Confidentiality and Consent in Medical Research:

Some Recurrent, Unresolved Legal Issues Faced by IECs

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1. *Medical Research and the Role of IECs*

Medical research in Australia is regulated by institutional ethics committees (IECs). The formal status of IECs has changed dramatically over the past two decades. In 1976, the National Health and Medical Research Council (NHMRC) amended the *NHMRC Statement on Human Experimentation* to require institutions to establish medical ethics review committees to consider ethical issues raised by research protocols, and NHMRC funding was made conditional upon an IEC's ethics approval. In 1982, the *NHMRC Statement* was revised and re-issued with supplementary notes. Supplementary Note 1 defined the membership and functions of IECs. Supplementary Note 1 of the most recent (1992) version of the *NHMRC Statement on Human Experimentation* states that the function of IECs is to review protocols on ethical grounds in accordance with the Statement and Supplementary Notes and to ensure that projects proceed in accordance with an approved protocol. There are currently 172 registered IECs in Australia, with a peak body, the Australian Health Ethics Committee (AHEC) given status and responsibilities under the *National Health and Medical Research Council Act* 1992 (Cth).[1]

This article will focus on two fundamental, recurrent and unresolved legal issues faced by IECs regulating medical research. The first issue concerns the use of human tissue in research without consent. The second concerns the use of confidential patient information in research without consent. The article will also note the potential for conflict between the ethical and legal regulation of medical research.

While the *NHMRC Statement on Human Experimentation* makes the obvious point that investigators have both ethical and legal duties toward their

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1 Sections 35–6. For a survey of the history and function of IECs in Australia, see Chalmers, D, "Institutional Ethics Committees" (1994) 3 *Aust Health L Bull* 37 (Part 1), (1995) 3 *Aust Health L Bull* 53 (Part 2).

subjects, the job of an IEC is ultimately only to determine whether the proposed research is ethical, not whether it is legal. The role of an IEC is not to give legal advice and this is obvious from its composition. On the other hand, Supplementary Note 1 requires that at least one lawyer shall sit on each IEC, and it goes without saying that an IEC would not knowingly approve a protocol which involved any illegal activity.

As a perusal of the *NHMRC Statement* and Supplementary Notes demonstrates, the ethical standards required of investigators are high, and IECs are required to "ensure that the rights of the subjects of research take precedence over the expected benefits to human knowledge".[2] Supplementary Note 1 singles out informed consent as a particularly important ethical value and requires IECs to ensure that investigators obtain the free and informed consent of all subjects involved in projects relating to health. However, an exception is granted where access to confidential medical information is required for epidemiological research, and where the process of obtaining consent would likely cause unnecessary anxiety to subjects or prejudice the scientific value of the research.[3]

Given the emphasis upon the rights of the subjects of human experimentation, in most cases one might expect that research which is regarded as ethically acceptable by an IEC will also be legal. It is not clear, however, that this will always be the case. It has been argued that the Supplementary Notes to the *NHMRC Statement on Human Experimentation* may tend to establish standards of reasonable practice, in view of the fact that these guidelines are taken to have been issued by a statutory body (the NHMRC) in furtherance of its statutory functions.[4] It does not follow, however, that research which impinges upon the legal rights of research subjects becomes legal simply because the relevant research protocol has been approved by an IEC, on the basis that it complies with the *NHMRC Statement* and Supplementary Notes. The role of the legal member of an IEC is therefore an important one.

In some cases, research protocols involving the use of (i) human tissue or (ii) confidential medical information in research without consent may be considered ethical by members of an IEC, but illegal by the legal member. On the other hand, legal uncertainty over these issues may mean that lawyers advising IECs are only of limited assistance when the committee considers whether to approve a project. Both issues, therefore, deserve continuing attention. The discussion below will draw upon my own experience as the legal member of an IEC, and on perceptions that certain activities which may have been illegal, were nevertheless considered ethical.

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2 NHMRC, *NHMRC Statement on Human Experimentation and Supplementary Notes* (1992), Supplementary Note 1, par 6(ii).

3 Id, Supplementary Note 1, par 6(iii) and Supplementary Note 6, par 7.

4 See *National Health and Medical Research Council Act* 1992 (Cth), s7(1)(a)(v) at 90–1; Chalmers (Part 1) above n1 at 42 (footnote 21).

2. *Patient Consent to Research Uses of Human Tissue*

Investigators frequently submit protocols which would involve the investigator using human tissue for experimental purposes when that tissue was originally obtained by the investigator, or was given up by the "donor", either in ignorance of the research purpose or for quite different purposes. This raises the issue of whether the law requires that "donors" should be given the opportunity to consent specifically to research uses of their tissue. The lawyer who preceded the writer on the IEC on which the writer currently serves argued that in most cases the law does not permit patient tissue to be used in research without specific knowledge and consent, although in my experience, the IEC itself has preferred a more flexible approach, while acknowledging the legal uncertainty of approving protocols in the absence of patient consent.

There are two important contexts in which this issue may arise. First, tissue may be collected for routine diagnosis and treatment, as well as for a concurrent research project. Second, tissue may be collected for diagnosis and then stored, to be retrieved later for a research purpose which may or may not have been contemplated at the time of collection.

In 1993, the AHEC circulated a discussion paper prepared on behalf of the Royal Prince Alfred Hospital Human Ethics Committee, which considered ethical issues relating to the use of human tissue in research.[5] The discussion paper recommended against obtaining "blanket" consent from patients to research on their tissue, preferring instead for IECs to consider research proposals on a case by case basis. The paper recommended that IECs decide whether to waive a requirement of "informed consent", taking into account the type of tissue involved, the nature of the research, whether the patient or family might have an interest in the research results, whether seeking consent might cause needless anxiety, and the possibility of commercial application. These seem to be reasonable recommendations, and draft guidelines embodying them are currently being prepared by AHEC for release in late 1995. Unless these guidelines are embodied within legislation, however, the legality of using patient tissue in research without the patient's knowledge and consent will continue to be an issue. A number of examples, drawn principally from past and present research protocols, illustrate the complexity of this issue. It is useful to briefly note the scientific objectives of the research in each example in order to emphasise the competing interests IECs must invariably weigh.

A. *Some Examples*

i A research proposal submitted to an IEC involves work on sequencing the genome of a particular virus frequently associated with outbreaks of gastroenteritis. Faecal and serum samples suitable for this research are already held by an infectious diseases hospital, as well as by an electron microscopy laboratory which analysed samples for diagnostic purposes during a recent outbreak. The laboratory and hospital are willing to send samples to the investigators. These samples were originally given by the patients to assist in diagnosis of their illness.

