

**Civil liability issues associated with a  
“heroin trial”**

**Natasha Cica BA LLB MA**

**Working Paper Number 11**

**Feasibility Research into the Controlled  
Availability of Opioids Stage 2**

**National Centre for Epidemiology and Population Health  
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# Contents

<i>Executive summary</i> .....	v
<i>Foreword</i> .....	vii
<b>Introduction</b> .....	<b>1</b>
<b>Liability in battery</b> .....	<b>2</b>
Any touching of another personÉ.....	2
Éwithout that person’s legally valid consent.....	2
Competence to consent.....	3
Information.....	5
Voluntariness .....	7
Not against the public interest.....	8
<b>Liability in negligence</b> .....	<b>9</b>
The duty of care– to whom is it owed?.....	9
Trial participants.....	9
Potential trial participants.....	10
Third parties.....	10
Foetuses (and potential foetuses).....	11
Breach of the duty– what is the standard of care?.....	13
Diagnosis and treatment.....	14
Advice and information.....	16
Causation.....	20
Damage.....	21
<b>Liability for disclosing confidential information</b> .....	<b>22</b>
Doctors and confidentiality.....	22
Researchers and confidentiality.....	23
Common law.....	23
ACT legislation .....	24
Commonwealth legislation.....	26
<b>Conclusion</b> .....	<b>26</b>
Feasibility research into the controlled availability of opioids.....	29
Publications .....	30



## Executive summary

In terms of civil liability, the legal duties owed by researchers in a heroin trial may be classified under three headings: liability in battery; liability in negligence; and liability for disclosing confidential information.

Each of these areas of liability is discussed in this paper. Particular attention is paid to situations where the researchers' legal duties are unclear or may be conflicting.

Liability in battery arises out of the touching of another person without that person's legally valid consent. Researchers therefore must obtain a valid consent to trial procedures from each trial participant. For this to occur, the following requirements must be satisfied:

- the trial participant must be competent to consent;
- the consent must be based on adequate information;
- the consent must be voluntarily given; and
- the consent must not be against the public interest.

These four requirements are examined in this paper.

Researchers will be liable in negligence to a trial participant or other person affected by the conduct of the trial if the following elements are all present:

- the researchers owed a duty of care to that person;
- the duty was breached;
- the breach caused that person to suffer damage; and
- the damage is compensable at law.

Each of these elements of liability in negligence is discussed. Issues raised include the scope of the duty owed by researchers towards children born damaged as the result of their parent's participation in the trial.

The discussion of liability for disclosing confidential information centres on the Epidemiological Studies (Confidentiality) Act 1992 (ACT), which specifically applies to the proposed heroin trial.

The legal rules outlined in this paper should be viewed as minimum standards only. The researchers should focus less on avoiding liability than on ensuring that each individual trial participant, and each other individual to whom a duty of care is owed, is treated with maximum respect.



## Foreword

The Stage 2 logistic investigations for Feasibility Research into the Controlled Availability of Opioids have two facets. One is to examine potential problems which could arise if a trial of controlled heroin availability eventuates and the other is to determine if a workable protocol for the conduct and evaluation of a trial can be designed.

In analysing civil liability issues this paper covers both facets. It describes potential legal problems which a trial might face and, more importantly, as stated in the conclusion, highlights the sorts of considerations which should be given to “ensuring that each individual trial participant, and each other individual to whom a duty of care is owed, is treated with maximum respect”. To this end a set of principles of practice for the service provision component of a trial have been developed (McDonald et al., 1994). These focus on health development rather than a narrow treatment approach.

This paper builds on the outline of civil liability issues developed in the first stage of the feasibility study. At that time, Jennifer Norberry also examined in detail international treaties to which Australia is a signatory and Commonwealth, State and Territorial legislation which would prohibit a trial (Norberry, 1991). It was concluded that:

A trial involving the controlled availability of opioids, including heroin, that was conducted for a medical or scientific purpose would not place Australia in breach of international treaty obligations.

The Commonwealth controls the importation and manufacture of narcotic goods and has extensive powers in relation to therapeutic goods. Under current legislation, those associated with a trial would commit a number of offences if heroin or other narcotic drugs were to be imported, possessed or manufactured. However a trial could proceed legally if a number of Commonwealth licences and permissions were obtained and if the Commonwealth agreed to notify estimates for heroin importation to the International Narcotics Control Board.

Under current ACT legislation, a trial to provide opioids, including heroin, in a controlled manner would not be lawful. For a trial to be able to proceed, one of three changes would have to be enacted:

- a non-enforcement agreement between the Commonwealth, ACT, some State governments (probably) and a range of agencies including the Australian Federal Police, the Director of Public Prosecutions and the ACT Board of Health,
- amendments to existing ACT legislation, or
- special legislation.

Of these options, the second or third are most desirable. (Bammer, 1991:3–4).

Norberry (1991) also outlined issues of criminal liability and we plan to publish a more detailed examination of these in a forthcoming working paper.

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**Feasibility Research Co-ordinator**

**References**

- Bammer, G. 1991 'Report and recommendations'. *Volume 1 of Feasibility Research into the Controlled Availability of Opioids*. National Centre for Epidemiology and Population Health, Australian National University, Canberra.
- McDonald, DN.; Bammer, G.; Legge, D.; Sibthorpe, B. (1994) 'Service provision considerations for the evaluation of a heroin trial. A discussion paper'. In National Centre for Epidemiology and Population Health and Australian Institute of Criminology, *Issues for Designing and Evaluating a 'Heroin Trial'. Three Discussion Papers*. Feasibility Research into the Controlled Availability of Opioids Stage 2 Working Papers Number 8, pp. 31–34.
- Norberry, J. 1991 'Legal issues' In *Feasibility Research into the Controlled Availability of Opioids Volume 2 Background Papers* National Centre for Epidemiology and Population Health, Australian National University, Canberra, pp 87-115.



## Introduction

The National Health and Medical Research Council's *Statement on Human Experimentation and Supplementary Notes* states that experiments on human beings "range from those undertaken as a part of patient care to those undertaken either on patients or on healthy subjects for the purpose of contributing to knowledge, and include investigations on human behaviour".<sup>1</sup> The proposed heroin trial, which is the subject of feasibility research currently being conducted by the National Centre for Epidemiology and Population Health in collaboration with the Australian Institute of Criminology, would involve the provision of heroin in a controlled manner to dependent users, with the aim of assessing changes in health and social behaviours.<sup>2</sup> It therefore would constitute experimentation on human beings. Those conducting the trial would be under the ethical and legal obligations owed by researchers to human participants in research.<sup>3</sup> This paper examines the obligations imposed by the civil law on the investigators in the proposed trial.

There is very little Australian case or statute law directly outlining the civil legal obligations owed to trial participants.<sup>4</sup> The scope and nature of the legal duties owed by researchers to trial participants nonetheless can be determined by examining the general principles that the common law has developed to protect the bodily integrity of the individual, in particular those principles that govern the legal duties owed by medical practitioners to their patients. The law governing medical treatment within the doctor/patient relationship is particularly relevant to the proposed heroin trial, because the trial may be characterised as "therapeutic" research (where the researchers have a dual intention: to treat the individual trial participants and to obtain data of a generalisable nature) rather than "non-therapeutic" research (where the researchers only have the latter intention).<sup>5</sup> The National Health and Medical Research Council's *Statement on Human Experimentation and Supplementary Notes*,<sup>6</sup> while not itself having the force of law,<sup>7</sup> also provides guidance as to the principles that shape the legal duties owed to trial participants.

The legal duties owed by the researchers in the proposed heroin trial may be classified under three headings: liability in battery; liability in negligence; and liability for disclosing confidential information.

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<sup>1</sup> National Health and Medical Research Council, *Statement on Human Experimentation and Supplementary Notes* Canberra, AGPS, 1992, p.2 (Statement— introductory paragraph).

<sup>2</sup> National Centre for Epidemiology and Population Health, *Feasibility Research Into the Controlled Availability of Opioids; Volume 1: Report and Recommendations* Canberra, NCEPH, 1991, p.7 (recommendations 5 and 6).

<sup>3</sup> See National Health and Medical Research Council, *supra* n.1, at p.2 (Statement— introductory paragraph).

<sup>4</sup> Some Australian States have enacted legislation to regulate research conducted on human embryos, but note that research on embryos involves quite different issues to research on human subjects: G. Dworkin, "Law and Medical Experimentation: On Embryos, Children and Others With Limited Legal Capacity" (1987) 13 *Monash University Law Review* 189 at 208.

<sup>5</sup> It is generally accepted that different legal and ethical rules govern "therapeutic" and "non-therapeutic" research on human beings: see A. Grubb, "The Law Relating to Consent" in C. Foster (ed.) *Manual for Research Ethics Committees*, London, Centre of Medical Law and Ethics (King's College London), 1993, p.II.17 at II.19; I. Kennedy and A. Grubb, *Medical Law: Text and Materials*, London, Butterworths, 1989 at pp. 869-923; G. Dworkin, *supra* n. 4. As the proposed trial would involve therapeutic research, the discussion in this paper is limited to the law regulating therapeutic research and does not extend to the law affecting the conduct of non-therapeutic research. Researchers include not only those evaluating the trial, but also those providing the drug treatment service.

<sup>6</sup> National Health and Medical Research Council, *supra* n.1.

<sup>7</sup> The NHMRC will not award a research grant unless an appropriate ethics committee has certified that the proposal complies with the *Statement on Human Experimentation and Supplementary Notes*.

## Liability in battery

Any touching of another person without that person's legally valid consent is unlawful. Anyone who conducts research without a trial participant's consent risks being sued for damages for trespass to the person, in particular for committing the tort of battery.<sup>8</sup>

### 1. Any touching of another person

The tort of battery seeks to uphold the fundamental common law principle that every person has a right to bodily integrity; a right "to choose what occurs with respect to his or her own person".<sup>9</sup> The tort is committed by bringing about a physical contact with a person to which that person does not consent. The physical contact may be slight and need cause no actual physical harm to the person, and may even improve the person's physical condition;<sup>10</sup> the insult in being touched without consent is regarded as harm in itself.<sup>11</sup>

Thus any physical contact between a researcher and a trial participant could give rise to a battery action. Examples might include the researcher touching the trial participant during a physical examination, or administering a drug by means of a hypodermic syringe. The self-administration of heroin in oral or smokable form by the research participant presumably would not involve the actual touching of the trial participant by the researcher. It is possible, however, that a court might seek to protect the bodily integrity of the trial participant in such a situation by viewing the self-administration of drugs as physical contact *directly caused* by the researcher, and allowing that self-administration to give rise to a battery action.<sup>12</sup>

### 2. Without that person's legally valid consent

A researcher will not be liable for battery if he or she has obtained a legally valid consent to the physical contact in question. Note that consent to one form of treatment or procedure does not amount to consent to another, albeit related, treatment or procedure.<sup>13</sup> The researchers therefore must obtain a valid consent to each form of treatment or procedure to be performed.

Commentators generally identify three elements of a valid consent.<sup>14</sup>

- (a) the person must be competent to consent;
- (b) the consent must be based upon adequate information; and
- (c) the consent must be voluntarily given.

A fourth element may also be identified:

- (d) the consent would not be against the public interest.

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<sup>8</sup> A researcher who acts without consent could also face criminal prosecution for the crime of battery; see I. Kennedy and A. Grubb, *supra* n. 5, p. 171 and A. Dix, M. Errington, K. Nicholson and R. Powe, *Law for the Medical Profession*, Sydney, Butterworths, 1988, p. 92-3.

<sup>9</sup> *Department of Health v. J.W.B. and S.M.B.* (1992) 66 A.L.J.R. 300 at 303 *per* Mason C.J., Dawson, Toohey and Gaudron JJ.

<sup>10</sup> *Mohr v. Williams* (1905) 104 N.W. 12 (Supreme Court of Minnesota); *Murray v. McMurdy* [1949] 2 D.L.R. 442 (Supreme Court of British Columbia).

