain that we are not making unacceptable use of the research subject, in a way that violates the value of respect for persons. Where this is assured, respect for persons demands that we honour the choices of research subjects where there is no good reason to restrict them.

Where a decision does pose risk, we should additionally focus on ensuring that the research subject is motivated to protect her own interests and that she is adequately informed to avoid harm. If the research subject shows either an insufficient motivation to treat her own interests as important, or if she does not display an adequate understanding of the risks of the situation, then this should form grounds to exclude the subject for participation in the research. This is necessary to ensure that the interests of the subject, and particularly her wellbeing, are adequately protected. Where there is a suspicion that the research subject’s proposed course of conduct signifies that she is not meeting one of these two requirements, the research subject

597 There are of course limits to this: the general fallibility of our knowledge means that we can never know with certainty what possibilities might be opened up by research.
should be asked to defend her proposed course of conduct. An explanation that affirms that the research subject is not acting due to a self-sacrificing and deferential attitude, but rather has a strong interest in pursuing her own (perhaps unconventional) values should be taken as evidence that the research subject does indeed have a sufficient interest in protecting her own interests, though her conception of what these interests are may be different to what others may feel is appropriate (as explained above, self-sacrificing and submissive values are excluded from consideration on the grounds that they show a failure of the subject to accord herself sufficient respect and moral standing).

**Conclusion**

Based on the arguments in the previous chapters, I have suggested that we take a new, choice-based approach to informed consent guidelines. Based on the argument about beneficence and its role in research in Chapter 3, namely, that beneficence in research is not well placed to take on the role of the protection of the wellbeing of individuals, I have suggested that we might be better off relying on informed consent guidelines to protect wellbeing in research. From the arguments about the role of autonomy in respect for persons in the recent research ethics guidelines, I have suggested that we need to find a way of expressing respect for persons without relying only on respecting their autonomous decisions.

I have contended, instead, that respect for persons in research is better displayed by respecting the choices that they have reason to value. Drawing from Scanlon, I have catalogued three reasons that agents generally have for wishing to make decisions for themselves, and have suggested that honouring these types of decisions where possible forms a good means for showing respect for persons in research. I also argue that there are grounds for restricting decisions, based on a concern for the wellbeing of the research subject. I suggested that these restrictions were minimal, and that incorporating an explicit concern for wellbeing into informed consent guidelines allows us to reduce paternalism through relying on informed consent to non-paternalistically protect wellbeing in the majority of cases.
and by allowing us to devise a flexible standard which lets us see that we should respect decisions when there is no good (i.e. harm-related) reason not to do so.

I suggested that a potential problem for my theory arises in high-risk research situations, where there is an increased risk that a subject will be judged to either not be adequately valuing his own interests, or not be adequately understanding the risks of the situation, if he wishes to pursue a course of action that others do not judge to be in his best interests. I suggested that a Lockean, authenticity-based account of autonomy might be a useful tool in these cases to affirm the subject’s ability to make judgments about his long term interests, and to display that it is indeed his own interests that are central to the decision (though they might not correspond to another’s judgment about what his interests should be). Subjects should be restricted from participation in research on the grounds that they display a general attitude of treating their own preferences as having insufficient weight – this undermines their ability to protect their own interests, and shows a lack of respect for themselves. Preferences, however, should not be judged on their content.

My choice-based theory, in conclusion, puts forth a theoretical basis for informed consent guidelines in research, which aims to protect and promote the interests of the research subject to a sufficient extent, against the benefit that can be produced for society as a whole. It provides a means of avoiding the problems with beneficence and autonomy in research as it currently stands, by taking a new approach specifically geared towards research. In suggesting that we incorporate both (individually-focused) beneficence-based concerns and concern for protecting and promoting the choices that people have reason to value into informed consent guidelines, I put forward a theory which can protect and promote both values, often simultaneously and with minimal conflict. This theory allows us to iron out ambiguities in the Belmont Report, and provide a theoretical account for how we might better achieve the demands of both the Belmont Report, and of Faden and Beauchamp’s theory of autonomy and informed consent.
Appendix I: Application of the Theory