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5 AHEC *Use of Routine Blood & Tissue Samples for Research* (1993).

ii A research proposal submitted to an IEC involves using hepatitis C virus (HCV) infected human livers taken from patients who received liver transplants as a result of end-stage liver disease. These livers were originally collected by a physician from a hospital liver transplant unit. The same physician also collected liver biopsy material obtained from patients before and after interferon therapy. To date, it has not been possible to grow sufficient quantities of natural virus in vitro for use in a confirmatory HCV assay (a diagnostic test for determining HCV infection). Current assays are thus based on cloned proteins and virus preparations which are similar to HCV, but which falsely identify a number of those who are not HCV infected. The proposal is for the human livers and the biopsy material to be used to test a new assay which, it is hoped, will have a higher specificity than first and second generation assays.

iii A research proposal submitted to an IEC involves the screening for human immunodeficiency virus (HIV) of a random sample of pregnant women presenting at a women's hospital. The sole purpose of the research is to monitor HIV prevalence among pregnant women, and testing will therefore be anonymous and "unlinked". No woman will be informed of her test results, as it will not be possible to relate any particular test result back to any of the women. It is not proposed to seek the consent of the women to do this research as this is only a prevalence study and refusal might introduce a bias into the results. Besides, blood samples suitable for HIV screening are already available as a result of other routine pre-natal tests.

iv A research proposal is submitted to an IEC which shares some similarities with (ii) above. In view of the limited number of livers available following transplantation, and the limited amount of liver biopsy material which can be taken from living patients, it is proposed to obtain livers from pathologists following post mortems carried out on cadavers at the relevant state institute of forensic pathology. Cadaveric liver tissue will then be tested and suitable tissue will be used, together with duck livers, to develop and further optimise a confirmatory HCV assay, the specificity of which will then be tested against current HCV assays using cloned viral material. It should be noted that the investigators in this project will seek a patent on the genetic structure of their new assay if it fulfils their expectations.

In view of the sensitive nature of HIV tests, the third proposal above might well be considered the most controversial from an ethical point of view.[6] In fact, a proposal to conduct an HIV prevalence study on pregnant women by

6 The ethics of anonymous, unlinked HIV screening have been widely debated in the literature: eg Doll, R, "A Proposal for Doing Prevalence Studies of AIDS" (1987) 294 *Brit Medical J* 244; Gillon, R, "Testing for HIV without Permission" (1987) 294 *Brit Medical J* 821; Garland, S and Kaldor, J, "Monitoring Heterosexual Transmission of HIV through Testing of Antenatal Women" (1994) 160 *Medical J Aust* 667; Bayer, B, Lumey, L and Wan, L, "The American, British and Dutch Responses to Unlinked Anonymous HIV Seroprevalence Studies: An International Comparison" (1991) 19 *Law, Medicine & Health Care* 222; Grant, I, "Consensus on HIV Testing" (1988) 297 *Brit Medical J* 356.

testing blood drawn randomly from 60 000 newborn babies in New South Wales, Victoria and Queensland, recently provoked wide media coverage and community debate.[7] Unlinked, anonymous HIV screening of pregnant women or their newborn babies without consent in order to obtain prevalence data appears to be an established practice,[8] although its legality is uncertain.

Before considering the legal subtleties of each of the above proposals, it is useful to consider briefly why some lawyers have argued that a patient's specific consent to the use of his or her tissue in research is more than just an ethical nicety, but also a legal requirement. There is little legal authority on this point, and the issues have been debated within the literature largely within the context of HIV testing without specific consent.[9]

B. Assault and Battery

Some writers have argued that the use of human tissue for a specific, non-disclosed purpose (particularly a "sensitive purpose" such as HIV testing) may be an assault. In *Rogers v Whitaker*, the High Court stated that "the consent necessary to negative the offence of battery is satisfied by the patient being advised in broad terms of the nature of the procedure to be performed".[10] The issue becomes, therefore, whether the fact that tissue will be used in research, and not merely to diagnose an illness, or for routine testing of which the patient is aware, changes the broad nature of the procedure and vitiates consent to the withdrawal of the blood or tissue. My view is that it does not. In *Doe v Dyer-Goode*,[11] the Superior Court of Pennsylvania held that the plaintiff, who had undergone a premarital blood test, had consented to the extraction of blood through a needle "for a testing purpose". Given that the plaintiff's consent was relevant only to "the prick of the skin by a needle", no assault was held to have been committed when an HIV test was subsequently performed on the plaintiff's blood without his specific consent.

Even so, some writers argue that without specific knowledge that blood will be tested for HIV, the patient may think that he or she is "consenting to a materially different procedure".[12] Obviously, the broader issue is whether courts would accept that the purpose for which tissue is withdrawn is relevant to determining the nature of that procedure. Unlike a surgical operation, the

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7 Larriera, A, "Proposal for Secret AIDS Tests Attacked" *The Sydney Morning Herald* 1 April 1995 at 3; Davies, J, "... They're After my Blood" *The Sunday Age* 9 April 1995 at 1; Buchanan, R, "AIDS Tests on Babies "Unethical"" *The Age* 10 April 1995 at 5; Editorial, *The Age* 11 April 1995 at 13; Skene, L, "The Wider Ethic of Baby Tests" *The Age* 14 April 1995 at 10.

8 For example, McLaws, M, Brown, A, Cunningham, P, Imrie, A, Wilcken, B and Cooper, D, "Prevalence of Maternal HIV Infection Based on Anonymous Testing of Neonates, Sydney 1989" (1990) 153 *Medical J Aust* 383; Chew, C, Downie, J and Cunningham, A, "Unlinked Anonymous Screening of Antenatal Patients for Antibody to Human Immunodeficiency Virus Type 1 (HIV-1)" (1994) 160 *Medical J Aust* 693.

9 For example, Keown, J, "The Ashes of AIDS and the Phoenix of Informed Consent" (1989) 52 *Mod LR* 790; Magnusson, R S, "Specific Consent, Fiduciary Standards and the Use of Human Tissue for Sensitive Diagnostic Tests and in Research" (1995) 2 *JL and Medicine* 206.

10 (1992) 175 CLR 479 at 490; *Chatterton v Gerson* [1981] 1 QB 432 at 443.

11 566 A 2d 889 (1989) at 892.

12 Grubb, A and Pearl, D, *Blood Testing, AIDS and DNA Profiling: Law and Policy* (1990) at 8.

removal of tissue is not an end in itself, so there is at least an argument that a patient who gives tissue samples in ignorance of the fact that the doctor intends that they will be used for research, is not really consenting to withdrawal. However, it is clear that an argument based on assault really only makes sense where tissue has been withdrawn for diagnosis/treatment and additionally for a concurrent research project which the patient has not been informed about. Where a doctor decides to use stored tissue in a research project he or she has lately become involved with, it makes little sense to argue that the withdrawal of tissue retrospectively becomes an assault.

C. Negligence

A number of writers have argued that it is a breach of the doctor's duty of care to use human tissue for an undisclosed purpose without specific consent. This argument draws an analogy with the doctor's duty to disclose material risks associated with a medical procedure. In *Rogers v Whitaker*, the High Court held that a doctor's duty to inform the patient of material risks will be discharged by disclosure of such risks to which a reasonable person in the patient's position would be likely to attach significance, if he or she were informed of them.[13] In line with this, some writers have argued that if a reasonable patient would wish to accept the medical, social and emotional consequences of, say, being diagnosed HIV positive before agreeing to undergo an HIV test, then HIV testing without specific consent will breach the doctor's duty to disclose.[14] Similarly, if the reasonable patient would wish to be informed whenever it was proposed to use his or her tissue for a research purpose having no therapeutic benefit for the patient, then the doctor's duty to disclose would seem to require this.