<sup>11</sup> *Collins v. Wilcock* [1984] 1 W.L.R. 1172 at 1177 *per* Robert Goff L.J.; Blackstone's *Commentaries* (17th ed), 1830, vol. 3, p. 120.

<sup>12</sup> *Mink v. University of Chicago* (1978) 460 F.Supp. 713 at 718; F. Trindade and P. Cane, *The Law of Torts in Australia*, Melbourne, Oxford University Press, 1985, p. 29.

<sup>13</sup> See A. Dix *et al.*, *supra* n. 8, p. 85.

<sup>14</sup> A. Grubb, *supra* n. 5, p.11.17.

## (a) Competence to consent

### *i. The test for competence*

The test for competence to consent to medical treatment is based on “understanding”. By analogy, the test for competence to consent to participating in therapeutic research, involving as it does a treatment element as well as a research element, will also be based on understanding. In general a person will be legally competent to consent to being involved in a trial if the participant is capable of understanding the nature and effect of what is involved in the trial.<sup>15</sup>

An adult— a person who has attained the age of 18 years— is presumed to be competent to consent to medical treatment. This presumption of capacity will also apply when an adult consents to being involved in therapeutic research. The presumption is rebuttable, however, and an adult’s competence is particularly likely to be called into question if he or she is mentally ill, intellectually disabled or affected by external factors such as drugs.<sup>16</sup> Given that every participant in the proposed trial would be a dependent user, the researchers would need to take care to satisfy themselves that each participant in the trial possesses the requisite understanding of the nature and effect of what is proposed, taking into account the possible effects of drug dependence.

The legal position with respect to children is more complicated. In New South Wales and South Australia, a minor’s capacity to consent to medical treatment is regulated by statute,<sup>17</sup> but in other Australian jurisdictions, including the Australian Capital Territory, the common law still applies. The basic common law rule is that a minor is capable of consenting to medical treatment if the minor is sufficiently mature and intelligent to be able to understand fully what is proposed, irrespective of any fixed age rule.<sup>18</sup> This test of a child’s capacity to consent to medical treatment probably also applies as the test of a child’s capacity to consent to therapeutic research. The standard of maturity, intelligence and comprehension that the law would demand of a child, however, is likely to be high when the child is purporting to consent to research.<sup>19</sup> The drug dependence of any child participant in the trial would again need to be considered carefully by the researchers when assessing competence. Even if a child does appear to possess the capacity to consent to participate in the proposed trial, it would be prudent for the researchers also to obtain the consent of the child’s parent or guardian.<sup>20</sup>

### *ii. Incompetent trial participants*

<sup>15</sup> *Ibid.*, pp.II.17 and II.19.

<sup>16</sup> *Ibid.*, p.II.17.

<sup>17</sup> Minors (Property and Contracts Act 1970 (N.S.W.), s.49(2) and Consent to Medical and Dental Procedures Act 1985 (S.A.), s.6(1).

<sup>18</sup> *Gillick v. West Norfolk A.H.A.* [1986] A.C. 112, as adopted by the High Court of Australia in *Department of Health v. J.W.B. and S.M.B.* (1992) 66 A.L.J.R. 300 at 305 *per* Mason C.J., Dawson, Toohey and Gaudron JJ.

<sup>19</sup> A. Grubb, *supra* n. 5, p. II.18; G. Dworkin, *supra* n. 4 at 197.

<sup>20</sup> The NHMRC *Statement on Human Experimentation and Supplementary Notes* advises researchers to obtain the consent of both the sufficiently mature and intelligent child trial participant *and* the child’s parent or guardian: National Health and Medical Research Council, *supra* n.1, p.8 (Supplementary Note 2 - para 4). In a case where a child is competent to consent, that child’s refusal to consent should be respected by the researchers. This is despite recent decisions by English courts stating that a competent child’s refusal to consent can be overridden by the valid consent of anyone with parental responsibility for the child: *Re R (A Minor)(Wardship: Consent to Treatment)* [1991] 3 W.L.R. 592; *Re W (A Minor)(Medical Treatment: Court’s Jurisdiction)* [1992] 3 W.L.R. 758. It is unlikely that these recent English developments would be followed by an Australian court: see *Department of Health v. J.W.B. and S.M.B.* (1992) 66 A.L.J.R. 300 at 305 *per* Mason C.J., Dawson, Toohey and Gaudron JJ.

In some situations a person may be given medical treatment despite that person's inability to give a legally valid consent.<sup>21</sup> The legal rules governing provision of medical treatment to incompetent adults and children would also govern their participation in therapeutic research.

If an adult is incompetent, non-emergency medical treatment (and thus therapeutic research) can only be performed with the consent of the persons or bodies to whom the law has given the power to consent on the incompetent person's behalf. Each Australian State and Territory has a different legal regime governing which persons or bodies may provide this proxy consent in any given circumstances.<sup>22</sup> Due to the complexity of and variation between the law in this area in each Australian jurisdiction, this discussion focuses on the relevant law in the Australian Capital Territory.<sup>23</sup> In the ACT, most forms of medical treatment may be performed on an incompetent adult with the consent of the patient's legal guardian (who may be a private guardian or the public guardian<sup>24</sup>) or of an agent appointed under a medical enduring power of attorney.<sup>25</sup> Some ethically controversial medical procedures can only be consented to by the Guardianship and Management of Property Tribunal. These medical procedures, known as "prescribed medical procedures", are abortion, sterilisation, hysterectomy, contraception procedures, tissue transplants and any other special medical procedures that are listed in Regulations.<sup>26</sup> No other medical treatments or procedures have yet been listed in Regulations. Although the proposed heroin trial may be considered by many to be ethically controversial, the procedures involved in the trial would not be "prescribed medical procedures" and therefore proxy consent to them could be given by a guardian or agent.<sup>27</sup>

In the Australian Capital Territory, a guardian or agent must apply the "substituted judgment principle" when making decisions concerning the medical treatment of an incompetent adult. Under this legal test the proxy must make the decision that the patient would have made if he or she were not incompetent.<sup>28</sup>

If the incompetent person is a child, a valid consent to therapeutic research may be given by the child's parent or other guardian. The proposed treatment must be in the child's "best interests". Those interests may not necessarily be confined to the child's medical interests. The child's emotional, psychological or social interests arguably may be considered

<sup>21</sup> See generally R. Creyke, *Who Can Decide: Legal Decision making by Others*, Canberra, AGPS, forthcoming publication.

<sup>22</sup> See P. MacFarlane, *Health Law: Commentary and Materials*, Sydney, Federation Press, 1993, pp. 62-68 and R. Creyke, *supra* n.21.

<sup>23</sup> For an analysis of the laws regulating decision-making on behalf of incompetent patients in all Australian jurisdictions, see R. Creyke, *supra* n. 21.

<sup>24</sup> Known as the Community Advocate or the Public Trustee.

<sup>25</sup> Note that only three Australian jurisdictions— the ACT, South Australia and Victoria— allow an agent appointed under an enduring power of attorney to make decisions concerning medical treatment: Powers of Attorney Act 1956 (ACT); Guardianship and Administration Act 1993 (SA); Medical Treatment Act 1988 (Vic.).

<sup>26</sup> Guardianship and Management of Property Act 1991 (ACT), ss 69(2) and 70(1).

<sup>27</sup> Compare the situation in New South Wales, where "special medical treatment"— being treatment to which only the Guardianship Board may consent— has been defined under the Guardianship Regulations 1989 to include: medical treatment that involves the administration of a drug of addiction (otherwise than in association with the treatment of cancer) over a period or periods totalling more than 10 days in any period of 30 days; medical treatment that involves an experimental procedure that does not conform to the document entitled "Statement on Human Experimentation and Supplementary Notes" issued by the NHMRC, as in force on July 1989; and medical treatment that involves the use of an aversive stimulus, whether mechanical, chemical, physical or otherwise. See further R. Creyke, *supra* n. 21.

<sup>28</sup> Powers of Attorney Act 1956 (ACT), s.14; Guardianship and Management of Property Act 1991 (ACT), s.14. Note that in every other Australian jurisdiction (except South Australia, where the substituted judgement principle also applies), the proxy can only consent to treatment that is in the incompetent adult patient's "best interests".

when deciding whether participation in the proposed therapeutic research would be in that child's "best interests".<sup>29</sup>

The "best interests" test could lead to a legal difficulty if a child is to be placed in a randomised controlled trial.<sup>30</sup> In such a trial, the researcher may think— or, in a "double blind" trial, be unable to tell whether— the child trial participant is not receiving what in the researcher's view is the best treatment. This arguably violates the researcher's duty to act in the "best interests" of the trial participant, but the law is untested on this matter.<sup>31</sup> Note that this potential problem would not bar the inclusion of incompetent adults in a randomised controlled trial conducted in the Australian Capital Territory. The substituted judgment test would allow proxy consent to procedures not necessarily in the best interests of the incompetent person, provided that the person would have consented to those procedures had he or she been competent.

## **(b) Information**

### *i. "In broad terms of the nature of the procedure"*

To be legally effective, a consent to medical treatment must be adequately informed. The patient must be informed in broad terms of the nature of the procedure which is intended.<sup>32</sup> To give a legally effective consent to therapeutic research, the trial participant therefore must be informed in broad terms of the nature of the intended trial procedures. Because the trial will have a dual character— involving research as well as treatment— it is essential that trial participants are informed that they are to be participants in a research trial, in addition to being informed about the nature of the treatment they are to receive.<sup>33</sup>

There are other matters that a court might consider basic to the nature of therapeutic research, and about which it might insist that trial participants be informed. The law may require trial participants to be informed that they may withdraw from the research at any time without adverse consequence to them;<sup>34</sup> that they may be part of a control group in the trial; and (where applicable) that the trial is a randomised controlled trial.<sup>35</sup>

### *ii. Fraud or misrepresentation*

A patient's consent to treatment, and therefore presumably also a trial participant's consent to therapeutic research, will be vitiated if it is induced through fraud or misrepresentation as to the nature of the procedures to be performed.<sup>36</sup> Researchers must resist any temptation to distort the truth about the nature of the trial, in an attempt to secure the consent of a person who they feel would benefit from participating in the trial but who may not consent if aware of the nature of the trial.

### *iii. Information as to risks, etc.*

<sup>29</sup> See *Strunk v. Strunk* (1969) 445 S.W.2d 145 (Kentucky); cf. *Little v. Little* (1979) 576 S.W.2d 493 (Texas). See further G. Dworkin, *supra* n.4 at 199.

<sup>30</sup> An "R.C.T." The proposed heroin trial would be an R.C.T.: National Centre of Epidemiology and Population Health, *supra* n.2, p.7 (recommendations 3 and 4).

<sup>31</sup> A. Grubb, *supra* n.5, p.II.21.

<sup>32</sup> *Rogers v. Whitaker* (1992) 109 A.L.R. 625 at 633 at 633 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ.; *Chatterton v. Gerson* (1981) Q.B. 432 at 443 *per* Bristow J; *Ellis v. Wallsend District Hospital* (1989) Aust. Torts Reports 80-259 at 68,770 *per* Cole J.

<sup>33</sup> I. Kennedy and A. Grubb, *supra* n.5, p.875. See further A. Dix *et al.*, *supra* n. 8, p.99.

<sup>34</sup> See National Health and Medical Research Council, *supra* n. 1, p. 3 (Statement - paragraph 9).

<sup>35</sup> A. Grubb, *supra* n.5, p.II.20; I. Kennedy and A. Grubb, *supra* n.5, p. 875-6.

<sup>36</sup> See I. Kennedy and A. Grubb, *supra* n.5, pp. 222-229.