I have focused on research ethics documents as the basis of my analysis throughout this text, but what I have provided is not a new set of research ethics guidelines, but rather an ethical underpinning for these guidelines – emphasising the considerations that I feel to be of the highest importance in research ethics. One might still ask, at this point, what would research ethics guidelines based on my arguments above look like? How would they differ from what is currently on offer? In this section, I will sketch a way forward; a suggestion of how my arguments above could be applied to a set of research ethics guidelines. I will focus on just three areas in which my theory might have significant implications on how ethical principles are applied in research; the balancing of various concerns and principles, the principle of beneficence, and informed consent guidelines. I will take the Belmont Report here as a basic model – recommending changes to this document based on the considerations I have outlined throughout the thesis.

I certainly don’t mean to suggest here that this is the only way my theory could be applied. But I take the Belmont Report as a template because its influence on subsequent research guidelines will mean that this contains easily translatable suggestions for reform, but also because it contains several attractive features that are worth emphasising and retaining. My work thus far has focused on critiquing several features of the Belmont Report, but this should not be taken to mean that it does not contain features of worth. Specifically, the Belmont Report’s emphasis on general principles for conduct, which should be applied according to the discretion of an independent research ethics committee, represents a sensible approach to research ethics. This can be brought out further through a discussion of balancing principles.

Balancing Principles

I have mentioned throughout the thesis that I do not aim to stipulate exactly how values should be balanced against each other, especially in certain concrete cases. In this respect, I mean my theory to resemble the approach in the Belmont Report. The Report opens with the following considerations:
[R]ules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted...The principles in this document] are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.598

This quote encapsulates several features of the Belmont Report’s generalizable, pragmatic approach. Firstly, it does not aim to resolve or dissolve conflicts between principles. In almost any ethical situation, it will be impossible to resolve conflicts between ethical principles to the satisfaction of every reasonable person. I have emphasised, especially in Chapter 3, the importance of recognizing conflicts. Any attempt to dissolve irresolvable conflicts, I believe, does more harm than good. The best thing we can do is to recognise the points of conflict – this gives us the best chance of achieving an optimal or acceptable balance between competing values in any given situation.

Secondly, and on a related note, the Belmont Report does not purport to provide a definitive guide to how the various principles and considerations in the document might be balanced against each other. It does not, for example, list the principles as a list of priorities. No consideration is thought to have absolute overriding force. It is operating at a high level of generality, in order to provide general guidance that can be applied to a diverse range of research situations. It leaves space for principles to be interpreted, and aims only to guide rather that to suggest, for specific cases, the ideal balance between competing principles and considerations. I take these features to be a strength of the Belmont Report, and a necessary way of formulating general guidelines that should be thought to give suitable

guidance, and capture the distinctive morally relevant features in a wide array of circumstances.

Determining exactly how the general principles and considerations should be applied in the Belmont Report is left to independent research ethics committees. This approach is a good way to ensure that a diverse variety of cases receive careful and considered scrutiny, and that the special features in any given case can be taken into account and dealt with appropriately and in the spirit of the guidelines. This provides another justification for emphasising conflicts in research ethics guidelines – these conflicts should be seen as focus points for discussion and consideration during the review process. This also supports my focus on ensuring that the guidelines are not informed by contradictory or ambiguous reasoning; in a framework where these principles are applied according to the discretion of research ethics committees. There is a risk, where such guidelines contain contradictions or ambiguities, they will be applied in ways that were not intended by the authors.

This is not to say, however, that it is not important to provide guidance concerning general questions about how values should be balanced against each other. To take an example that I have criticised earlier, we do not want to say that it is appropriate to evaluate considerations of wellbeing in research through balancing the possible risks and benefits of this research. To use such a calculus is to risk having considerations for the wellbeing of the research subject overwhelmed by possible benefits to others. A primary aim of the considerations I have laid out above is to ensure that the interests of the research subjects are given appropriate weight in this calculus, and are not overwhelmed by the other benefits that research might bring. My suggestions for the approach to informed consent guidelines, therefore, should be seen as attempting to achieve a more appropriate

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599 This is one of the reasons why I prefer the general principle approach in the Belmont Report to the more specific edicts of the Declaration of Helsinki. As well as being more flexible, general principles that must be balanced against each other can emphasise certain values without making contradictory demands, as we see in the Declaration of Helsinki.
balance between the competing values in research than the Belmont Report, but these recommendations should be taken as concordant with these general recommendations from the Belmont Report; an attempt to provide guidance about general questions concerning balance, without attempting to dissolve conflicts or specify exactly how these considerations should be applied in any given circumstance.