The problem with this argument is that the doctor's duty to inform the patient of material risks is a duty developed and recognised by courts when a doctor is performing medical procedures involving a risk of misadventure and injury to the patient. The withdrawal of blood into a syringe, or the withdrawal of other tissue, may involve very few material risks, and these risks will not in any event be affected by the eventual use to which the tissue is put. Courts are yet to recognise any broader duty owed by the doctor to inform the patient of whatever the reasonable person in the patient's position would wish to be informed about at the time tissue is withdrawn, however, attractive this might appear in principle, and however much this may promote the autonomy of the patient. It is far from clear, therefore, that doctors owe their patients a duty of care to obtain each patient's specific consent to research or other uses of tissue, over and above consent to the original act of withdrawal. This would mean, therefore, that blood taken from pregnant mothers for routine tests could also be tested for HIV without specific knowledge. Similarly, tissue removed during an operation, for example, a diseased liver, could be used for research without even mentioning this to the patient.

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13 Above n10 at 490. Additionally, a risk will be "material" if "the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it".

14 The present discussion only concerns the common law. Relevant statutory duties will be considered below.

D. Why is the Issue of Specific Consent Important?

There are several reasons why lawyers have argued that the law should require doctors to obtain specific consent from patients to the use of tissue in research, when that tissue was originally given up on the assumption that it would only be used for certain specific, or routine (non-sensitive) diagnostic tests.

i Privacy

First, as the HIV testing example shows, patients are concerned when sensitive information about them is generated without their consent. It is obvious that this is a serious concern in some cases. However, if diagnostic testing is anonymous and unlinked, as in example (iii) above, privacy concerns may be met. On the other hand, it can also be argued that if testing without consent is unlawful, testing anonymously can only compound that illegality because it prevents the doctor from informing the patient of diagnosed illnesses, thereby potentially interfering with the doctor's duty of care.[15] In my view, this latter argument is inappropriate. The underlying conflict is between the ethics of epidemiological research and the ethics of clinical intervention. The legitimate objective of public health surveillance should not be confused with case finding.[16] Furthermore, if surveillance is the objective, anonymous non-consensual testing may be necessary to eliminate the bias introduced by voluntary participation in prevalence studies.[17] A strong argument can therefore be made in favour of anonymous, unlinked prevalence testing involving non-consensual use of human tissue, since no name-identifying sensitive information is thereby generated. There are, however, two additional, closely-related considerations which oppose non-consensual use of tissue in research, regardless of whether privacy concerns are met.

ii Patient Autonomy

The general trend of the law in granting patients autonomy over their bodies gives further support to the importance of patient consent. If patients have the right to refuse medical treatment, and the right to be fully appraised of material risks associated with treatment, they would also seem to have the right to veto the use of tissue taken from their bodies in research. This argument makes sense if the doctor/patient relationship is characterised as one in which the doctor has a duty to act in the patient's interests, rather than his or her own.

iii Conflict of Interest

A third reason why specific consent to research uses of human tissue is important is because researchers may have a professional or career interest in obtaining tissue which potentially conflicts with their role as physicians. This is illustrated by the well-known case of *Moore v Regents of the University of*

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15 Grubb and Pearl, above n12 at 25.

16 See Bayer et al, above n6.

17 See Krasinski, K, Borkowsky, W, Bebenroth, D and Moore, T, "Failure of Voluntary Testing for Human Immunodeficiency Virus to Identify Infected Parturient Women in a High-Risk Population" (1988) 318 *New England J Medicine* 185; Hull, H, Bettinger, C J, Gallaher, M M, Keller, N M, Wilson, J and Mertz, G J, "Comparison of HIV-Antibody Prevalence in Patients Consenting to and Declining HIV-Antibody Testing in an STD Clinic" (1988) 260 *J American Medical Association* 935.

California,[18] in which a physician treating a patient with hairy-cell leukaemia took numerous samples of body fluids from the patient, following a splenectomy, to assist in growing a cell line established with cells from the patient's spleen.[19] The patient periodically flew from Seattle to Los Angeles, often at his own expense, to make these donations. The patient had no idea that they were unrelated to his monitoring and treatment, and only became suspicious when his physician asked him to sign over all rights to the cell lines derived from his spleen.[20] In 1990, the court estimated the market potential for the derivative products from the cell line to be US$3 billion.[21] The California Supreme Court held that the patient, Moore, had a good cause of action against his physician for breach of fiduciary duty, for non-disclosure of the defendant's economic interest in the Moore cell-line. Even so, Moore only received a small settlement. The case is, however, better known for the debate it has sparked over whether an individual may enjoy a proprietary right in his or her own removed issue.[22]

The potential for tissue obtained from patients to be used for purposes unrelated to the patient's own health, and to the economic advantage of the researcher, gives a sharp edge to the issue of patient consent for research purposes. It is, however, important to distinguish between those cases where a patient's tissue produces a unique compound which is valuable to science (as in Moore's case) and those in which a patient's tissue is simply used as a vector to "get at" the genetic inheritance which all humans share. Scientists at the Howard Florey Institute in Melbourne, for example, have patented the gene coding for the human hormone "relaxin", derived from the ovarian tissue of pregnant women undergoing surgery for ectopic pregnancies at the Queen Elizabeth Hospital in Adelaide.[23] The women involved did, incidentally, consent to donation for the purpose of research. The point is, however, that although the full complement of genes is found in the nucleus of virtually every human cell, the ovaries produce an RNA copy of the gene which edits out the so-called "junk DNA", thereby speeding up the process of cloning the gene. Thus, while the fact that the tissue used to "get at" the underlying structure of human relaxin was ovarian tissue donated by pregnant women, there was, unlike

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18 793 P 2d 479 (1990); see also Vidal, J and Carvel, J "Genetic Harvest" *The Age* 24 November 1994 at 13; Keens, L, "Robbed of his Spleen" *Who Weekly* 20 February 1995 at 38.

19 The culture of cells cloned in the laboratory from Moore's original cells contained large amounts of protein which stimulate the growth of white blood cells. The "Mo cell line" was therefore useful in treating people with suppressed immune systems. For example, GCSF (granulocyte colony stimulating factor), a blood regulator used for immunosuppression, including in the treatment of AIDS, was one molecule to come out of the Mo cell line.

20 Moore's physician, Dr Golde, formed a company to exploit the economic potential of Moore's cell line. Dr Golde received stock options worth US$3 million from the Genetics Institute in the US, which also gave UCLA Medical Centre, where Golde was stationed, a US$440 000 research grant, in exchange for use of Moore's cell line. Golde had already been granted a patent on the cell line in 1984.

21 249 Cal Rptr 494 (1988) at 498 (Ct of Appeal).

22 See, eg, Magnusson, R S, "The Recognition of Proprietary Rights in Human Tissue in Common Law Jurisdictions" (1992) 18 *MULR* 601; Mortimer, D, "Proprietary Rights in Body Parts: The Relevance of *Moore's* case in Australia" (1993) 19 *Monash ULR* 217.