The requirement that a trial participant be informed “in broad terms” of the nature of the trial procedures does not demand the provision of a particularly high level of information. The consent of a trial participant will not be vitiated if he or she is not provided with information about the risks inherent in the trial, treatment alternatives, or other details concerning participation in the trial. This does not mean, however, that researchers are under no legal obligation to disclose such information. The obligation to disclose risks and other relevant information exists, but failure to meet it exposes a researcher to liability in negligence, not battery.<sup>37</sup> This duty to inform a trial participant more fully about the proposed research is discussed later in this paper under “Liability in negligence”.

#### *iv. Consent forms*

The legal effect of consent forms is often misunderstood. There is no legal requirement that consent be in writing. Additionally, the fact that a trial participant has signed a consent form does not mean that the trial participant has given a legally valid consent. A consent form will only serve as evidence of consent if it reflects what actually happened before its signing.<sup>38</sup> In the words of Bristow J. in *Chatterton v. Gerson*:

I should add that getting the patient to sign a pro forma expressing consent to undergo an operation [the effect and nature of which has been explained to me] should be a valuable reminder to everyone of the need for explanation and consent. But it would be no defence to an action based on trespass to the person if no explanation had in fact been given. The consent would have been expressed in form only, not in reality.<sup>39</sup>

This does not mean that consent forms have no place in medical research. Beyond reminding researchers “of the need for explanation and consent”, they can and should serve as a useful tool to assist researchers in communicating with trial participants. This matter is discussed further below under “Liability in negligence”.

### **(c) Voluntariness**

Consent to medical treatment must be freely given. It must not be the result of coercion or pressure which overbears the patient’s will.<sup>40</sup> Those contemplating research on human beings should take particular care to ensure that the requirement of voluntariness is satisfied.<sup>41</sup>

Whether a trial participant’s consent is voluntary will be a question of degree and will depend on the circumstances of each individual trial participant.<sup>42</sup> Some categories of individuals, although competent to give consent, will be particularly vulnerable to coercion. They will be in some sort of unusually dependent relationship or other position of weakness that gives rise to a danger of their will being overborne.<sup>43</sup> Prisoners or those threatened with imprisonment, children, the elderly, students, sick people (especially those who are in pain or depressed), and people under the influence of or dependent on drugs are examples of

<sup>37</sup> *Rogers v. Whitaker* (1992) 109 A.L.R. 625 at 633 at 633 per Mason C.J., Brennan, Dawson, Toohey and McHugh JJ.; *Reibl v. Hughes* (1980) 114 D.L.R. (3d) 1 at 11 per Laskin C.J.; *Chatterton v. Gerson* (1981) Q.B. 432 at 443 per Bristow J; *Ellis v. Wallsend District Hospital* (1989) Aust. Torts Reports 80-259 at 68,770 per Cole J.

<sup>38</sup> A. Dix *et al.*, *supra* n. 8 p. 105.

<sup>39</sup> (1981) 1 Q.B. 432.

<sup>40</sup> See A. Dix *et al.*, *supra* n. 8, p. 84.

<sup>41</sup> See National Health and Medical Research Council, *supra* n. 1, pp.2-3 (Statement— paragraphs 5, 8, 9, 10 and 13) and p.9 (Supplementary Note 2— “Those in dependant relationships or comparable situation”).

<sup>42</sup> See A. Grubb, *supra* n.5, p.II.18.

<sup>43</sup> See *Re T (Adult: Refusal of Treatment)* [1992] 3 W.L.R. 782 (English Court of Appeal).

vulnerable groups. Although it might be argued that members of at least some of these groups should be considered automatically incapable of giving free and voluntary consent,<sup>44</sup> this is probably not the law in Australia. The legal position seems instead to be that, where there is a danger of undue influence or coercion, a court will be alive to that risk in determining whether the consent is in fact voluntary.<sup>45</sup> Those conducting the proposed heroin trial should similarly be alive to that risk, to which the drug dependence of the trial participants will alert them, when assessing the voluntariness of each individual's consent to participation in the trial.

The consent of trial participants will not be rendered involuntary solely because they receive payment for participating in the trial.<sup>46</sup> Any payment offered, however, should not be so large as to be an inducement to participate in the trial, and should ideally represent no more than payment for inconvenience and time spent on the trial.<sup>47</sup>

#### **(d) Not against the public interest**

There are some forms of physical contact to which the law prevents any individual from consenting. Usually these forms of physical contact would cause the individual actual or more serious bodily harm.<sup>48</sup> The law prohibits consent on the basis that some harms involve public, not just personal, interests.<sup>49</sup>

These public policy limits on consent may be relevant in the context of research on human beings if the research is likely to harm the trial participants. The law may intervene to prevent an individual from participating in research if the danger the research poses to that individual outweighs countervailing benefits to that individual and/or society.

##### *i. Danger to the individual research subject*

The greater the risk of harm to the individual that is inherent in the proposed research, the more likely it will be that the law will not permit participation in that research.

The fact that an individual belongs to a particularly vulnerable group should not automatically disqualify that individual from consenting to research, provided the consent satisfies the voluntariness requirement.<sup>50</sup> Membership of a vulnerable group, however, may justify the law lowering the level of risk considered acceptable for the conduct of research.

As dependent users of heroin may be considered to comprise a vulnerable group,<sup>51</sup> the researchers should be especially aware of the need to devise trial procedures that minimise risks to participants. If any of these dependent users are also members of other vulnerable groups<sup>52</sup> then the researchers should be doubly careful to minimise risks. For example, the trial should include "stopping rules" under which a participant is removed from the trial (or

<sup>44</sup> See *Kaimowitz v. Michigan Department of Mental Health* (1973) 42 U.S.L.W. 2063 at 2064 (involuntarily detained mental patients cannot give voluntary consent to experimental surgery because of the inherently coercive nature of their relationship with institutional authorities).

<sup>45</sup> *Freeman v. Home Office (No 2)* [1984] 1 All E.R. 1036 at 1044-5 (English Court of Appeal) *per* Lord Donaldson M.R.

<sup>46</sup> G. Dworkin, *supra* n.4 at 204.

<sup>47</sup> National Health and Medical Research Council, *supra* n.1, p.3 (Statement - paragraph 13). See further "Payments to Research Subjects" in C. Foster, *supra* n.5, pp.II.51-52

<sup>48</sup> See *Attorney-General Reference (No 6 of 1980)* [1981] Q.B. 715; *R. v. Coney* (1882) 8 Q.B.D. 534; *R. v. Donovan* [1934] 2 K.B. 298; *Pallante Stadiums Pty Ltd (No 1)* [1976] V.R. 331; *R. v. Brown* [1993] 2 W.L.R. 566.

<sup>49</sup> *Department of Health v. J.W.B. and S.M.B.* (1992) 66 A.L.J.R. 300 at 303 *per* Mason C.J., Dawson, Toohey and Gaudron JJ. and at 318 *per* Brennan J.

<sup>50</sup> See discussion of voluntariness of consent, *supra*.

<sup>51</sup> See discussion of voluntariness of consent, *supra*.

<sup>52</sup> For example children, the mentally ill, prisoners or those threatened with imprisonment.

the entire trial is modified or even discontinued) as soon as it becomes apparent that continued participation would either harm or not benefit the trial participant.

*ii. Countervailing benefits*

Society has a strong interest in ensuring that research on human beings continues to take place, because “the collection of data from planned experimentation on human beings is necessary for the improvement of human health”.<sup>53</sup>

In the case of therapeutic research, this societal interest in the advancement of medical science is joined by the individual trial participant’s interest in obtaining the direct therapeutic benefits that the trial may offer. The individual trial participant will not receive direct therapeutic benefits in the case of non-therapeutic research. For this reason, the law will allow an individual to consent to exposure to greater risk of harm when the proposed research is therapeutic<sup>54</sup> rather than non-therapeutic in nature. The law is likely to permit an individual to participate in non-therapeutic research only when the research would expose the individual to no more than “minimal risk”.<sup>55</sup> How much more than “minimal risk” the law will allow an individual to face during therapeutic research cannot be predicted with any certainty.

## Liability in negligence

The researchers conducting the heroin trial could face liability in negligence in relation to their conduct of the trial. A successful action in negligence would require the person bringing the action (the plaintiff) to prove the following:

- (1) the researchers (defendants) owed the plaintiff a duty of care;
- (2) the researchers breached the duty, *i.e.* failed to meet the requisite standard of care;
- (3) the breach of duty caused the plaintiff to suffer damage; and
- (4) the damage was compensable at law.

### 1. The duty of care—to whom is it owed?

The duty of care is based on there being a relationship of closeness or proximity between the parties.<sup>56</sup> The researchers will not owe a duty of care to the world at large. Rather, they will owe a duty to all those who can be reasonably foreseen as likely to be injured by their acts or omissions:

Éif the plaintiff was within the range of reasonable foresight this creates a relationship of neighbourhood or proximity between him and the defendant which gives rise to a duty on the part of the defendant to take care not to injure the plaintiff.<sup>57</sup>

#### (a) Trial participants

In the context of medical care, the doctor owes the patient a duty of care because the doctor has assumed responsibility for the care, treatment or examination of the patient,

<sup>53</sup> National Health and Medical Research Council, *supra* n.1, p.2 (Statement— introductory paragraph).

<sup>54</sup> As in the case of the proposed heroin trial.

<sup>55</sup> A.Grubb, *supra* n.5, pp..II.19, II.21 and II.22 (“minimal risk” of death being 1 to 100 per million, “minimal risk” of major complication being 10 to 1000 per million, and “minimal risk” of minor complication being 1 to 100 per 1000); G. Dworkin, *supra* n.4 at 205.

<sup>56</sup> P. MacFarlane, *supra* n.22, p.86.

<sup>57</sup> F. Trindade and P. Cane, *supra* n.12, p.279; see *Donoghue v. Stevenson* [1932] A.C. 562 *per* Lord Atkin.



establishing a sufficiently proximate relationship between the parties.<sup>58</sup> Researchers will owe a duty of care to the trial participants, because by including them in the trial the researchers will have assumed a similar responsibility for care, treatment and examination.

### **(b) Potential trial participants**

The law is reluctant to impose duties of affirmative action. Where no duty of care exists between two parties, the law will not impose a duty on one party to assume responsibility and thus a duty of care towards the other party. No-one is required to come to the aid of a stranger in need of assistance.<sup>59</sup>

The law therefore does not require a doctor to provide medical assistance to a stranger, even in an emergency.<sup>60</sup> Similarly, the law will not require the researchers to include in the trial a dependent drug user who could benefit from inclusion. The law will not require the researchers to assume a duty of care towards such a person by including that person in the trial. The researchers therefore could not be held negligent if a person dependent on drugs (or someone affected by the actions of that person) suffered injury or loss as a result of not being included in the heroin trial, even if that person had wanted and asked to be included.

### **(c) Third parties**

The researchers might owe a duty of care to all those who the researchers can reasonably foresee might be injured as a result of the behaviour of trial participants, even though those people are not themselves trial participants. The law on this matter is untested in Australia. Courts in other common law jurisdictions, however, have examined the question of a doctor's duty to non-patient third parties who are put at risk by the behaviour of a patient. A number of these courts have held that the existence of a doctor-patient relationship is sufficient to impose on a doctor an affirmative duty to act to protect identifiable third persons from foreseeable risks emanating from a patient's illness.

Courts in the United States have long recognised that a doctor may be liable to persons infected by a patient, if the doctor negligently fails to diagnose a contagious disease, or having diagnosed the illness, fails to warn family members or others who are foreseeably at risk of exposure to the disease.<sup>61</sup> This approach was given broader application by the Supreme Court of California in the seminal case of *Tarasoff v. Regents of University of California*.<sup>62</sup> In that case, the court held that, where a psychotherapist is aware or should be aware that his patient presents a serious danger of violence to another, he is under a duty to use reasonable care to protect the intended victim.<sup>63</sup> Depending on the facts of the case, the psychotherapist can discharge the duty by warning the intended victim, notifying the police, or taking whatever

<sup>58</sup> I. Kennedy and A. Grubb, *supra* n.5, p.107, quoting Lord Nathan, *Medical Negligence* (1957) at pp. 8 and 10.