I will now turn to a discussion of the changes my approach might be thought to imply for the Belmont Report, turning first to the principle of beneficence, before looking at the informed consent guidelines. Beforehand, however, one final preliminary remark is in order; I will again be omitting a discussion of justice, but this does not mean that justice is not a crucial consideration here and should not be taken into account when determining ethical conduct in human research; rather, as I have explained in Chapter 1, my approach does not have implications concerning revision of the principle of distributive justice.600

**Beneficence**

The main purpose of the principle of beneficence in the Belmont Report is to ensure that the possible risks and benefits resulting from a given study are assessed, with a focus on minimising harms and maximising benefits. This is an appropriate aim for a principle of beneficence. It should no longer purport to provide adequate protection for the wellbeing of the individual research subject through such efforts, as the measures put in place to give the wellbeing of the research subjects extra weight do not suffice to protect the wellbeing of research participants. This is not to say, however, that there are not appropriate measures that fall under this principle that may play an important role in protecting the wellbeing of the individual. A focus on designing research in a way that minimises risk, particularly unnecessary risk in order to achieve the aims of the research, properly falls under the considerations included in this domain, and also forms an essential (though by no means sufficient) means of protecting the research subject from

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600 See p.28.
unnecessary harm.\footnote{This is not to say that the goal of minimising possible risk should trump all other goals – there might be circumstances in which other goals (expediency, for example) might need to be taken into account here and balanced against this concern. Like all considerations in research, there should be a certain degree of flexibility and give and take. But this should certainly be a primary and essential goal in research design.} This evaluation should also be used to gauge the level of risk that the research involves, which should be used to evaluate what should be required in terms of consent (see below). It should also be ensured that the research has merit and thus warrants the possibility of putting people at risk of harm or inconvenience. This question must be answered before a calculation of risks and benefits can be undertaken.\footnote{For more on this, see National Health and Medical Research Council, National Statement on Ethical Conduct in Human Research, p.12} Questions of research design with a view towards harms and benefits form an appropriate domain of scrutiny when discussing concerns of beneficence in research ethics.

\textit{Informed Consent}

The vast majority of my arguments in the thesis have been focused around the notion of informed consent, and how to structure it in a way that shows respect by protecting and promoting the interests of research subjects including wellbeing, the choices that they have reason to value, and also, where relevant, respects their ability to act autonomously in an authenticity-based sense. This is where my theory has a substantial contribution to make. Here I will provide a sketch of what informed consent guidelines informed by my approach might look like.\footnote{Again, I repeat the caveat that while informed consent guidelines function as an essential and primary means for showing respect for persons in research, they should by no means be regarded as the only means of showing respect for persons in research.}

I have suggested that incorporating considerations of wellbeing into informed consent guidelines has two distinct advantages over the approach taken in the Belmont Report; firstly, it ensures that the wellbeing of research subjects is given adequate weight and protection, as opposed to the existing risk-benefit calculation (even with the additional caveats put in place to attempt to ensure that the wellbeing of the research subject is not completely overwhelmed). This is designed to shift the balance back to the wellbeing
of the research subject, and to put in place a means for its protection that cannot simply be ignored or overridden where the benefits are significant. Because informed consent is seen as of essential importance in research, a requirement that may only be relaxed in special cases and with careful justification, properly designed informed consent guidelines can be an ideal means to ensure that the interests of the individual are not overlooked or inadequately represented.

Secondly, I have suggested that we can tie what is required in terms of consent to the risk involved in the research, thus allowing us to require less from the subject in low-risk research, and increase the number of valuable choices that the subject can make. How should this function in terms of informed consent guidelines? Jim Drane gives us an indication of how this might work in his “sliding scale” of competency. He suggests three levels of informed consent that should be required depending on the risk involved in a proposed intervention. His suggestions are geared towards therapeutic interventions, but I will use the basic framework of his theory to discuss how we might tie informed consent requirements to research risk.