23 Ewing,T, "Patent on Genes Challenged" *The Age* 9 December 1994 at 3; Keens, above n18 at 41.

Moore, nothing unique in the functioning of the women's bodies which was the focus of the research.[24]

E. Fiduciary Duty

Elsewhere, I have argued that, for the three reasons given above, the doctor/patient relationship should, for some purposes, be analysed in fiduciary terms, and that the failure to obtain patient consent to use of tissue either for sensitive diagnostic tests, or for non-therapeutic research purposes, should be regarded as a breach of fiduciary duty.[25] To date, however, Australian courts have been reluctant to import fiduciary duties into the doctor/patient relationship. In *Breen v Williams*,[26] a majority of the New South Wales Court of Appeal rejected the arguments that doctors have a fiduciary duty to provide patients with access to their medical records, and that patients have a corresponding right of access enforceable in equity. In a strong dissent, however, Kirby P followed a Canadian Supreme Court decision[27] which had analysed the doctor/patient relationship in fiduciary terms. Two of the three judges (Kirby P and Meagher JA) recognised that a doctor may owe fiduciary duties, although Meagher JA limited this to the duty of a doctor "not to profit at his patient's expense (beyond his agreed fees) and not to put himself in a position where his interest would conflict with his patient's".[28] It is likely that Meagher JA was referring to some conflict between the financial or proprietary interests of the doctor and patient. The imposition of a fiduciary duty which has nothing to do with undermining the financial or proprietary interests of the patient, therefore, remains speculative.[29] On 12 May 1995, the High Court granted leave to appeal in *Breen v Williams*, so the last word on the imposition of fiduciary duties within the doctor/patient relationship is yet to be heard.

The above discussion of assault and battery, negligence and fiduciary duties suggests that lawyers differ over whether the law requires researchers to obtain specific patient consent to research uses of human tissue. It is uncertain how courts would decide this issue. The examples of research protocols given above, however, involve added complications which IECs must also face.

F. Human Tissue Legislation

The legality of using human tissue in research may be affected by human tissue legislation. Uniform legislation in all jurisdictions authorises the donation, with consent, of regenerative tissue (including blood) and non-regenerative tissue, by adult donors. The purpose of this legislation, as suggested by the Australian Law Reform Commission report which preceded it, was to provide for the removal of tissue only with consent, to expressly approve voluntary

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24 Interview with Professor Geoff Treager, Associate Director, Howard Florey Institute, 30 May 1995.

25 Magnusson, above n9 at 226–9.

26 (1994) 35 NSWLR 522.

27 *McInerney v MacDonald* (1992) 93 DLR (4th) 415.

28 Above n26, Meagher JA at 570.

29 See, further, Magnusson, R S, "A Triumph for Medical Paternalism: *Breen v Williams*, Fiduciaries, and Patient Access to Medical Records" (1995) 3 *Torts LJ* 27 at 36–40.

donation, and to remove potential liability when legislative requirements were complied with.[30] The legislation provides for consent to donation for specified purposes: non-regenerative tissue may be donated for transplantation to another living person,[31] and regenerative tissue (including blood) may be donated for transplantation to the body of another living person; or alternatively for other therapeutic purposes or for medical or scientific purposes.[32] Blood donation does not require written consent, although the donation of other regenerative, as well as non-regenerative tissue does, and the wording of the legislation suggests that in the case of regenerative tissue, consent may refer to transplantation, or to therapeutic, medical or scientific purposes, or both. Donation under the Act therefore requires specific knowledge of, and consent to, the use of tissue for the purposes specified. It is an offence to remove tissue for transplantation or research except in accordance with a consent which is sufficient under the Act.[33]

Returning to the first of the examples given above, it is suggested that human tissue legislation is irrelevant when considering the legality of using blood and faecal samples originally given for diagnostic purposes, for the purposes of research on viruses causing gastroenteritis. Although faecal tissue arguably comes within the definition of "tissue" under the Act (a substance extracted from the body), it can hardly be regarded as either non-regenerative or regenerative tissue within the meaning of the Act. More importantly, it is clear that the giving of a sample of blood or faeces to assist in diagnosing an illness suffered by the patient would not be regarded as a donation "for a therapeutic purpose" under the Act.[34] Human tissue legislation is limited to donations originally intended to benefit others, and this is confirmed by uniform provisions in the legislation which provide that the Act does not apply to (and therefore does not prohibit) the removal of tissue from a patient in the course of a procedure carried out (with the patient's consent) "in the interests of the patient's health", nor to the use or disposal of the tissue so removed.[35]

A patient with gastroenteritis who provided blood and faecal samples to assist in diagnosis would thus fall outside the scope of the human tissue Acts, because tissue removed for diagnosis would be removed in the interests of the patient's health. Such a patient would not have the protection of the specific consent provisions in the legislation — which do seem to require that specific consent be obtained, although only when the tissue is donated altruistically for (i) transfusion/transplantation; or (ii) other therapeutic, medical or scientific purposes. The legality of using tissue originally given up for a diagnostic purpose, for research purposes, thus falls to be determined under the common law, the

30 Australian Law Reform Commission, *Human Tissue Transplants*, Report no 7 (1977) pars 23–4, 111, 201.

31 *Human Tissue Act* 1983 (NSW) s8; *Human Tissue Act* 1982 (Vic) s8; *Transplantation and Anatomy Act* 1979 (Qld) s11.

32 *Human Tissue Act* 1983 (NSW) ss7, 19; *Human Tissue Act* 1982 (Vic) ss7, 21; *Transplantation and Anatomy Act* 1979 (Qld) ss10, 17.

33 *Human Tissue Act* 1983 (NSW) s36(1); *Human Tissue Act* 1982 (Vic) s44(1); *Transplantation and Anatomy Act* 1979 (Qld) s48(1).

34 Above n32.

35 *Human Tissue Act* 1983 (NSW) s34(1); *Human Tissue Act* 1982 (Vic) s42(1); *Transplantation and Anatomy Act* 1979 (Qld) s47(1).

uncertainties of which have already been discussed. Human tissue legislation has rightly been criticised for failing to regulate tissue "donated" for the patient's own benefit. For example, the legislation would do little to protect patients such as Moore, whose tissue was "harvested" (at least initially) during the period of post-operative monitoring, for the economic benefit of his physician.[36] Indeed, the non-application of the legislation when tissue is removed in the interests of the patient's health may even encourage doctors to obtain tissue samples, ostensibly in order to monitor the patient's health, while in reality they are used in research without the need to inform the patient or request the patient's consent.

This deficiency in the human tissue legislation also means that this legislation is irrelevant in the second example given above: the use of human livers and liver biopsy material in research to test an HCV assay. Diseased tissue removed as "waste" during surgery is removed in the interests of the patient's health, and thus the legality of using it in research after the operation would be an issue for the common law. This is also the case in the third example given above: the use of pre-natal blood samples for HIV prevalence testing. Where blood from pregnant women was originally taken for diagnostic purposes performed in the interests of their health, human tissue legislation will not prevent its subsequent use in research without specific patient knowledge or consent.