<sup>59</sup> P. MacFarlane, *supra* n.22, p.87.

<sup>60</sup> “[A] good swimmer on the beach is free to ignore the call for help from someone in danger of drowning”: see J. Fleming, *The Law of Torts* (7th ed.), Sydney, Law Book Company, 1987, p. 135. Note *Barnett v. Chelsea and Kensington Hospital Management Committee* [1969] 1 Q.B. 428 (hospital had assumed duty of care to those needing emergency assistance by virtue of having an emergency department).

<sup>61</sup> Recent cases include *Gammill v. United States* (1984) 727 F.2d 950 (10th Circuit); *Hoffman v. Blackmon* (1970) 241 So.2d 752 (Florida District Court of Appeal); *Shepard v. Redford Community Hospital* (1986) 390 N.W. 2d 239 (Michigan); *Bradshaw v. Daniel* (1993) 854 S.W. 2d 865 (Supreme Court of Tennessee).

<sup>62</sup> (1976) 551 P.2d 334.

<sup>63</sup> *Cf.* the decision of the English Court of Appeal in *W.v. Egdeell*, where a psychiatrist was held to be *entitled* (rather than under a duty) to warn the relevant public authorities of his concern that his patient posed a “real risk of consequent danger to the public”: [1990] 2 W.L.R. 474 at 493 *per* Bingham L.J. See further discussion under “Liability for disclosing confidential information”, *infra*.

steps are reasonably necessary in the circumstances. The *Tarasoff* approach has been followed widely by other courts in the United States.<sup>64</sup>

If the *Tarasoff* approach represents the legal position in Australia, it is possible that the researchers in the proposed trial would have a duty at common law to protect identifiable third persons facing a real risk of violence or other danger from trial participants. If this duty to protect includes a duty to warn, it should not be forgotten that this duty must be balanced against their legal duty to respect the confidences of trial participants. The parameters of the researchers' legal duty to maintain confidentiality in respect of the proposed trial are determined by ACT legislation, the terms of which may have eliminated any duty to warn that the researchers owed third parties at common law.<sup>65</sup>

#### **(d) Foetuses (and potential foetuses)**

##### *i. Pre-natal injury*

If any of the trial participants are pregnant women, the researchers will owe a duty of care in respect of the foetus as well as to the pregnant research participant. Although a foetus has no legal rights of its own while it is *in utero*, it does gain legal personality and rights once it is born alive.<sup>66</sup> If a child is born damaged due to negligently inflicted pre-natal injuries, the child may bring a successful action in negligence against the person responsible for those injuries.<sup>67</sup>

In *Watt v. Rama*, the full Supreme Court of Victoria held that a child born with brain damage due to its injury in a car accident before birth had an action in negligence against the driver of the other car.<sup>68</sup> The principle that a child may sue at common law in respect of pre-natal injuries has also been upheld by the New South Wales Court of Appeal<sup>69</sup> and courts in other common law jurisdictions<sup>70</sup>, in cases involving negligent medical treatment. There is no reason why the principle would not permit recovery of damages where the pre-natal injuries are the result of the negligent behaviour of researchers. It therefore would be possible for a baby born drug dependent or with some other injury, as the result of the negligent behaviour

<sup>64</sup> The duty has even been extended in some States beyond protection of people named by the patient or readily identifiable as potential victims, to protect all persons foreseeably endangered by the patient's conduct: see M. Neave, "AIDS - Confidentiality and the Duty to Warn" (1987) 9 *University of Tasmania Law Review* 1 at 29. But compare the restrictive approach of the Supreme Court of Indiana in *Webb v. Jarvis* (1991) 575 N.E. 2d 992. In that case a shooting victim brought a negligence action against the doctor of the person who had shot him. The shooting victim alleged that the doctor had breached a duty owed towards him, by overprescribing anabolic steroids for the patient which turned the patient into a toxic psychotic who was unable to control his rages, and by failing to warn others of the patient's propensity for violence. The court held that the doctor held no duty to the shooting victim, on the basis that: (1) a doctor owes no duty to third persons unless the doctor had actual knowledge that those known and identified persons would rely on his rendering of professional services; (2) it was not reasonably foreseeable as a matter of law that prescribing steroids to the patient would make him dangerous; and (3) imposing a duty on a doctor to predict a patient's behavioural reaction to medication and to identify possible plaintiffs would be against public policy, as it would force the doctor to weigh the welfare of unknown persons against the welfare of his patient and thereby cause a divided loyalty. For a criticism of this decision, see I.Kennedy (1993) 1 *Med.L.Rev.* 267.

<sup>65</sup> See discussion under "Liability for disclosing confidential information", *infra*.

<sup>66</sup> *Watt v. Rama* [1972] V.R. 353 (Supreme Court of Victoria); *Paton v. B.P.A.S.* [1979] Q.B. 276; *Re F (In Utero)* [1988] Fam 122; *C. v. S.* [1987] 1 All E.R. 1230; *K. v. T.* [1983] 1 Qd R. 396 at 401; *A-G (ex rel Kerr) v. T.* (1983) 1 Qd R. 404 at 406-7; *A-G for the State of Qld (ex rel Kerr) v. T.* (1983) 57 A.L.J.R. 285 at 286; *F. v. F.* (1989) 13 Fam.L.R. 189.

<sup>67</sup> See I. Kennedy (1993) 1 *Med. L.Rev.* 105 for discussion of exactly when the duty of care to the damaged child would arise.

<sup>68</sup> [1972] V.R. 353. See also *Duval v. Seguin* (1972) 26 D.L.R. (3d) 418 (High Court of Ontario).

<sup>69</sup> *X. and Y. v. Pal and Others* (1991) 23 N.S.W.L.R. 26.

<sup>70</sup> For example *Burton v. Islington Health Authority and De Martell v. Merton and Sutton Health Authority* [1992] 3 W.L.R. 637 (English Court of Appeal) - note that in England the common law in this area has been replaced by the Congenital Disabilities (Civil Liability) Act 1976 in respect of events occurring after 21 July 1976; *Cherry v. Borsman* (1991) 75 D.L.R. (4th) 668 (British Columbia Supreme Court).

of researchers towards the baby's mother when she was a pregnant trial participant, to bring a negligence action against the researchers.

*ii. Pre-conception injury*

Children can also recover damages in cases where the negligent act took place prior to their conception.<sup>71</sup> In *Kosky v. The Trustees of the Sisters of Charity*, Tadjell J. of the Supreme Court of Victoria held that a duty of care was owed by a hospital to a child in respect of medical treatment administered to his mother eight years before the child's conception.<sup>72</sup> More recently, in *X. and Y. v. Pal and Others*<sup>73</sup>, the New South Wales Court of Appeal held that doctors owed a duty of care to a child born deformed and suffering from syphilis, which they breached when they failed to screen the child's mother for syphilis prior to the child's conception. Again, there is no reason why recovery of damages would not be permitted where the child's injuries are the result of the negligent behaviour of researchers prior to the child's conception.

There also seems to be no reason why recovery of damages would be limited to cases where the researchers' pre-conception negligence involved acts or omissions in relation to the damaged child's mother; the principle permitting recovery of damages should also extend to pre-conception negligence in relation to the damaged child's father. If a woman may be reasonably foreseen to be likely to get pregnant, it may also be reasonably foreseen that a man may become a parent.<sup>74</sup> Any negligent behaviour on the part of researchers that affects the capacity of a trial participant to conceive (or, in the case of women, to gestate) a healthy child— for example, by affecting sperm or ova or the reproductive organs— therefore could expose the researchers to liability.

*iii. Selecting trial participants*

The risk of liability to children born damaged due to negligent behaviour prior to their birth or conception may make researchers reluctant to include pregnant women, or even women who might become pregnant, in the proposed trial. If the researchers did decide to exclude pregnant women and/or women of childbearing age and capacity from the proposed heroin trial, the law as it stands would not force them to assume a duty of care towards these women by including them in the trial.<sup>75</sup>

The ethical, social and political debate surrounding the question of excluding pregnant or potentially pregnant women from therapeutic research is complex and beyond the scope of this paper.<sup>76</sup> Any decision to exclude women from the trial on this basis should not be made, however, in ignorance of the growing international concern about the under-representation of

<sup>71</sup> See *Renslow v. Mennonite Hospital* (1977) 367 N.E. 2d 1250 (doctor negligently administered a transfusion of Rh-positive blood to an Rh-negative woman, leading to the birth of a damaged child); *Bergstresser v. Mitchell* (1978) 577 F.2d 22 (doctor carrying out an operation negligently damaged a woman's uterus, causing complications during a subsequent pregnancy which resulted in the birth of a damaged child); *Yeager v. Bloomington Obstetrics and Gynaecology Inc.* (1992) 585 N.E. 2d 696 (doctor negligently failed to administer drug to an Rh-negative woman during a previous pregnancy with an Rh-positive foetus, to prevent her from developing sensitivity to Rh-positive blood, which resulted in the birth of a damaged child).

<sup>72</sup> [1982] V.R. 961.

<sup>73</sup> (1991) 23 N.S.W.L.R. 26.

<sup>74</sup> I. Kennedy (1993) 1 Med. L.Rev. 106.

<sup>75</sup> See discussion under "Liability in Negligence: 1.Duty of care; (b) Potential trial participants", *supra*.

<sup>76</sup> See R. Ostini, G. Bammer, P. Dance and R. Goodin, "The Ethics of Experimental Heroin Maintenance" (1993) 19 *Journal of Medical Ethics* 175 at 179; D. Wermeling and A. Selwitz, "Current Issues Surrounding Women and Minorities in Drug Trials" (1993) 27 *The Annals of Pharmacology* 904 at 906–909.

women of childbearing age in research conducted on human beings.<sup>77</sup> That concern recently led to a reversal of the US Food and Drug Administration's policy that excluded women of reproductive age from participating in new drug studies.<sup>78</sup> It has also prompted the US Congress to enact an amendment to the Public Health Service Act, which aims to ensure "clinical research equity" by requiring the National Institutes of Health to take steps to ensure that women and members of minority groups are, where appropriate, included in clinical research projects conducted or supported by the NIH.<sup>79</sup> Researchers should also bear in mind that the law does not demand perfection, it merely requires them to exercise "reasonable care".<sup>80</sup> They must exercise reasonable care towards *all* persons to whom they owe a duty of care when conducting research. Liability therefore will only attach where the harm caused—to a trial participant, a child of a trial participant or any other third party within the scope of the duty of care—is the result of the researchers' dereliction of their duty to conduct research procedures with reasonable care.

## 2. Breach of the duty—what is the standard of care?

The law imposes on health care professionals a duty to exercise reasonable care and skill in their provision of professional services.<sup>81</sup> The duty is a "single comprehensive duty covering all the ways in which a doctor [or a researcher] is called upon to exercise his skill and judgment".<sup>82</sup> This extends to the examination, diagnosis and treatment of the patient and to the provision of information and advice.<sup>83</sup>

The standard of reasonable care and skill required is that of the ordinary skilled person exercising and professing to have that special skill.<sup>84</sup> A doctor (or researcher) need not possess the highest expert skill: it will be sufficient if the doctor (or researcher) exercises the ordinary skill of an ordinary competent person exercising that particular art.<sup>85</sup> An inexperienced doctor (or researcher) will not be permitted to meet a lower standard by virtue of that inexperience, and instead will be judged by the same standard as his or her more experienced colleagues.<sup>86</sup>

### (a) Diagnosis and treatment

In Australia, the standard of professional care to be met by a doctor in respect of diagnosis and treatment is not determined solely by the practices of the medical profession. Australian courts have chosen not to adopt "the *Bolam* test", an approach to the standard of

<sup>77</sup> M. Angell, "Caring for Women's Health - What is the Problem?" (1993) 329(4) *New England Journal of Medicine* 271; R. Merkatz, R. Temple, S.Sobel, K. Feiden, D. Kessler and the Working Group on Women in Clinical Trials, "Women in Clinical Trials of New Drugs: A Change in Food and Drug Administration Policy" (1993) 329(4) *New England Journal of Medicine* 292; D. Wermeling and A. Selwitz, *supra* n.76.