We should first determine, using the risks and benefits calculation as I have suggested above, the likely risks involved in any proposed research study. If the risk involved in the research is low, Drane suggests that only two basic criteria should be met; awareness, and assent.\footnote{Drane, “Competency to Give an Informed Consent”, p.926.} Much of what he says here cannot be applied well to the different circumstances involved in research, but we can take modified versions of these two criteria to gain an idea of what might be required here. Drane’s notion of assent here risks being too passive to function as an appropriate standard for research, even at this low level; the agency of the subject is essential here; they should demonstrate genuine interest in participating.\footnote{Manson and O’Neill’s notion of informed consent as a \textit{waiver} is useful here, particularly where the research does not have therapeutic benefit. The use of a subject for others is something that constitutes an ethical violation without a genuine consent that waives this generally applicable ethical requirement. What should be required for an assent should be sensitive to the notion that a norm needs to be waived to make the proposed conduct ethically acceptable. See Manson and O’Neill, \textit{Rethinking Informed Consent} } This is not to say that assent at this level
need be fully explicit or specific. Awareness (again departing from Drane’s use) should involve an awareness of what is being consented to. Information concerning the experiment should be communicated to the potential subject, with a particular focus on its relation to the expressed reasons that the subject has for participating, and it should be ascertained that the subject does not hold any false beliefs concerning the goals of the experiment in relation to her aims in participating. The main aim here is to honour the wish of the subject, and to ascertain that she can share, in some way, in the ends of the experiment, or that her ends in participating are being respected.

At the second level, in our terms, where research presents moderate risk, Drane suggests that the requisite standard should be the ability to “understand the risks and outcomes of the different options and then be able to choose a decision based on this understanding”.

At this moderate level of research risk, Faden and Beauchamp’s informed consent requirements, particularly the condition of understanding, provide a good account of what should be required. Understanding should be focused on an adequate understanding of the act descriptions that are important to the research subject. It is at this level that we should begin to pay particular attention to subjects who wish to participate in research due to their submissive or self-sacrificing values, and exclude them accordingly.

Drane suggests that the third, “most stringent and demanding standard of competency is reserved for those decisions that are very dangerous and fly in the face of both professional and public rationality.” He suggests that what is required at this level is appreciation – the patient must go beyond simply understanding the relevant details of the situation; he must “appreciate the implications of this decision for his life”. He must also demonstrate that he has thought about this decision rationally, by giving

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606 See Manson and O’Neill, Rethinking Informed Consent in Bioethics, p.91
607 Drane, “Competency to Give an Informed Consent”, p.926.
609 Drane, “Competency to Give an Informed Consent”, p.927.
610 Drane, “Competency to Give an Informed Consent”, p.927.
reasons for his decision. Drane notes that this level may be criticised for shifting too much power back to the physicians evaluating the decision, but claims that this is justified due to concerns for the patient’s welfare. This potential paternalistic element is undesirable in the original, therapeutic context in which Drane is writing, and the situation is more complicated in research, by the fact that no third party has a sole interest in the wellbeing of the individual research subject. To avoid an over-reliance on the judgments of third parties, we can supplement this level with a Lockean model of authenticity-based autonomy. A potential research subject must still demonstrate an appreciation of the implications of a decision, and provide reasons for undergoing this procedure, in my model. But he can point to an independent framework here to demonstrate that these requirements are being met, even if his decision is not in accordance with what the evaluator expects from someone acting rationally and with an appreciation of the situation.