It should be noted, however, that other HIV-specific legislation may be relevant where HIV testing is performed. For example, in Tasmania, the *HIV/AIDS Preventive Measures Act* 1993 (Tas) prohibits HIV testing without patient consent, and none of the statutory exceptions appear to authorise unlinked prevalence testing for epidemiological purposes, although name-identifying HIV test results (obtained legally) may be disclosed for epidemiological research if authorised by the Secretary, and anonymous HIV results may also be disclosed.[37] Legislation imposing HIV and/or Sexually Transmitted Diseases (STDs) test counselling requirements exists in several states,[38] and compliance would obviously involve informing a person that testing was taking place, although a closer reading of these provisions suggests that HIV prevalence testing would only be unlawful (in the absence of specific consent), in Tasmania.

Example iv above (obtaining human livers from forensic pathologists performing post-mortems for use in developing HCV assays) again raises the issue of human tissue legislation. Under the legislation, the coroner, a hospital authority, or senior next of kin of the deceased may authorise the removal "for therapeutic purposes, medical purposes or scientific purposes", of human tissue "for the purpose of the post-mortem examination of the person's body".[39] However, tissue removed for research, rather than for the purpose of a post-mortem, is unauthorised and would therefore be unlawful. Tissue may, of

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36 See Mortimer, above n22 at 249–50.

37 *HIV/AIDS Preventive Measures Act* 1993 (Tas) ss7, 19(1)(g), 19(2).

38 Id ss14–5; *Health Act* 1958 (Vic) s127; *Public Health Act* 1991 (NSW) s12; *Notifiable Diseases Act* 1981 (NT) s10.

39 *Human Tissue Act* 1983 (NSW) s31. See also *Human Tissue Act* 1982 (Vic) s30; *Transplantation and Anatomy Act* 1979 (Qld) s29.

course, be removed after death, either for (i) transplantation or for (ii) therapeutic, medical or scientific purposes, in accordance with various statutory provisions requiring either the consent of the deceased prior to death, the consent of the senior next of kin where the deceased has made no objection during life, or other statutory authority.[40] It follows that a forensic pathologist would have no authority to pass on to researchers, for the purposes of scientific research, liver tissue removed during a post-mortem, unless consent to removal for this purpose had been previously obtained in accordance with statutory requirements. The legislation therefore imposes a specific consent requirement over dead bodies which does not operate for living patients, because of the exception which makes the human tissue Acts inapplicable when tissue is removed in the interests of the health of a living patient.

The consent issues raised by example iv above are not only theoretical. On 28 June 1994, the *Inquiry into the Use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease* (the Allars report) was tabled in federal Parliament.[41] The report details the history of the use of human pituitary glands for treatment of infertility, and the discovery that the use of virally infected pituitary hormone was implicated in the transmission of Creutzfeldt-Jakob's disease. The report also found that pituitary glands were harvested from cadavers in hospitals and morgues, with members of the Human Pituitary Advisory Committee approaching pathologists and pressuring them to increase their rate of collection of pituitaries at various times during the period of collection (1967 to 1985). The inquiry found that human tissue legislation (during the period it existed) was ignored, and that glands were removed during post mortems regardless of whether this was necessary for histological examination.

G. What Should be Done?

The discussion of examples i — iii above demonstrates the uncertainty of legal controls over the use, in research, of tissue removed from living patients for diagnosis or during medical procedures. In these circumstances, the human tissue Acts do not apply, and the application of specific consent requirements through the doctrines of assault, negligence, and breach of fiduciary duty, is uncertain. As research protocols including examples similar to those discussed above regularly come before IECs, it is important for the law to be clarified.

From a policy viewpoint, there are obvious considerations weighing against obtaining patient consent to the use of tissue for research purposes. The process of obtaining patient consent may be time consuming and may be a trivial exercise where the research use is non-controversial. In some research, for example, prevalence studies, patient refusal may introduce a bias into the results. Some researchers argue that the public interest in medical research outcomes should outweigh patient autonomy. Where tissue has been stored for a long time it may be impossible or impractical to contact the patients involved.

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40 See *Human Tissue Act* 1983 (NSW) ss23–7; *Human Tissue Act* 1982 (Vic) s27; *Transplantation and Anatomy Act* 1979 (Qld) ss22–5.

41 House of Representatives, *Inquiry into the Use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease*, Executive Summary, 28 June 1994.

The contrary consideration, as noted above, is that if patient tissue is used without consent for research purposes having no immediate therapeutic benefit for the patient, there is the potential for conflict between the doctor's duty to promote the patient's health and interests, and the doctor's own research or career interests. Economic benefits flowing from research only underscore the importance of ensuring that the doctor/patient relationship does not become an exploitative one.[42] In my view, the importance of protecting the integrity of the doctor/patient relationship, patient privacy, and the patient's interest in self-determination support the imposition upon doctors of a fiduciary duty not to use patient tissue except for diagnosis and treatment in the patient's direct interests. Any exceptions to this principle should be introduced by legislation. This will ensure that doctors continue to act with integrity, and in the patient's interests, rather than their own. While the scope of doctors' fiduciary duties remains to be clarified, therefore, it is hoped that courts will eventually clarify the common law by adopting such an approach.

This is not to deny the importance of medical research using human tissue. Use of patient tissue in research with consent is unexceptional. However, as the AHEC discussion paper pointed out, problems may arise when tissue is stored and later used for research not envisaged at the time of collection.[43] "Blanket" consent to the use of tissue for unspecified research given when the tissue was withdrawn cannot be regarded as informed, nor is it sufficient for different kinds of research which may take place in the future.

In my view, IECs may rightly be regarded as providing a suitable mechanism for determining whether non-consensual use of human tissue in research is justified. IECs provide a cheap, informal, accessible and apolitical mechanism for considering whether the research use is so sensitive as to require specific consent, whether there are any potential economic benefits which may potentially undermine the integrity of the doctor/patient relationship, and whether the process of obtaining patient consent would undermine the scientific objectives of the research, bearing in mind the general principle "that the rights of the subjects of research take precedence over the expected benefits to human knowledge".[44] Perhaps a tolerable legislative solution which would resolve legal uncertainty would be to authorise the use of human tissue in research without specific consent where an appropriately constituted IEC had approved this use in accordance with NHMRC guidelines directing the IEC to consider the competing issues of patient autonomy and public benefit. As discussed below, a similar mechanism authorising the use of confidential information obtained by researchers without patient consent currently exists under section 95 of the *Privacy Act* 1988 (Cth). However, in my view, any guidelines followed by IECs when reviewing protocols involving research uses of human tissue should give particular attention to ensuring that sensitive information, such as HIV test results or genetic test information, are not generated

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42 As noted above, the judgments of Kirby P and Meagher JA in *Breen v Williams* arguably support a duty to obtain specific patient consent to use of patient tissue in research, if only where such research places the researcher in a position of conflict of interest with the financial or proprietary interests of the patient; above n29 and accompanying text.

43 Above n5.

44 Above n2.

on a name-identifying basis without specific consent. Second, IECs should be particularly careful in approving protocols where the economic incentives for the researcher may potentially undermine the doctor's duty to act in the patient's interests. The issue of a patient's proprietary interest in his or her tissue, and the issue of whether patients should have a right to share in the economic rewards of research which has used their tissue, are obviously related issues which are looming on the horizon. While they cannot be discussed here, in my view, the AHEC should also consider them as a matter of priority.