<sup>78</sup> See R. Merkatz *et al.*, *supra* n.77.

<sup>79</sup> See M. Angell, *supra* n.77.

<sup>80</sup> See "Liability in negligence: 2. Breach of the duty— what is the standard of care?", *infra*.

<sup>81</sup> *Rogers v. Whitaker* (1992) 109 A.L.R. 625 at 628 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ.

<sup>82</sup> *Ibid*, approving on this point *Sidaway v. Board of Governors of Bethlem Royal Hospital* [1985] A.C. 871 at 893 *per* Lord Diplock.

<sup>83</sup> *Rogers v. Whitaker* (1992) 109 A.L.R. 625 at 629 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ. and at 636 *per* Gaudron J.; *Gover v. State of South Australia* (1985) 39 S.A.S.R. 543 at 551.

<sup>84</sup> *Rogers v. Whitaker* (1992) 109 A.L.R. 625 at 628 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ.; *Bolam v. Friern Hospital Management Committee* [1957] 1 W.L.R. 582 at 586; see also *Whitehouse v. Jordan* [1981] 1 W.L.R. 246 at 258 *per* Lord Edmund-Davies and *Maynard v. West Midlands R.H.A.* [1984] 1 W.L.R. 634 at 638 *per* Lord Scarman.

<sup>85</sup> See *Bolam v. Friern Hospital Management Committee* [1957] 1 W.L.R. 582 at 586.

<sup>86</sup> *Wilsher v. Essex Area Health Authority* [1986] 3 All E.R. 801 at 831 and at 812-3; *Cook v. Cook* (1986) 162 C.L.R. 376; *Jones v. Manchester Corporation* (1952) 2 Q.B. 852; see I. Kennedy and A. Grubb, *supra* n.5, p.400.

care which was developed by McNair J. in *Bolam v. Friern Hospital Management Committee*<sup>87</sup> and which has been applied almost invariably by English courts.<sup>88</sup> Under that test, what constitutes the exercise of reasonable care in any given circumstances is not determined by the courts, but instead is determined by deferring to medical professional opinion:

The *Bolam* principle may be formulated as a rule that a doctor is not negligent if he acts in accordance with a practice accepted at the time as proper by a responsible body of medical opinion even though other doctors adopt a different practice. In short, the law imposes the duty of care: but the standard of care is a matter of medical judgment.<sup>89</sup>

By contrast, in *Albrighton v. Prince Alfred Hospital*, Reynolds J.A. of the New South Wales Court of Appeal stated that it is not the law that a doctor who has provided medical treatment in accordance with the usual and customary practice and procedure cannot be found to have been negligent.<sup>90</sup> In *F. v. R.*,<sup>91</sup> King C.J. of the Supreme Court of South Australia stated that although “much assistance will be derived from evidence as to the practice obtaining in the medical profession” in determining the standard of care, he was “unable to accept that such evidence can be decisive in all circumstances”. He stated that the court “has an obligation to scrutinize professional practices to ensure that they accord with the standard of reasonableness imposed by law”. The judgment of Bollen J. in the same case was in a similar vein. It was his view that the court “will not produce an answer merely at the dictation of the expert evidence”. He also commented that:

I respectfully think that some of the cases in England have concentrated rather too heavily on the practice of the medical profession.<sup>92</sup>

Most recently, the High Court of Australia in *Rogers v. Whitaker* dispelled any doubts that may have lingered as to whether the *Bolam* principle represented the law in Australia in relation to medical diagnosis or treatment. In their joint judgment, the majority of the High Court acknowledged that “responsible professional opinion will have an influential, *often* a decisive, role to play” when a court is examining whether a doctor provided diagnosis or treatment according to the appropriate standard of care.<sup>93</sup> The majority was not prepared to accept, however, that such opinion would *always* be determinative of the standard of care, and stated the following:

In Australia, it has been accepted that the standard of care to be observed by a person with some special skill or competence is that of the ordinary skilled person professing to have that special skill. But, that standard is not determined solely or even primarily by reference to the practice followed or supported by a responsible body of opinion within the relevant profession or trade. Even in the sphere of

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<sup>87</sup> [1957] 1 W.L.R. 582.

<sup>88</sup> See *Whitehouse v. Jordan* [1981] 1 W.L.R. 246; *Maynard v. West Midlands R.H.A.* [1984] 1 W.L.R. 634; *Hills v. Potter* [1984] 1 W.L.R. 641; *Sidaway v. Board of Governors of Bethlem Royal Hospital* [1985] A.C. 871. Cf. *Hucks v. Cole* (1968) 1123 Sol. Jo. 483 and *Clarke v. Adams* (1950) 94 Sol. Jo. 599.

<sup>89</sup> *Sidaway v. Board of Governors of Bethlem Royal Hospital* [1985] A.C. 871 at 881 *per* Lord Scarman.

<sup>90</sup> (1980) 2 N.S.W.L.R. 542 at 562. See Australian Torts Reporter 9-180 at 15,273.

<sup>91</sup> (1983) 33 S.A.S.R. 189. Although this case concerned a doctor’s alleged negligence in relation to the provision of information and advice, the court’s general comments on the extent to which the law should defer to medical professional opinion are also instructive in relation to diagnosis and treatment.

<sup>92</sup> *Ibid.*

<sup>93</sup> (1992) 109 A.L.R. 625 at 633 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ., emphasis added.

diagnosis and treatment, the heartland of the skilled medical practitioner, the *Bolam* principle has not always been applied.<sup>94</sup>

Gaudron J. in her minority judgment was even clearer in her rejection of the *Bolam* principle in relation to diagnosis and treatment:

Even in the area of diagnosis and treatment there is, in my view, no legal basis for limiting liability in terms of the rule known as “the *Bolam* test” which is to the effect that a doctor is not guilty of negligence if he or she acts in accordance with a practice accepted as proper by a responsible body of doctors skilled in the relevant field of practice. That is not to deny that, having regard to the onus of proof, “the *Bolam* test” may be a convenient statement of the approach dictated by the state of the evidence in some cases. As such, it may have some utility as a rule-of-thumb in some jury cases, but it can serve no other useful function.<sup>95</sup>

The above judicial comments were made with reference to allegedly negligent medical treatment or diagnosis, in the context of medical care that did not have a research component. The doubts expressed in these cases on the wisdom of a court deferring to medical opinion may carry even greater force in relation to the conduct of therapeutic research, because determining the standard of care that should be met by researchers arguably is a matter for public policy and not professional opinion.<sup>96</sup> An Australian court therefore would not defer unquestioningly to the professional opinion of a competent body of medical researchers when the court is assessing whether the defendant researchers exercised reasonable care in performing trial procedures. This does not mean that the researchers in the proposed trial should ignore the opinions and practices adopted by their fellow researchers, both in Australia and internationally. Evidence of the researchers’ awareness of and adoption (where appropriate) of measures used by other researchers to maximise the protection of research participants would support a court’s conclusion that the researchers exercised reasonable care when carrying out trial procedures. This would be particularly true if those measures adhered to the principles developed by the scientific community specifically to protect research participants, as contained in documents such as the NHMRC *Statement on Human Experimentation and Supplementary Notes*<sup>97</sup> and the *Declaration of Helsinki*.<sup>98</sup>

## **(b) Advice and information**

### *i. A patient-centred test*

The provision of information and advice is a very important aspect of the duty of care owed by researchers to trial participants. Unless trial participants are adequately informed about what is involved in the proposed procedures and about the implications to them of participating, any consent they give will be meaningless.<sup>99</sup>

This duty to provide adequate information to a trial participant therefore is often described as a duty to obtain “informed consent”. The use of the term “informed consent” was disapproved, however, by the majority of the High Court in *Rogers v. Whitaker*.<sup>100</sup> The

<sup>94</sup> *Ibid.* at 631 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ.

<sup>95</sup> (1992) 109 A.L.R. 625 at 635-6.

<sup>96</sup> For a similar argument, see I. Kennedy and A. Grubb, *supra* n.5, p. 876.

<sup>97</sup> National Health and Medical Research Council, *supra* n.1.

<sup>98</sup> Recommendations guiding physicians in biomedical research involving human subjects, adopted by the 18th World Medical Assembly (Helsinki) 1964; and amended by the 19th World Medical Assembly (Tokyo) 1975, 35th World Medical Assembly (Venice) 1983 and 41st World Medical Assembly (Hong Kong) 1989.

<sup>99</sup> *Rogers v. Whitaker* (1992) 109 A.L.R. 625 at 633 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ.

<sup>100</sup> *Ibid.* at 633.

term is misleading, because it suggests that failure to meet the standard of care with respect to provision of information will vitiate the trial participant's consent (and render the researcher liable in battery) as well as constituting negligence. This is not the case, as a consent will be adequately informed provided the trial participant has been informed in broad terms of the nature and effect of the proposed procedures.<sup>101</sup> The level of information that a researcher must provide to avoid liability in negligence is considerably higher, therefore a researcher may be liable in negligence without having committed a battery.

The standard of care in Australia with respect to the provision of information and advice concerning medical procedures is not determined by medical professional practice. In *Rogers v. Whitaker*, the High Court of Australia unequivocally rejected the application of the *Bolam* test in this context, stating that whether a patient has been given all the relevant information to choose between undergoing and not undergoing the proposed treatment is not a question the answer to which depends upon medical standards or practices.<sup>102</sup> The High Court adopted the following approach to determining the standard of care in relation to the provision of information and advice to a patient:

The ultimate question, however, is not whether the defendant's conduct accords with the practices of his profession or some part of it, but whether it conforms to the standard of reasonable care demanded by the law. That is a question for the court and the duty of deciding it cannot be delegated to any profession or group in the community.<sup>103</sup>

To conform to the standard of reasonable care demanded by the law, a doctor must inform a patient of any material risk inherent in the proposed medical procedure. A risk is material if, in the circumstance of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it; or if the doctor is or should reasonably be aware that this particular patient, if warned of the risk, would be likely to attach significance to it.<sup>104</sup>

The test developed by the High Court is patient-centred, as the doctor's duty to inform "takes its precise content, in terms of the nature and detail of the information to be provided, from the needs, concerns and circumstances of the patient".<sup>105</sup> The scope of the duty is determined not by the medical profession, but rather by the special needs or concerns of the individual patient of which the doctor is made aware (for example, by the patient's specific inquiries), or by the needs and concerns of a reasonable person in this patient's condition. The practice or practices of the medical profession will only be considered when a court must assess whether a doctor was justified in invoking "therapeutic privilege" to withhold information from a patient. This will only be justified where "there is a particular danger that the provision of all relevant information will harm an unusually nervous, disturbed or volatile patient".<sup>106</sup>

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<sup>101</sup> See discussion under "Liability in Negligence: 2. ...without that person's legally valid consent; (b) Information", *supra*.

<sup>102</sup> (1992) 109 A.L.R. 625 at 633 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ. and at 636 *per* Gaudron J.

<sup>103</sup> *Rogers v. Whitaker* (1992) 109 A.L.R. 625 at 631-2 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ., quoting with approval *F. v. R.* (1983) 33 S.A.S.R. 189 at 194 *per* King C.J. *Cf.* the approach of the English courts to this issue in *Sidaway v. Board of Governors of Bethlem Royal Hospital* [1985] A.C. 871 and *Bolam v. Friern Hospital Management Committee* [1967] 1 W.L.R. 582, disapproved by the High Court of Australia in *Rogers v. Whitaker*.

<sup>104</sup> *Rogers v. Whitaker* (1992) 109 A.L.R. 625 at 634 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ.