Conclusion
The suggestions outlined here are not intended to be conclusive, rather, I just mean to sketch the kinds of implications that my theory might have for the practice of research ethics. Drane notes that his proposal for a sliding scale of competence is not meant to be definitive; that more empirical research, and consultation with doctors and ethics committees would be necessary steps in developing an adequate theory. I close with the same caveat; that the suggestions contained above are intended simply as a “contribution to the discussion”. 611 I hope, however, that outlining the applications of my theory in an applied context clarifies the theory in the main text. This sketch of how my theory might be translated into informed consent guidelines is intended to demonstrate how the various elements of wellbeing and freedom of choice can hang together in a single theory of informed consent. I have attempted to illustrate the benefits of using concern for wellbeing to create a more context-sensitive account of informed consent; going beyond Faden and Beauchamp’s requirements (and

611 Drane, “Competency to Give an Informed Consent”, p.927.
the requirements in the Belmont Report) both by honouring more decisions on the low end of risk, and by insulating decisions against the ever-present risk of paternalism (or third-party judgments) on the high end of risk. In providing this sketch, I hope the potential contributions that this theory may make to research in the real world might begin to be demonstrated.
Appendix II: Social Science Research

I have suggested that the problems concerning autonomy and beneficence in current approaches to research ethics can be avoided by a new approach to informed consent, based on promoting and protecting the choices that people have reason to value, and concern for the individual wellbeing of the research subject. However, there are significant problems, particularly in social science research, concerning deception and covert observation, which are not addressed through a focus on informed consent guidelines. To do justice to these problems, and issues that are specific to or prevalent in social science research, would require in-depth and specialized treatment, far beyond the scope of what I can do here. What I would like to suggest, however, is that my proposed approach may have some promise in identifying what is ethically at issue with these sorts of practices in social science research. Current, autonomy-based approaches, I contend, struggle with identifying precisely what is ethically questionable about these practices. Though this does not answer the question of the extent to which the social goals of social science research can justify these sorts of prima facie ethical violations, it allows us to identify what is ethically problematic about deceiving research subjects, or observing them without their knowledge. Discussion of these issues in social science research often focuses on the value of privacy. Violations of privacy are often thought to be ethically suspect because they compromise one’s autonomy. I will explore the problems with this approach, before suggesting that my approach has more promise in highlighting the problems with these practices in social science research.

In his exploration of the ethical issues involved in social science research, Herbert Kelman uses the following definition of privacy: “the freedom of the individual to pick and choose for himself the time and circumstances under which, and most importantly, the extent to which, his attitudes, beliefs, behaviour and opinions are to be shared with or withheld from others.”612 Both covert observation and deception in research violate

privacy in this sense. Deception about the purpose of an experiment, for example, violates the research subject’s ability to control the circumstances under which he reveals certain information. We can see the Milgram experiment, discussed in Chapter 2, as an example of this; subjects were not aware that the purpose of the experiment was to gather information about the extent to which people will obey authority. Because of this, subjects were not in control of the circumstances under which their behaviour was shared with the experimenters. Covert observation clearly and straightforwardly violates this definition of privacy. By observing individuals under false pretences, the researcher is able to gather information about individuals that would not be revealed to them if they were overt about their purposes. Looking at these problems through the lens of privacy allows us to connect these problems to a vast philosophical literature on this concept. Privacy has been a focus of philosophical discussion in part because it can be difficult to define exactly why privacy is ethically valuable, or why privacy might constitute a right which people should be granted.

Drawing a contrast to autonomy is a good way to bring out this problem. Respect for autonomy, as we have seen in Chapter 4, is seen as an ethical imperative due to its close ties to respect for persons. Because autonomous actions form an expression of the self, respecting autonomy provides a clear means through which we may accord respect to persons. In contrast, it is not immediately apparent that respecting someone must involve respecting their privacy. A theoretical basis must be given to show why violations of privacy undermine respect. The most common means of providing this theoretical basis involves positing that privacy is a necessary condition of autonomy. Failing to respect privacy, this line of argument suggests, risks undermining autonomy, and thus undermines the value of respect for

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613 This is not to say that one must approach these issues by way of privacy, see e.g. M. Bulmer (ed.), *Social Research Ethics: An Examination of the Merits of Covert Participation Observation*, Macmillan, London, 1982.


615 I will not, here, address how this concern relates to the literature in a systematic way, I aim more to indicate a possible response to a problem that has arisen.
One philosopher to advance such an argument is Joseph Kupfer, in his paper “Privacy, Autonomy and Self-Concept”. Kupfer takes a similar definition of privacy to that outlined above as the basis of his argument, contending that privacy can be understood as including “some control over some information about us and who can experience us.”