3. *Medical Research and Confidential Information*

Research protocols submitted to IECs frequently involve access to confidential, name-identifying patient information by investigators who are not involved in the provision of health care to the patient. In hospital, for example, a team of researchers may be involved in research involving information relating to patients of only one of those researchers. In other cases, all the researchers may be external to the organisation from which medical information is sought; for example, information may be sought from a government department such as the Commonwealth Department of Social Security, or from a public health register maintained by a State Health Department, or researchers may rely upon the cooperation of staff in another medical institution to pass on information or refer patients. An issue frequently faced by IECs, therefore, is whether to approve protocols which involve access to, and use of, confidential information by researchers who are not part of the patient's "health care team" and so have no right of access within the context of an existing confidential and therapeutic relationship.

Even where medical practitioners conduct research using information relating to their own patients, good practice requires that patients should consent to that research use, in view of the fact that research constitutes a use of the information distinct from treatment or diagnosis. The discussion below, however, relates solely to the use of medical information in research by researchers who are third parties to the doctor/patient relationship.

It is incontestable that the conduct of medical research is crucial to the progress of medical science, and to advances in the diagnosis, treatment and elimination of illness. Epidemiologists, for example, point out that medical research using nominal patient data has yielded important knowledge on the causes of illnesses, has permitted the development of vaccinations and treatments, and the implementation of public health measures.[45] In addition, researchers cite broad public support for medical research in support of their claim that non-consensual access to nominal data for research should be permitted, provided that the research protocol has been approved by a properly constituted ethics committee.[46] Since research results are required to be published in

45 For example, Gordis, L and Gold, E, "Privacy, Confidentiality and the Use of Medical Records in Research" (1980) 207 *Science* 153; Stanley, F, "Confidentiality of Medical Records and Medical Research: An Epidemiologist's View", Dean's Lecture Series: Privacy in Medicine: Issues Old and New, Melb U, (1991) 2 *Chiron* 8.

46 For example, Gray, N, Hill, D and Lovell, R, "Privacy and Medical Research: Most Peo-

depersonalised form,[47] the issue of confidentiality relates most frequently to access by third party medical researchers to name-identifying information stored in medical files or registers during the course of research. It is generally conceded that a doctor who discussed a patient's condition anonymously in a learned article would not be breaching confidence,[48] nor would a doctor who provided statistical information, or detailed information relating to an anonymous patient, to a researcher.[49] A few examples adapted from past and present protocols submitted to IECs may assist in showing how the issue of confidentiality in medical research arises in practice. Some details of typical research methodology have also been included to show the context in which these issues arise before IECs.

A. Some Examples

i A research proposal submitted to an IEC involves a cohort study of viral markers associated with AIDS-defining illnesses. T4 cell counts have long been used as an indicator of the risk of the onset of AIDS-defining illnesses, and the protocol proposes to test blood obtained from patients attending a regular HIV outpatient clinic in a variety of ways to determine viral load. The study involves the withdrawal of 10 ml of blood three times a year, which will be drawn by clinic physicians. Some of the investigators involved in this project have never been involved in seeing patients in the HIV outpatient clinic. It is proposed that the full medical file relating to patients involved in the study will be made available to all of the investigators.

ii A research proposal submitted to an IEC involves a pilot study of a new drug in the treatment of AIDS dementia complex. Patients attending a hospital clinic and fulfilling certain criteria will be eligible to enter the trial. Patients will be allocated at random to receive either a placebo or the new experimental drug. The study is "double blinded": neither the patients nor the investigators will be aware of whether the patient is receiving the placebo or the experimental drug. In all trial records, patients will only be identified by a subject number, together with their clinic code number. All patients will be required to give their written consent to participation in the trial, as it involves frequent visits to the clinic for physical examination, blood tests and neurocognitive testing, as well as lumbar punctures at the beginning and end of the trial. At the end of the trial period (16 weeks), the study will be unblinded, and the investigators will compare trial records and patient medical records in the light of the knowledge of what drug the patient was receiving. The study which the IEC is being asked to approve is part of a wider pilot study involving the same drug, which is taking place in several countries, on cohorts of patients with mild AIDS dementia complex. The protocol provides that employees of the sponsor company may

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ple Support Current Practice" (1990) 153 *Medical J Aust* 740.

47 Above n2, Supplementary Note 6 (Epidemiological Research), par 11.

48 *W v Egdell* [1990] 1 Ch 359 at 419.

49 Law Reform Commission of Western Australia, *Report on Confidentiality of Medical Records and Medical Research* (1990) Report No 65, Pt II, par 3.1.

inspect study report forms, as well as the patient medical records stored in the clinic.

iii A research proposal submitted to an IEC involves the creation of a database on factors associated with sudden infant death syndrome (SIDS). The protocol involves the investigators accessing the full medical file of mothers whose newborn babies have died of SIDS within the first year of their life. The study is being carried out Australia-wide, although the current proposal being considered by the IEC relates to access to relevant medical records held by a state funded women's hospital.

iv A research protocol submitted to an IEC involves a study of osteoporosis in Melbourne, using data obtained from the Heidelberg Repatriation Hospital. The protocol provides for the identification to the researchers of all patients admitted with a hip fracture, who will then be requested by the researchers to undergo tests, with the consent of their treating doctors.

The issue of confidentiality in medical research is one context where a conflict between what is considered ethical, and what is legal, seems a real possibility. Supplementary Note 6 to the *NHMRC Statement on Human Experimentation* provides that while the consent of subjects should normally be obtained for the use of their records in epidemiological research, IECs may in certain circumstances approve access without consent. An IEC may do this where (i) the procedures required to obtain consent are likely to cause either unnecessary anxiety or to prejudice the scientific value of the research, and also where (ii) the IEC concludes that the research will not be to the disadvantage of the subjects. It is quite possible, however, that third party access to confidential patient information, in accordance with an IEC approved protocol, would nevertheless be considered by courts to be a breach of confidence. The position is further complicated by legislation governing confidentiality and medical research in various Australian jurisdictions.

B. Breach of Confidence and the Public Interest Exception

Under the common law, the use or disclosure of confidential medical information for an unauthorised purpose will be a breach of confidence. It follows that a doctor who permitted a researcher to access information from which a patient could be identified for research purposes not directly related to the patient's care, would breach the duty of confidence owed to the patient.[50] In addition, the researcher would also be in breach, having actual, or certainly constructive knowledge of the doctor's duty.

Some commentators, particularly epidemiologists, regard this position as incongruous, given the public interest society has in epidemiological research. They argue that the public benefits of medical research provide a sufficient basis for accessing name-identifying data without patient consent:

> The social contract that facilitates the existence of individuals within social groups requires that each individual occasionally yield some of his rights,

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50 Australian Law Reform Commission (ALRC), *Privacy* (1983) Report No 22, par 907.