<sup>105</sup> *Ibid.* at 636 *per* Gaudron J; see also at 632-634 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ. (approving the approach of King C.J. in *F. v. R.* (1983) 33 S.A.S.R. 189 at 192-3).

<sup>106</sup> See *ibid* at 633-4 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ. Note that Gaudron J. confined the application of the "therapeutic privilege" to cases involving medical emergency and cases where the patient is unable

The issue in *Rogers v. Whitaker* was whether a doctor's failure to disclose to his patient the risk of sympathetic ophthalmia associated with eye surgery constituted negligence. Judicial analysis in that case therefore focused on when a doctor is obliged to disclose a *risk inherent in medical treatment*. The principles stated by the High Court in *Rogers v. Whitaker* nonetheless provide guidance as to how an Australian court would define a researcher's duty to provide information to a participant in therapeutic research. The scope of that duty would be similarly "patient-centred", as what should be disclosed would be determined by the needs and concerns of trial participants.

In addition to disclosing any information essential to avoid a claim in battery,<sup>107</sup> researchers would need to disclose any information to which a trial participant would attach significance in deciding whether to participate in the research. That information would be the information to which a reasonable person in the trial participant's position would attach significance; or, where the researcher is aware of any special needs or concerns of an individual trial participant, the information to which that individual would attach significance.

The information to which a reasonable person, in the position of a dependent user considering whether to participate in the proposed heroin trial, would attach significance would include information about the risks (which are not "far-fetched or fanciful"<sup>108</sup>) associated with the research; information about alternative methods of treatment available to the dependent user if he or she did not participate in the trial; information about any specific tests, hospital visits or trial procedures that might inconvenience or worry the dependent user; and information about any treatment or assessment that would be needed or provided after the conclusion of the trial.<sup>109</sup> This is not an exhaustive list, and indeed an exhaustive list cannot be provided because what a dependent user would reasonably want to know about the trial will depend on exactly what the trial involves. The more full and frank the researchers' disclosure about what the trial involves and about the possible and likely consequences for trial participants, the less likely the researchers will be liable in negligence.

It is not clear whether the law would impose a duty on researchers to question the individual trial participant in an attempt to discover whether that individual has any special needs or concerns that would require the provision of "extra" information. It does seem, however, that inquiries by the trial participant should alert the researchers to the special needs and concerns of an individual,<sup>110</sup> and that the researchers should provide information to address those special needs and concerns. This would be so whether the inquiries took place before the commencement of the trial or at any time during the trial. Any questions asked by a trial participant should of course be answered truthfully.<sup>111</sup>

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to "receive, understand or properly evaluate the significance of the information that would ordinarily be required with respect to his or her condition or the treatment proposed": *ibid* at 637.

<sup>107</sup> See discussion under "Liability in Negligence: 2. ...without that person's legally valid consent; (b) Information", *supra*.

<sup>108</sup> *Rogers v. Whitaker* (1992) 109 A.L.R. 625 at 636 *per* Gaudron J.; *Wyong Shire Council v. Shirt* (1980) 29 A.L.R. 217.

<sup>109</sup> See I. Kennedy and A. Grubb, *supra* n.5, p.877; A. Grubb, *supra* n.5, p.II.20.

<sup>110</sup> In *Rogers v. Whitaker*, the plaintiff lost the sight in her left eye due to sympathetic ophthalmia resulting from surgery performed in an unsuccessful attempt to restore the sight in her right eye. Sympathetic ophthalmia occurs once in approximately 14 000 such operations. Before the operation, the plaintiff had "incessantly" questioned the defendant doctor about possible complications of the eye surgery. Although she had not specifically asked him whether the operation on her right eye could affect her left eye, she had repeatedly expressed her great concern that no injury should befall her one good eye. Her inquiries made the doctor aware that she had special needs and concerns, and he should have informed her of the risk of sympathetic ophthalmia because that risk was one to which she, as a person greatly concerned about losing the sight in her good eye, would have attached significance.

<sup>111</sup> See *Smith v. Auckland Hospital Board* (1965) N.Z.L.R. 191.



It is unclear whether the law would permit a researcher to invoke “therapeutic privilege” and withhold information on the basis that disclosure would endanger the trial participant’s physical or mental health. In *Halushka v. University of Saskatchewan*, Hall J.A. of the Saskatchewan Court of Appeal made the following comment:

Éthe duty imposed upon those engaged in medical researchÉto those who offer themselves for experimentationÉis as least as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient. There can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practiceÉThe example of risks being properly hidden from a patient when it is important that he should not worry can have no application in the field of research. The subject of medical experimentation is entitled to [É] full and frank disclosureÉ<sup>112</sup>

The medical research that had taken place in *Halushka* was clearly non-therapeutic, but it can be argued that the comments of Hall J.A. are also applicable to therapeutic research.<sup>113</sup> Those conducting therapeutic research therefore would be advised to exclude an individual from the trial if at any stage it becomes apparent that the individual would be harmed by receiving full information about the research.

*ii. Communication and consent forms*

In *Rogers v. Whitaker*, the High Court outlined a legal test that determines *what* a doctor should tell a patient, not *how* the patient should be told. The test enunciated by the High Court was driven, however, by the principle that doctors should provide information to meet the needs, concerns and circumstances of the patient rather than conform to medical professional opinion. The patient’s needs, concerns and circumstances cannot be addressed without attention to *how* the patient should be told, because the doctor will not have an understanding of what those needs, concerns and circumstances are unless doctor and patient communicate effectively. The doctor cannot know what would be significant to a reasonable person in the patient’s position unless the doctor understands that position; nor can the doctor respond to the individual patient’s “special needs” if the doctor does not understand the reason for the patient’s particular and perhaps unusual concerns. This argument applies equally to the relationship between researcher and trial participant.

The more effective the communication between researchers and trial participants, therefore, the more likely it will be that the researchers discharge their legal duty to provide trial participants with information and advice about the proposed research. Well-crafted consent forms can assist researchers in providing information to trial participants, provided they are not used as a substitute for explanation and discussion. Recall that the fact that a trial participant has signed a consent form will not of itself protect researchers from liability in battery;<sup>114</sup> nor will a signed consent form of itself protect them from liability in negligence. The law is concerned with the information about risks, alternatives and so on that is actually received by the trial participant. The trial participant is most likely to receive that information if the researchers provide the information in both written and spoken form, in a way in which the trial participant is most likely to understand what is being explained. Written and spoken information (especially explanations of medical terms) should be simply worded, but this should not be used as an excuse to omit explanations that a researcher may feel are too

<sup>112</sup> (1965) 52 W.W.R. 608.

<sup>113</sup> See A. Grubb, *supra* n.5, p.II.20.

<sup>114</sup> See discussion under “Liability in Negligence: 2. ...without that person’s legally valid consent; (b) Information”, *supra*.

complicated.<sup>115</sup> Researchers would be advised to provide potential trial participants with the following:<sup>116</sup>

- a) a letter inviting the person to participate in the research;
- b) an information sheet, containing explanation of all the matters necessary to discharge the researcher's obligation to inform (and thereby avoid liability in battery and negligence). Where possible, the information sheet (and the letter of invitation) should be written in the conditional tense: *e.g.* "If you were to agree to take part, we would ask you toÉ" because consent should not be assumed;<sup>117</sup>
- c) encouragement to ask questions;
- d) enough time (at least 24 hours) to take away the written information and consider whether to take part;
- e) a means of contacting the researcher while deciding.

### 3. Causation

To bring a successful claim in negligence, a plaintiff must also establish that the defendant's breach of duty caused the damage suffered. It can be difficult to prove causation in cases involving damage that occurs in the context of medical treatment, and many negligence actions against doctors fail on this point.<sup>118</sup> This difficulty would also face a plaintiff who suffers damage in the context of therapeutic research.

The High Court of Australia has adopted a "common sense" approach to causation. Causation will be established if the defendant's breach of duty was so connected with the plaintiff's injury that, as a matter of ordinary common sense and experience, it should be regarded as a cause of the injury.<sup>119</sup> Considerations of policy and value judgments will necessarily enter the assessment of whether the breach caused the injury.<sup>120</sup>

Where the breach of duty involves the researchers' failure properly to inform a trial participant, it will be necessary to prove more than that the harm suffered arose by virtue of the trial participant's participation in the trial. Additionally it must be shown that the trial participant would not have consented to being involved in the trial had he or she been properly informed. An Australian court would determine this by asking what this particular trial participant (rather than a reasonable person in the position of the trial participant) would have decided in the circumstances.<sup>121</sup> Note that the court must evaluate the evidence given by the plaintiff in the light of all the circumstances and need not necessarily accept the trial participant's assertions as to what he or she would have decided.<sup>122</sup>

Establishing causation also requires the plaintiff to show that the damage suffered was a "reasonably foreseeable" consequence of the defendant's negligence, rather than one that was

<sup>115</sup> T. Hughes and C. Foster, "Communicating With the Potential Research Subject" in C. Foster, *supra* n. 5, pp. II.23-25.

<sup>116</sup> *Ibid.*, p.II.25.

<sup>117</sup> *Ibid.*, p.II.23.

<sup>118</sup> For example, *X. and Y. v. Pal and Others* (1991) 23 N.S.W.L.R. 26.

<sup>119</sup> *March v. E. & M.H. Stramare Pty Ltd* (1991) 171 C.L.R.506 *per* Mason C.J., Deane, Toohey and Gaudron JJ.

<sup>120</sup> *Ibid.*

<sup>121</sup> *H. v. Royal Alexandra Hospital* (1990) Aust.Torts Reports 81-000; *Rogers v. Whitaker* (1991) Aust. Torts Reports 81-113 (NSW Court of Appeal); see also *Gover v. State of South Australia* (1986) 39 S.A.S.R. 543.

<sup>122</sup> *H. v. Royal Alexandra Hospital* (1990) Aust. Torts Reports 81-000; *Rogers v. Whitaker* (1991) Aust. Torts Reports 81-113 (NSW Court of Appeal).

too remote. Consequences are foreseeable if they are the result of the occurrence of a risk that a reasonable person would describe as “real” rather than “far-fetched”.<sup>123</sup> What must be foreseeable is the type or kind of injury suffered, not its exact extent or manner of occurrence.<sup>124</sup> The recent case of *Miller v. State of Tasmania* illustrates the application of this aspect of establishing causation.<sup>125</sup> The plaintiff in that case was a psychiatric nurse, who had been caring for a severely disabled young boy who later choked to death. After his death the nurse suffered from a mental illness, which was said not to have been a reasonably foreseeable consequence of her employer’s failure to provide her with adequate emotional support following the boy’s death.

#### 4. Damage

Unlike battery, negligence is not a tort that is actionable *per se*. To bring a successful negligence action, a plaintiff must have suffered actual damage of a kind recognised by the law.

A plaintiff injured as the result of the negligent conduct of therapeutic research is most likely to have suffered physical injury. The courts have placed very few limits on recovery for physical injury, because the law considers this type of damage to be the most serious and therefore the most worthy of compensation. A successful plaintiff will be compensated for his or her pecuniary losses (including loss of earning capacity, the cost of medical or nursing care, and the cost of housekeeping services) and non-pecuniary losses (pain and suffering, loss of amenities, and loss of expectation of life).<sup>126</sup>

The law also compensates for “nervous shock”, which is injury caused by the impact on the mind of external events.<sup>127</sup> This impact on the mind can be the result of suffering physical injury oneself; of fearing injury will be suffered by oneself or by another; or of witnessing an event (or its immediate aftermath) in which another is injured.<sup>128</sup> The law generally is reluctant to compensate for this type of injury and has limited the circumstances in which a plaintiff may be awarded damages. A plaintiff seeking to recover for nervous shock resulting from the negligent conduct of therapeutic research therefore will not succeed unless he or she has suffered one or more of the following: physical injury (such as miscarriage, a heart attack or a stroke); a “recognised psychiatric illness” such as hysteria, neurosis or depression; or the psychosomatic effects of a psychological illness (such as paralysis).<sup>129</sup>

### Liability for disclosing confidential information

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<sup>123</sup> F. Trindade and P.Cane, *supra* n.12, p.372.