Kupfer argues that the imperative to respect privacy comes from the fact that it is a necessary condition of autonomy. He argues that people must be given a certain amount of privacy to develop what he refers to as an “autonomous self-concept”, and that this in turn is a necessary for the ability to act autonomously. Kupfer argues that an agent’s ability to act in a self-determining or autonomous manner is contingent on, among other things, her conceiving of herself as empowered to determine the course of her own life according to her own values. If an agent does not see herself as in control of her own life, she will lack the ability to act autonomously. In order to develop this concept of the self as autonomous, however, others must “affirm the social boundaries of this self.”

This requires the agent having control over both her movements and information about herself. It also requires that the agent have some control over who can experience her and when.

Though Kupfer mounts a compelling case for linking the value of privacy to the value of autonomy, it is important to understand the limits of this approach. As Kupfer himself admits, this defence of the value of privacy does not actually require that one’s privacy is respected. Rather, the formation of an autonomous self-concept only requires that the agent believe her privacy is being respected. As long as the agent is not aware that her privacy is being violated, her ability to form an autonomous self-concept

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616 Pinkard, “Invasions of Privacy in Social Science Research”, p.264
618 Though what he suggests is required is more limited than what is suggested by Kelman, as we shall see.
619 Kupfer, “Privacy, Autonomy and Self-Concept”, p.82.
620 Kupfer, “Privacy, Autonomy and Self-Concept”, p.82.
and thus act autonomously is not compromised. Kupfer defends his conclusions by noting that in a practical sense it would be difficult to keep widespread violations of privacy secret, but does note that his account of the value of privacy does not provide a basis for the value of privacy *per se*.\textsuperscript{621} James Taylor notes that this is a common problem for autonomy-based defences of the value of privacy. This strategy, he contends, shows that there is a problem with overt violations of privacy, but says nothing against covert violations of privacy.\textsuperscript{622} It seems that covert violations of privacy will not compromise autonomy, and thus are not captured by an appeal to autonomy as a foundation for the value of privacy. It may be useful to look for a non-autonomy-based justification for the value of privacy if we wish to affirm that even covert violations of privacy pose an ethical problem. This will include covert observation of research subjects, as well as deception, if subjects are not told about it afterwards. A bizarre consequence of this view is that it may indicate that it is better not to tell subjects that they have been deceived in research after the fact (which is currently regarded as a means to ameliorating some of the harm done when deception is utilised in psychological research). Because informing the subject could do damage to his self-concept, but deceiving, in itself, does no harm, it may be better to withhold this information from the subject under this view.

My theory provides a different means of approaching the problems with deceiving and covertly informing subjects, and the problems that arise from sidestepping informed consent requirements. With reference to the cases in Chapter 2, we can see what my approach identifies as ethically problematic, and why this constitutes a more promising approach. I’ve argued that a primary reason for the importance of informed consent in research is that allowing subjects to make their own informed decisions is a means to allowing subjects to pursue their goals, particularly the avoidance of harm. In cases in which there is a risk of harm, I have argued, informing, and obtaining informed consent, is particularly important.

\begin{footnotesize}
\textsuperscript{621} Kupfer, “Privacy, Autonomy and Self-Concept”, p.87.
\textsuperscript{622} J. Taylor, \textit{Practical Autonomy and Bioethics}, Routledge, New York, 2009, p.120.
\end{footnotesize}
We can see this concern echoed in both the Milgram experiment and the Tearoom Trade experiment – critics raised issues about lack of consent due to contentions that subjects were not given an opportunity to protect themselves against risk of harm.\textsuperscript{623} Both the Milgram and Tearoom Trade cases involved (respectively) deception and covert observation that put the subjects at risk of harm. These experiments led to critics suggesting that subjects should not be put at risk of harm in social research unless informed consent procedures have been utilised.\textsuperscript{624} This sentiment is echoed by Kelman when he argues that “Risks of injury – and ethical concerns about such risks – are generally increased when the norm of informed consent is in any way violated or sidestepped, since research participants are then deprived of the full opportunity to protect their own interests.”\textsuperscript{625} Kelman’s contention makes explicit what Baumrind and Glazer assumed in their response to the Milgram experiment, as seen in Chapter 2; that informed consent functions as a safeguard for the wellbeing of individual research participants. However, as we have seen, this is not an aspect of informed consent that is explicitly recognised in the Belmont Report. Recent documents have moved away from this assumption, viewing informed consent as a means to recognising autonomy. Through positing that informed consent has a role to play in protecting wellbeing, my theory can make sense of these claims, and acknowledge the fact that as the risk of harm in a given situation appears and increases, it becomes increasingly problematic to sidestep informed consent requirements. Where a link between informed consent and wellbeing is not recognised, as I have argued in Chapter 5, it makes no sense to claim that informed consent becomes more important as the risk of harm to research subjects increases.