> including privacy and freedom of action, for the benefit of society as a whole. ... Each society must decide when a limited compromise of individual rights is justified by the potential benefits to be derived by the community as a whole.[51]

However convincing this argument may be from an ethical standpoint, as a legal argument it misunderstands the way in which the law takes public interest considerations into account in circumscribing the limits of duties of confidence. The law has never attempted to balance the public interest in disclosing confidential information against an individual's private interest in non-disclosure. Confidential information may sometimes be legally disclosed in the public interest, but only where the public interest supporting disclosure overrides the public interest in protecting confidentiality.[52] Within the doctor/patient relationship, courts have emphasised the public health basis for protecting confidential information, in the sense that a lack of confidentiality may discourage people from volunteering relevant information to their doctors and from seeking medical treatment. The result, as Thomson has pointed out, is that the argument that the public interest justifies access to data for medical research may be answered by the argument that the public interest equally requires the protection of confidential relationships.[53]

The fact that the promotion of public health underlies both (i) medical research using nominal data, and (ii) the non-disclosure of confidential information, is not itself problematic. The question of whether it is legal for third parties to access identifying information cannot, however, be resolved merely by asserting that private claims must bow to the greater good. On the other hand, the question of whether public health is more likely, rather than less likely, to be advanced by permitting non-consensual access to name-identifying information will depend upon numerous factors including the demonstrated value of the proposed research, the sensitivity of the information, and the extent of intrusion into the privacy of the patient and the doctor/patient relationship which access involves.

It is entirely proper that the law should be unwilling to allow researchers themselves to decide whether access to, or sharing of, confidential information should be permitted in order to foster the public health interest in medical research. Arguably, this function is most appropriately fulfilled by an administrative mechanism through which specific proposals can be evaluated in detail, their benefits to public health assessed, together with their negative impact upon the public health interest in preserving the confidentiality, and thus the integrity, of the doctor/patient relationship. Supplementary Note 6 of the *NHMRC Statement on Human Experimentation* evidently regards IECs as suited to this purpose, which they may well be. Indeed, the Law Reform Commission of Western Australia has recommended clarification of the law to ensure that the use in medical research of patient-identifying information in circumstances where it would constitute a breach of confidence shall be lawful, provided that the research has been approved by a prescribed IEC in accordance

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51 Gordis and Gold, above n45 at 156.

52 See above n48 at 415, 420.

53 Thomson, C, "Records, Research and Access: What Interests Should Outweigh Privacy and Confidentiality? Some Australian Answers" (1993) 1 *JL and Medicine* 95 at 99.

with specified criteria.[54] However, in the absence of any such law reform, there is the potential for conflict between ethical guidelines and the law, for the following reason.

While the public interest defence to the action for breach of confidence means that sometimes confidential information may be disclosed quite legally, courts have not been willing to regard the duty of confidence as subject to countervailing public interests in all circumstances. Courts have limited the categories of public interest which may be weighed against the public interest in protecting confidentiality, as well as the circumstances in which those categories will operate. Australian courts, in particular, have been reluctant to extend the public interest exception beyond cases where disclosure is necessary to avert positive harm, thereby excluding cases where disclosure could accomplish something which was merely socially desirable.[55] It is generally conceded, therefore, that the public interest defence would not justify the disclosure of nominal patient information, without consent, to medical researchers.[56] On the other hand, the public benefits of medical research using nominal information (at least in some circumstances) are acknowledged, and legislatures have enacted various mechanisms to allow this (see below).

C. *Implied Consent and Access to Confidential Information*

It is also doubtful whether the disclosure of nominal patient information to medical researchers could be justified on the basis of the patient's implied consent.[57] Consent cannot be implied merely because medical research is socially desirable: consent, implied or expressed, is an expression of the patient's independence and volition, although its limitations may, perhaps, in the absence of express knowledge, be based upon the reasonable expectations of ordinary patients. Expressions of general public approval of the sharing of confidential information for research purposes do not, however, translate into approval from patients themselves, who are no longer considering hypotheticals, and who would surely expect their own medical information to remain confidential in the absence of express consent to disclosure.

D. *The Common Law Requires Consent*

Under the common law, therefore, it appears that a patient's express consent is required if name-identifying, confidential medical information is to be accessed for research purposes by researchers not directly involved in the patient's

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54 Above n49. These recommendations have not been acted upon: Syrota, G, "The Problem of Confidentiality in Medical Research in Western Australia" (1994) 24 *Western Australian LR* 118.

55 See *Castrol Australia Pty Ltd v Emtech Associates Pty Ltd* (1980) 51 FLR 184 at 214–5; *David Syme & Co Ltd v General Motors Holden's Ltd* [1984] 2 NSWLR 294 at 306; *Corrs Pavey Whiting & Byrne v Collector of Customs (Vic)* (1987) 14 FCR 434 at 451; *Bacich v Australian Broadcasting Corporation* (1992) 29 NSWLR 1 at 16.

56 For example, Thomson, above n53 at 97–9; Bravender-Coyle, P, "The Law Relating to Confidentiality of Data Acquired by Researchers in the Biomedical and Social Sciences" (1986) 8 *U Tas LR* 333; Hayes, R, "Epidemiological Research and Privacy Protection" (1984) 141 *Medical J Aust* 621 at 623; above n50, par 859.

57 See Hayes, id at 623.

care. Thus, in example i above, investigators studying viral markers associated with AIDS-defining illnesses could not legally access name-identifying patient records unless they were also in a doctor/patient relationship with that patient. Similarly, in example ii above, employees of a pharmaceutical company sponsoring a drug trial could not legally inspect the medical records of participants without their consent. In examples iii and iv, medical practitioners could not access the medical records of other patients in other hospitals, without their consent.

This analysis suggests a direct conflict between the legal duty of confidentiality, which requires patient consent before releasing information to medical researchers, and ethical directives such as paragraph 7 of Supplementary Note 6 to the *NHMRC Statement*, which would permit IECs to dispense with consent in certain circumstances.

In some cases, simple procedures can be introduced into research protocols to ensure that the legal rights of patients are respected. In example ii above, patients enrolling in a randomised, double blinded drug trial would obviously be given patient information sheets to read, and consent forms to sign, before joining the trial. The patient information sheets could easily note that the patient's medical and trial records would ultimately be made available both to the researchers, and to employees of the industry sponsor. Prior to inspection, industry employees could be asked to sign a form undertaking to preserve the confidentiality of patient information and to use it only for the purposes of monitoring the research. This would ensure that third parties outside the relevant hospital or medical organisation who nevertheless had access to sensitive information would themselves be subject to a duty of confidence with respect to that information. Indeed, the IEC on which the writer serves regularly uses a form for this purpose in drug trials.

On the other hand, in my view, IECs are less likely to require researchers themselves to sign such a form on the basis that they are third parties accessing confidential information, at least when they are employed in the same hospital or organisation which the patient attends. Even so, in cases where the research itself involves medical treatment or investigation, the process of obtaining patient consent to the risks of treatment could obviously be extended to give the patient the opportunity to consider the issue of disclosure of confidential information to all researchers involved in the project. Thus, in an example such as i above (a cohort study of viral markers associated with AIDS-defining illnesses), where the size of the study would not preclude obtaining patient consent (and where the withdrawal of blood for research means that consent should in any event be sought), the consent process could easily include the issue of disclosure of information to researchers not on the patient's health care team.