<sup>124</sup> *Ibid.*

<sup>125</sup> (1992) Aust. Torts Reports 81-175; see P. MacFarlane, *supra* n.22, p.103.

<sup>126</sup> See F. Trindade and P. Cane, *supra* n.12, pp.390-404.

<sup>127</sup> *Ibid.*, p.286.

<sup>128</sup> See *ibid.*, pp.289-293.

<sup>129</sup> *Ibid.*, p.286.

## 1. Doctors and confidentiality

A doctor is under both an ethical and a legal obligation to respect the confidences of patients.<sup>130</sup> The doctor may be characterised as the patient's "confidant", under the following broad general principle:

Éa duty of confidence arises when confidential information comes to the knowledge of a person (the confidant) in circumstances where he has notice, or is held to have agreed, that the information is confidential, with the effect that it would be just in all the circumstances that he should be precluded from disclosing the information to others.<sup>131</sup>

The legal obligation to maintain confidentiality extends to all information concerning a patient that the doctor receives, either directly from the patient or from other sources, in his or her capacity as the patient's doctor.<sup>132</sup> A patient may go to court to obtain an injunction to prevent disclosure of confidential information,<sup>133</sup> or to obtain damages if the disclosure has already occurred.<sup>134</sup> The precise legal basis of an action for breach of confidence, however, is unclear. It could be argued that the action lies in contract (breach of confidence amounting to breach of an implied term in a contract between the parties), in negligence (breach of confidence being a failure to exercise reasonable care) or in equity (breach of confidence violating the equitable principle that confidences should be respected).<sup>135</sup>

It is also unclear whether unauthorised disclosure of confidential information is actionable *per se*, *i.e.* the disclosure is sufficient harm in itself, or whether damages will only be awarded if the plaintiff has suffered some additional detriment.<sup>136</sup> It is, however, always open to a plaintiff who has suffered physical harm as a result of a breach of confidence to bring an ordinary negligence action. This was the approach taken by the plaintiff in *Furniss v. Fitchett*, a New Zealand case in which the plaintiff successfully sued her doctor in negligence for disclosing information about her mental state in a letter to her husband. She became aware of the existence of this letter during subsequent divorce proceedings and as a result suffered injury to her health. The court held that the doctor had breached his duty of care towards his patient, because he should reasonably have foreseen that the letter would come to her attention and cause her injury.<sup>137</sup>

A doctor's duty at common law to maintain confidentiality is not absolute. Disclosure is permitted with the consent of the patient, or if authorised or required by statute. Disclosure may also be justified in the public interest.<sup>138</sup> It is important to note that "there is a wide difference between what is interesting to the public and what it is in the public interest

<sup>130</sup> A. Dix *et al.*, *supra* n.8, p.65 - 71; I. Kennedy and A.Grubb, *supra* n.5, p.160-167; *Furniss v. Fitchett* [1958] N.Z.L.R.396; *Slater v. Bissett* (1986) 69 ACTR. 25.

<sup>131</sup> *A-G v. Guardian Newspapers (No 2)* [1988] 3 All E.R. 545 at 658 *per* Lord Goff.

<sup>132</sup> I. Kennedy and A. Grubb, *supra* n.5, p.162, quoting F. Gurry, *Breach of Confidence*, Clarendon Press, 1985, pp.148-149; A. Dix *et al.*, *supra* n.8, p. 65.

<sup>133</sup> *Goddard v. Nationwide Building Society* [1986] 3 All E.R. 264 at 271 *per* Nourse L.J.

<sup>134</sup> See A. Dix *et al.*, *supra* n. 8, p. 67; I. Kennedy and A. Grubb, *supra* n.5, p.164.

<sup>135</sup> P. MacFarlane, *supra* n.22, p.124; A. Dix *et al.*, *supra* n. 8, p.68. See also I. Kennedy and A. Grubb, *supra* n.5, p.161, quoting F. Gurry, *Breach of Confidence*, Clarendon Press, 1985.

<sup>136</sup> A. Dix *et al.*, *supra* n. 8, p.67.

<sup>137</sup> [1958] N.Z.L.R. 396.

<sup>138</sup> *Ibid.*; *X. v. Y.* [1988] 2 All E.R. 648.

to make known”.<sup>139</sup> In *W. v. Egdell*, the English Court of Appeal stated that disclosure may only be justified in the public interest if it is necessary to avoid a “real risk of consequent danger to the public”.<sup>140</sup> The case involved the disclosure by a psychiatrist of a medical report he had prepared concerning a detained prisoner under the Mental Health Act. Disclosure to the hospital authorities and to the Home Secretary was considered to be justified in the public interest, on the basis that the report revealed the danger of violence the patient posed to others.

It can also be argued that in certain circumstances the public interest places a doctor under a *duty* to disclose confidential information, for example where disclosure is necessary to protect identifiable third persons from a serious risk of violence or other danger.<sup>141</sup>

Whether the doctor has a discretion or is under a duty, any disclosure to avert danger would only be justified if done in a way that preserved the patient’s confidence as fully as possible in the circumstances. The public interest requires that “care should be exercised in deciding what shall be reported and to whom”.<sup>142</sup> For example, if disclosure to the threatened third party or to the relevant authorities would be sufficient to avert the potential harm, a doctor would not be justified in disclosing confidential information to the world at large.

## 2. Researchers and confidentiality

### (a) Common law

If the law views a doctor as the patient’s confidant, the relationship between a researcher and a trial participant must also impose a common law duty on the researcher to maintain confidentiality. The duty will apply in respect of information the researcher learns about the trial participant in his or her capacity as a researcher. The scope and nature of a researcher’s duty of confidentiality at common law will be determined by the same principles that shape a doctor’s duty to maintain the confidences of patients.

### (b) ACT legislation

That common law duty appears not to apply, however, to the conduct of the proposed heroin trial. This is due to the enactment of the Epidemiological Studies (Confidentiality) Act 1992 (ACT), which imposes a statutory duty to maintain confidentiality in respect of any “prescribed study”. The proposed heroin trial has been declared to be a “prescribed study” for the purposes of this Act.<sup>143</sup> The Act therefore prohibits anyone involved in conducting the proposed trial from directly or indirectly “making a record of, divulging or communicating to any person” any information concerning the affairs of another person, where that

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<sup>139</sup> *British Steel Corporation v. Granada Television Ltd* [1981] 1 All E.R. 417 at 155 *per* Lord Wilberforce. For example, in *X. v. Y.* [1988] 2 All E.R. 648, Roe J. granted an injunction to restrain a newspaper from publishing the names of two doctors who were HIV-positive, rejecting the argument that disclosure of this information would be in the public interest.

<sup>140</sup> [1990] 2 W.L.R. 474.

<sup>141</sup> *Tarasoff v. Regents of the University of California* (1976) 551 P.2d 334; *Furniss v. Fitchett* [1958] N.Z.L.R. 396 (“Take the case of a doctor who discovers that his patient entertains delusions in respect of another, and in his disordered state of mind is liable at any moment to cause death or grievous bodily harm to that other. Can it be doubted for one moment that the public interest requires him to report that finding to someone?”); *Duncan v. Medical Practitioners Committee* [1986] 1 N.Z.L.R. 513 at 521 (“There may be occasions...when a doctor receives information involving a patient that another’s life is immediately endangered and urgent action is required. The doctor must then exercise his professional judgment based upon the circumstances, and if he fairly and reasonably believes such a danger exists then he must act unhesitatingly to prevent injury or loss of life even if there is a breach of confidentiality”).

<sup>142</sup> *Furniss v. Fitchett* [1958] N.Z.L.R. 396; *Duncan v. Medical Practitioners Committee* [1986] 1 N.Z.L.R. 513 at 521.

<sup>143</sup> Epidemiological Studies (Confidentiality) Regulations, No. 24 of 1992.

information was acquired by virtue of the conduct of the trial.<sup>144</sup> This prohibition will not prevent the publication of “conclusions based on, statistics derived from, or particulars of procedures used in” the trial, provided they are not published in a manner that enables the identification of any individual person.<sup>145</sup>

“Information concerning the affairs of another person” is an extremely broad phrase,<sup>146</sup> and would certainly extend to any information about a trial participant’s drug dependence, lifestyle or participation in the trial. It would also extend to any information gained in the course of the trial concerning the personal affairs, including the drug dependence or other behaviours, of any person who was not a participant in the trial. Information protected under the Act therefore is not confined to information that relates to the affairs of trial participants. Disclosure of information in contravention of the Act carries a penalty of \$5 000 and/or imprisonment for 12 months.<sup>147</sup>

The statutory prohibition is not absolute. Protected information may be disclosed “for the purpose of the conduct of that study”.<sup>148</sup> The Act does not define this phrase, but presumably it would at a minimum allow the researchers to communicate freely with other members of the research team about matters relating to trial participants.<sup>149</sup> Any doubt regarding this conclusion is dispelled by section 12 of the Act, which permits disclosure of “information concerning the affairs of a person to whom a prescribed study relates to a person assisting in the conduct of that study”. The Minister may also give permission for the researchers to give access to documents prepared or obtained in the conduct of the trial to researchers engaged in another “prescribed study”.<sup>150</sup>

The researchers would also be permitted to discuss information protected under the Act with the person who supplied them with the information.<sup>151</sup> The Act also expressly permits disclosure of protected information to the person whose affairs the information concerns,<sup>152</sup> because that person may not be the person who supplied them with the protected information. Where the protected information concerns the affairs of more than one person, the information can be disclosed to any of those people, provided the researchers obtain consent to the disclosure from each person whose affairs that information concerns.<sup>153</sup> Where protected information may be disclosed to a person because that person is in one of the categories discussed in this paragraph, the information can also be disclosed to anyone nominated by that person.<sup>154</sup>

The researchers would have been able at common law to disclose confidential information in the public interest. The public interest exception would have permitted or required them to disclose confidential information to the extent necessary to protect third

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<sup>144</sup> Sections 4 and 6.

<sup>145</sup> Section 11(1).

<sup>146</sup> Section 3(3) provides that “information concerning the affairs of another person” includes information as to the existence, non-existence or whereabouts of a document concerning the affairs of a person.

<sup>147</sup> Sections 4 and 6.

<sup>148</sup> Sections 4 and 6.

<sup>149</sup> This would reflect the position at common law: see *Slater v. Bisset* (1986) 69 ACTR. 25.

<sup>150</sup> Section 5.

<sup>151</sup> Section 7(a).

<sup>152</sup> Section 7(b).

<sup>153</sup> Section 7(c).

<sup>154</sup> Section 7(d).

parties from danger.<sup>155</sup> The Epidemiological Studies (Confidentiality) Act, however, seems to have removed this common law exception to the researchers' duty to maintain confidentiality. The Act does not expressly permit disclosure in the public interest, and it would be very difficult for a court to hold that the exception is implicit in this legislation.<sup>156</sup> The only section of the Act that acknowledges that protected information may concern the affairs of more than one person requires the consent of each of those people to disclosure of the information.<sup>157</sup> This would only allow researchers to warn a third party endangered by a trial participant if that trial participant consented to the disclosure, which is unlikely.<sup>158</sup>

A court determined to preserve something resembling the common law exception might do so by offering an extremely wide interpretation of the phrase "for the purpose of the conduct of the study" in sections 4 and 6. Disclosure to protect a third party could be seen as necessary to ensure that the trial was conducted in a safe and responsible manner, with due consideration for its impact on other members of society, and thus as "for the purpose of the [proper] conduct of the study". Another way of avoiding the statutory barrier to disclosure in the public interest might be for a researcher to ask the court for an injunction to restrain a potentially dangerous trial participant. Although section 8 of the Act prevents a researcher from being *required* to divulge or communicate protected information to a court, it does not seem to prevent a researcher from *volunteering* that information to a court. Although section 11(2) would prohibit disclosure of "conclusions based on, statistics derived from, or particulars of procedures used in" the trial to a court in a manner that would enable the identification of an individual person, a researcher might be able to present information carefully to a court in a way that did not involve reference to conclusions, statistics or particulars of procedures.