However, we want an account of what is ethically at issue here to go beyond concern with outcome; a chief problem with autonomy-based accounts is that they can’t account for cases in which one’s actions are not altered,

\textsuperscript{623} See pp.70-73; pp.76-79.
\textsuperscript{624} Baumrind, “Some Thoughts on the Ethics of Research”, p.423; Glazer, “Impersonal Sex”, p.221.
\textsuperscript{625} Kelman, “Ethical Issues in Different Social Science Methods”, p.50.
disrupted or interfered with.\textsuperscript{626} This is particularly true for cases concerning covert observation. If a given deception or instance of covert observation doesn’t interfere with your ability to conduct your life according to your plans, it does not compromise autonomy. We can think of autonomy in this sense as one special type of goal that an agent may have – the goal of living her life according to her own values. Conceived of in this way, it becomes apparent that the autonomy-based value of making choices is ultimately instrumental – choices are valuable insofar as they provide a means of allowing the agent to achieve this goal. This makes it clear that when covert observation and deception do not compromise the agent’s ability to act in a way that will allow her to achieve this goal, these practices cannot be criticised on autonomy-based grounds. Similarly, if an experiment does not pose any risk of harm, it cannot be criticised on the wellbeing-based ground I have outlined above.

It is difficult to pinpoint how those deceived or covertly observed are wronged, when this deception or covert observation does not affect them. While some violations of privacy might have detrimental effects on one’s wellbeing, on one’s autonomy, or might somehow affect some other choice one makes in an ethically problematic manner, it is not necessarily the case that these effects will follow (especially, as discussed above, if the agent is not aware that her privacy is being violated). Similarly, though deception might have some sort of material effect on wellbeing or might cause the subject to act differently than she otherwise would, or to reveal information that she would not otherwise reveal, it is not the case that deception will necessarily have any effect on the agent’s decisions and actions. If we wish to produce an account that highlights something ethically problematic about covert observation and deception \textit{per se}, this cannot be contingent on its instrumental effects.

My account can explain not only why informed consent is particularly important in cases in which wellbeing is compromised, but can also

\textsuperscript{626} This includes disruption or interference with one’s self-concept, which is a necessary condition of having the ability to act in certain ways (that is, autonomously).
highlight the ethical problems with cases in which deception or covert observation does not have any negative effects for the agent, or compromise or affect their conduct in any way. This is due to a recognition of the non-instrumental value of choice, particularly its symbolic value. My theory of how we should show respect for persons in research, in moving away from a focus on autonomy as the basis of respect for persons, gives us an alternative means of linking the value of privacy\textsuperscript{627} to the value of respect for persons. I have argued that respect for persons needs to involve taking not just the autonomous choices of the agent, but all of the choices that she has reason to value, into account. Though some of these types of choice are valuable because of their instrumental effects, there are certain choices that are not valuable because of their consequences, but because allowing people to make these types of decisions allows them to express something about themselves, or shows that society respects their ability to make certain decisions for themselves. The latter type of choice, as we have seen in Chapter 5, is referred to by Scanlon as a symbolic choice,\textsuperscript{628} and it is this type of choice that holds the key to pinpointing what is ethically problematic about deception and covert observation in research.

As we have seen, Scanlon maintains that symbolic choices are valuable because being granted the ability to make this choice shows that the chooser has a certain standing in society. The value of the choice stems from what making this choice says about the agent. The value of these choices are thus related to showing respect for persons; by allowing people to make symbolically valuable choices, we are affirming that they are a person that deserves respect. By covertly observing someone, or deceiving them in research, we deprive them of the choice about whether to participate in this research, or to participate the in research under circumstances that they accept. This choice may not have any instrumental effects on their conduct, but it undermines the fact that they, as persons, have the ability to make this choice. This represents a symbolic denial of personhood, and thus shows a lack of respect for persons. This approach better accounts for the sense of

\textsuperscript{627} In Kelman’s specialized sense.
\textsuperscript{628} Scanlon, \textit{What We Owe to Each Other}, p.253.
outrage that people typically feel on deceived or observed without their permission; rather than stemming from a concern that this has violated their autonomy, this feeling stems from a denial of personhood through a denial of the ability to make a choice with symbolic value.

On a related note, Kelman states in his paper highlighting the ethically problematic nature of widespread deception in social psychology: “Serious ethical issues are raised by deception per se and the kinds of use of human beings that it implies.” Kelman maintains that using human beings in such a way is a “violation of the respect to which all fellow humans are entitled”. The idea about the use of human beings links back to a point that I made at the end of Chapter 5, concerning the argument that obligations to inform a research subject can be grounded in Kant’s categorical imperative. When a researcher seeks someone’s consent to be involved in an experiment, the subject is given the chance to take on the ends of the experiment, or to become involved in the experiment for ends of his own. Therefore, the fact that the subjects are ends in themselves is recognised and respected, and they are not treated just as a means. When a subject is covertly observed for research purposes, or deceived about the purpose or certain aspects of the experiment, they are being used purely as a means to achieving the goals of the experiment. By failing to give subjects a choice about whether to enter into research, or by deceiving them in research, we are undermining their dignity as persons, and failing to show them the appropriate respect that they deserve in virtue of being persons.

This approach more adequately captures what is wrong with using people in this way. It is important to reiterate at this stage that this is not to say that this kind of behaviour might not be mitigated by appropriate measures, or justified based on the benefits that it might produce – but it does mean that we need to seriously question these practices when we wish to show an appropriate respect for persons. A focus on autonomy, in the contemporary, authenticity-based sense, as the means to respect for persons, as we see in

the research ethics documents, will not capture the root of what is ethically problematic about deception and covert observation. My theory enables us to understand how deception and covert observation per se represent a challenge to the value of respect for persons. Respect requires not just that we honour and protect the decisions that reflect the settled values of the agent, but also that we recognise the symbolic value of making choices in themselves, regardless of their content, and the links between these choices and Kantian contentions about human dignity and respect.

**Conclusion**

In moving away from autonomy as the sole expression of respect for persons, and in explicitly acknowledging that the protection and promotion of individual wellbeing is a function of informed consent, my theory is better equipped to identify the ethical issues that arise in the context of social science research. Through acknowledging that some choices that do not have instrumental effects are valuable, namely symbolic choices, we can devise a theoretical basis for the intuition that deception and covert observation are ethically problematic even when they don’t have an effect on a research subject’s ability to act autonomously, or any other instrumental effect on the decisions that they make. Deception and covert observation deny the subject’s ability to make the choice about whether or under what circumstances to participate in the research in question, and through doing so, represent a symbolic denial of the respect that is their due as a person.

I do not mean to suggest here that this necessarily makes all actions of this type ethically unacceptable; as with any ethical question, there will be competing values that must be balanced against each other. My theory attempts rather to clarify what ethical issues arise in these circumstances, and what is involved in the principle of respect for persons, allowing us to effectively take this value into account in the overall calculation of what is ethically acceptable. As Kelman suggests, deception is often essential to the research design in psychology, and as Humphreys claimed, he could not have gathered his observations without deception concerning his purpose.
To ban all types of research that utilise these practices would clearly prohibit much valuable research from taking place. However, clarifying what is at stake here allows us to see how these practices violate respect for persons, and allows us to take this into account when deciding whether research is permissible, and how we can minimise disrespectful behaviour. Similarly, in noting the wellbeing-protecting function of informed consent, we can see that additional justification must be given to sidestep informed consent requirements where the wellbeing of individual research subjects is at stake.
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