### (c) Commonwealth legislation

The conduct of the proposed heroin trial could also be affected by the Epidemiological Studies (Confidentiality) Act 1981 (Cth). The provisions of this Commonwealth Act that restrict disclosure of information are substantially the same as those of the ACT legislation. In order for the proposed trial to fall within the ambit of the Epidemiological Studies (Confidentiality) Act 1981 (Cth), the trial would need to be declared by Regulations made under the Act to be a "prescribed study" for the purposes of the Act. This has not been done, and cannot be done unless the proposed trial will be an epidemiological study "conducted by, or on behalf of, the Commonwealth".<sup>159</sup>

The *Guidelines for the Protection of Privacy in the Conduct of Medical Research*<sup>160</sup> will apply to the proposed trial if it either involves disclosure of personal information by a Commonwealth agency, or involves the collection of personal information by a Commonwealth agency.<sup>161</sup> These Guidelines have been approved by the Privacy Commissioner under section 95 of the

<sup>155</sup> See discussion under "Liability for Disclosing Confidential Information: 1. Doctors and Confidentiality" and under "Liability in Negligence: 1. The duty of care— to whom is it owed?; (c) Third parties", *supra*.

<sup>156</sup> The Act contains no general phrase such as "except with lawful excuse" into which the public interest exception could be read easily. Note, however, the creative approach adopted by the court in *Tarasoff v. Regents of the University of California* (1976) 551 P.2d 334; see M. Neave, *supra* n.64 at 26-28.

<sup>157</sup> Section 7(c).

<sup>158</sup> See *W. v. Egde* [1990] 2 W.L.R. 474.

<sup>159</sup> Section 3(1); *cf.* s3(1) of the Epidemiological Studies (Confidentiality) Act 1992 (ACT) legislation, which states that the ACT legislation may apply to any epidemiological study "conducted in the Territory", presumably regardless of by whom or on whose behalf the study is conducted.

<sup>160</sup> *Commonwealth of Australia Gazette* No.P 19, 1 July 1991, Canberra, AGPS

<sup>161</sup> *Ibid.*, p.5 (Preliminary Notes).

Privacy Act 1988 (Cth), and are in force until 30 June 1994.<sup>162</sup> Compliance with the Guidelines when conducting research will prevent the researchers from infringing any of the Information Privacy Principles set out in the Privacy Act.<sup>163</sup> Note that it is preferable for researchers to obtain an individual's consent to any disclosure of personal information relating to that individual, rather than disclosing that information without the individual's consent simply because non-consensual disclosure would be justified under certain provisions of the Privacy Act<sup>164</sup> or under the Guidelines.<sup>165</sup>

## Conclusion

The legal duties owed by the researchers in the proposed trial are important because non-compliance on the part of the researchers would expose them to civil liability: in battery, in negligence, and/or for disclosure of confidential information. To avoid civil liability, the researchers will need to be aware of the scope and detail of their legal obligations. They must also be alerted to situations in which their legal duties may be unclear or conflicting.

Non-compliance with these legal duties would do more than expose the researchers to liability. It would also constitute a violation of those rights and dignities of the trial participants (and of others affected by the trial, to whom the researchers owe a duty of care) that the law deems sufficiently important to protect. For this reason, the legal rules outlined in this paper— particularly the rules relating to battery and negligence— should be viewed as minimum standards only. The researchers should focus less on avoiding liability than on ensuring that each individual trial participant, and each other individual to whom a duty of care is owed, is treated with maximum respect.

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<sup>162</sup> At which time the Guidelines shall either continue to apply or be replaced with new or revised Guidelines, according to the decision of the Privacy Commissioner: *ibid.*, p.16 (Review of Operations of the Guidelines).

<sup>163</sup> *Ibid.*, p.6 (Introduction: paragraph 1.3). The possible consequences of failure to comply with an Information Privacy Principle are outlined in Part V of the Privacy Act 1988 (Cth).

<sup>164</sup> Disclosure of personal information by Commonwealth agencies is permitted under the circumstances specified in Information Privacy Principle 11.

<sup>165</sup> *Commonwealth of Australia Gazette* No.P 19, 1 July 1991, Canberra, AGPS, p.5 (Preliminary Notes).



## Feasibility Research into the Controlled Availability of Opioids

The Feasibility Research into the Controlled Availability of Opioids arose from a request to the National Centre for Epidemiology and Population Health (NCEPH) from the Select Committee on HIV, Illegal Drugs and Prostitution established by the Australian Capital Territory (ACT) Legislative Assembly.

A first stage of research, conducted in collaboration with the Australian Institute of Criminology (AIC), found that a trial to provide opioids, including heroin, to dependent users was feasible in principle. It was recommended that a second stage of feasibility investigations to examine logistic issues be conducted.

The first stage investigations examined illegal drug use in the ACT, the arguments for and against the controlled availability of opioids as reviewed in the literature, the current Australian political context for a trial, the role of interest groups in social controversies, legal issues, possible options for a trial, ethical issues, attitudes to a trial in the general community and among key interest groups (police, service providers, and illegal drug users and ex-users), and evaluation by a randomised controlled trial.

In addition, a proposal for a trial was developed as the starting point for the Stage 2 investigations.

The research which needs to be conducted to determine Stage 2 logistic feasibility can be divided into five areas:

- core information (for example, estimating numbers of users, determining relevant characteristics of ACT-based users, documenting the known information about the psychopharmacological and toxicological effects of opioids);
- information relevant to trial design and evaluation;
- information relevant to service provision;
- information about relevant legal, law enforcement and criminological matters;
- community and key stakeholder acceptability of a specific trial proposal.

The Stage 2 research is also governed by the following principles:

- the research should have intrinsic value so that, regardless of whether or not a trial goes ahead, the research should be of value to treatment services or to drug policy generally;
- research should be conducted in all relevant disciplines and the disciplinary findings should be integrated to address the central problem;
- the process should involve to the greatest extent possible the key interest groups— illicit drug users, ex-users, service providers, police, policy makers and the community.

Stage 2 of the feasibility research into the controlled availability of opioids has many components. As significant advances are made in each particular substudy, we publish the results as a working paper, so that the information is available for discussion in the public arena.

## Publications

### Reports

- \* National Centre for Epidemiology and Population Health (1991), *Feasibility Research into the Controlled Availability of Opioids. Volumes 1 and 2*. NCEPH, The Australian National University, Canberra.
- \* Bammer, G. and Gerrard, G. (eds) (1992), *Heroin Treatment – New Alternatives*, Proceedings of a one-day seminar, Becker House, Canberra, November 1991.

### Working papers

- \* Larson, A. (1992), *Estimating the numbers of heroin users in the ACT*, Feasibility Research into the Controlled Availability of Opioids Stage 2, Working Paper Number 1.
- \* Bammer, G. (ed) (1993), *Australian drug markets research: What are we doing? Where are we going? What are the gaps? Proceedings of a one-day workshop held at the Scarth Room, University House, The Australian National University, Monday 22 February 1993*, Feasibility Research into the Controlled Availability of Opioids Stage 2, Working Paper Number 2.
- \* Sibthorpe, B., Sengoz, A. and G. Bammer in collaboration with The Youth Affairs Network of the ACT (1993), *Drug use and HIV risk among homeless and potentially homeless youth in the Australian Capital Territory*, Feasibility Research into the Controlled Availability of Opioids Stage 2, Working Paper Number 3.
- \* Bammer, G. and S. Weekes (1993), *Becoming an ex-user: Would the controlled availability of heroin make a difference?* Feasibility Research into the Controlled Availability of Opioids Stage 2, Working Paper Number 4.
- \* Bammer, G. (ed) (1993), *Does childhood sexual abuse contribute to alcohol, heroin and/or other drug problems? Proceedings of a one-day workshop held at the National Centre for Epidemiology and Population Health, The Australian National University, Tuesday 22 June 1993*, Feasibility Research into the Controlled Availability of Opioids Stage 2, Working Paper Number 5.
- \* Humes, G; Moloney, M; Baas Becking, F. and G. Bammer, in collaboration with Winnunga Nimmityjah (1993), *'It will kill us faster than the white invasion': Views on alcohol and other drug problems and HIV/AIDS risk in the Canberra/Queanbeyan Aboriginal community and on the suitability of a 'heroin trial' for Aboriginal heroin users*, Feasibility Research into the Controlled Availability of Opioids Stage 2, Working Paper Number 6.
- \* Butler, J.R.G. and A.L. Neil (1994), *Economic issues in a trial of the controlled provision of heroin*, Feasibility Research into the Controlled Availability of Opioids Stage 2, Working Paper Number 7.
- \* National Centre for Epidemiology and Population Health and Australian Institute of Criminology (1994), *Issues for designing and evaluating a 'heroin trial'. Three discussion papers*, Feasibility Research into the Controlled Availability of Opioids Stage 2, Working Paper Number 8.
- \* Bammer, G, Tunnicliff, D. and J. Chadwick–Masters (1994), *How could an influx of users be prevented if Canberra introduces a trial of controlled availability of heroin?* Feasibility Research into the Controlled Availability of Opioids Stage 2, Working Paper Number 9.
- \* Bammer, G. and A. Sengoz (1994), *How would the controlled availability of heroin affect the illicit market in the Australian Capital Territory? An examination of the structure of the illicit heroin market and methods to measure changes in price, purity and availability, including heroin-related overdoses*. Feasibility Research into the Controlled Availability of Opioids Stage 2, Working Paper Number 10.
- \* Cica, N. (1994), *Civil liability issues associated with a 'heroin trial'*. Feasibility Research into the Controlled Availability of Opioids Stage 2, Working Paper Number 11.

## Published papers

- # Hartland, N; McDonald, D; Dance, P. and G. Bammer (1992), 'Australian reports into drug use and the possibility of heroin maintenance', *Drug and Alcohol Review*, 11, pp.175–182.
- # Bammer, G. (1992) 'A trial of controlled availability of heroin for the ACT?', in White, J. (ed) *Drug problems in our society: dimensions and perspectives* (Selected papers from the Window of Opportunity, First National Congress. An Intersectoral Approach to Drug Related Problems in Our Society, December 2–5, Adelaide), pp.57–62.
- # Bammer, G. (1993), 'Should the controlled provision of heroin be a treatment option? Australian feasibility considerations', *Addiction*, 88, pp.467–475.
- # McDonald, D; Stevens, A; Dance, P. and G. Bammer (1993), 'Illicit drug use in the Australian Capital Territory: Implications for the feasibility of a heroin trial', *Australian and New Zealand Journal of Criminology*, 26, pp.127–145.
- # Bammer, G; Douglas, B; Moore, M. and D. Chappell (1993) 'A heroin trial for the Australian Capital Territory? An overview of feasibility research', in Heather, N; Wodak, A; Nadelman, E.A. and O'Hare, P. (eds) *Psychoactive drugs and harm reduction: from faith to science* (Selected papers from the Third International Conference on the Reduction of Drug-related Harm), Whurr, London, pp.137–150.
- # Ostini, R; Bammer, G; Dance, P. and R. Goodin (1993) 'The ethics of experimental heroin maintenance', *Journal of Medical Ethics*, 19, pp.175–182.
- # Larson, A., Stevens, A. and G. Wardlaw (1994) 'Indirect estimates of "hidden" populations: capture-recapture methods to estimate the numbers of heroin users in the Australian Capital Territory', *Social Science and Medicine*, 39, pp.823–831.

## Newsletters

- # Newsletters reporting project results are also published from time to time.

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# These publications are available free from:  
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