The real difficulties arise principally within the context of epidemiological research: where consent is impractical because of the large number of medical records involved, or where the volume of material precludes removing patient identifiers, or where the research depends upon the linkage of information contained in records obtained from different sources, or where it would be difficult to contact the patient to obtain consent, or where the process of obtaining consent is likely to cause needless worry to the patient, or where refusal may affect the scientific validity of the project, or additionally where the initial disclosure of information to researchers is necessary to determine if the

patient is a suitable candidate for research (prior to any consenting process). Examples iii (creation of a SIDS database) and iv (a study of osteoporosis using data from a repatriation hospital) involve several of these concerns, although their resolution additionally requires a consideration of legislation regulating confidentiality and medical research in various Australian jurisdictions.

E. Commonwealth Legislation Regulating Privacy and Medical Research

Even a cursory glance at legislation regulating confidentiality in medical practice confirms my view that this is an area in need of urgent reform, particularly at the state level. It is useful, however, to begin with a brief review of Commonwealth regulation in this area.

The *Privacy Act* 1988 (Cth) applies to information obtained from Commonwealth (and ACT) agencies such as the Health Insurance Commission or the Department of Social Security. The Act contains 11 information privacy principles (IPPs) which set minimum standards for the privacy of personal information held by federal agencies. Federal agencies are prohibited from breaching the IPPs.[58] Of particular importance are IPPs 10 and 11, regulating the use and disclosure of personal information. Since the exceptions to compliance with the IPPs make no provision for the use or disclosure of name-identifying medical information for purposes of research, compliance with the IPPs requires specific patient consent if the information is to be used in research.[59] An exception is created, however, by section 95 of the Act, which provides that the NHMRC may issue guidelines for the protection of privacy in the conduct of medical research, which may also be approved by the Privacy Commissioner, if the Commissioner is satisfied that the public interest in the promotion of research carried out in accordance with the guidelines outweighs to a substantial degree the public interest in adhering to the IPPs.[60] Actions done in the course of medical research in accordance with approved guidelines are not regarded as breaching the IPPs.[61]

The current approved guidelines for the protection of privacy in medical research are under review by the AHEC. AHEC has circulated a discussion paper, together with new draft guidelines,[62] and in the meantime the operation of the current guidelines has been extended to 30 June 1995. No major overhaul of the current guidelines is envisaged as a result of the AHEC review. The current guidelines provide that (i) disclosure by a Commonwealth agency of identifying information for medical research, without consent and where the information was not originally collected for that purpose, and (ii) the collection of such information by an agency on behalf of a medical researcher, without consent, will be lawful if an IEC has found that the public interest in the medical research outweighs to a substantial degree the public interest in privacy.[63] Researchers seeking approval are required to submit written proposals

58 *Privacy Act* 1988 (Cth) s16.
59 Id s14: IPPs 10–1.
60 Id 95(1)–(2).
61 Id s95(4).
62 NHMRC, *Aspects of Privacy in Medical Research* (1994).
63 The relationship between the *Privacy Act* and the common law is uncertain. It may be ar-

detailing the IPPs which might be infringed in the course of the research, why name-identifying information is needed and how it will be collected, disclosed, used and protected. The IEC must also determine whether any IPPs will be breached, and whether there are sufficient grounds for not seeking consent to the collection and disclosure of the information. Only then is the IEC required to make a public interest determination in accordance with the guidelines.[64] In determining whether the public interest in medical research substantially outweighs the public interest in privacy, the IEC must consider a range of matters, including the social benefit of the research, scientific problems which might arise if the research were not conducted as proposed, and the degree of risk of harm or embarrassment to individuals whose nominal information is used in the research. Where approval is given, the IEC must monitor research projects to ensure that they proceed in accordance with the guidelines.

In addition to the approval of medical research by IECs under the guidelines, there is also a mechanism in the Act for a direct determination by the Privacy Commissioner that an act or practice carried out in the course of medical research shall not be regarded as infringing the IPPs.[65] This mechanism is really only meant for Commonwealth agencies seeking exemptions from compliance with the IPPs; however, the NHMRC can also apply for an exemption on behalf of organisations concerned with medical research. Again, the exemption will only be granted if the public interest in doing the act, or engaging in the practice, "outweighs to a substantial degree the public interest in adhering to [the particular] Information Privacy Principle".[66]

The above regime has been criticised on the basis that although it correctly identifies the issue as one involving a balance of public interests, it delegates the decision to groups of volunteers constituting IECs, whose expertise is in the area of medical ethics, and whose experience is in assessing the impact of medical decisions upon individual welfare, rather than in weighing competing public interest considerations in order to determine where the balance of public welfare lies.[67] Even so, existing IEC machinery permits the issue of privacy in medical research to be dealt with cheaply, informally, quickly, free from political bias and with due regard to the individual circumstances of each research project. For these reasons it is likely that IECs will remain central to any balancing mechanism. Compliance with the section 95 guidelines should at least stimulate detailed protocols enabling IECs to thoroughly canvass all the issues.

However, it is a mistake to overestimate the operation of the IPPs and the section 95 guidelines, as they only apply to medical research using federally-held information. In example iv above (the study of osteoporosis using data

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gued that the disclosure of nominal information in accordance with an IEC decision based on the s95 guidelines merely avoids liability for breaching the IPPs, but not liability at common law. My view, however, is that the reasonable intention of the legislature was that medical research conducted in accordance with the s95 guidelines should be lawful, and should not provide a cause of action for breach of confidentiality.

64 See *Commonwealth of Australia Gazette*, No P19, 1 July 1991, par 3.6.

65 *Privacy Act* 1988 (Cth) ss72–3.

66 Id s72(b).

67 Thomson, above n53 at 104–7.

from a Commonwealth-funded repatriation hospital), the legality of access to patient records would depend on whether the IEC had made a determination approving access under the section 95 guidelines. However, the states have no equivalent to the *Privacy Act*, and most medical research does not rely on federally-held data. If the history of privacy law reform in the states is any indication, reform will come slowly, if at all.[68]

F. *State Legislation Regulating Privacy and Medical Research*

In New South Wales, Queensland, South Australia and the ACT, medical research using name-identifying information without patient consent is permitted by executive order. Typically, the legislation authorises the release and use of such information for the purposes of research into "morbidity or mortality" occurring within the state with the approval of the Minister, and imposes upon the recipients of such information (the researchers) a duty not to use the information for any other purpose.[69] Victorian legislation provides that nominal information may be used in medical research if an IEC has approved the research protocol.[70]

These provisions are necessary, in view of the common law situation, and other provisions prohibiting disclosure of patient information by employees of public sector health services.[71] However, the scope of provisions allowing use of name-identifying information with ministerial permission is unclear in some cases. In New South Wales, for example, it is unclear whether it would extend to HIV information, disclosure of which is specifically prohibited by section 17 of the *Public Health Act* 1991 (NSW) with no relevant exceptions, not even where disclosure is otherwise authorised by law. More importantly, in view of the volume of medical research taking place, ministerial approval appears a tedious way of obtaining legal access to patient information, and there is no obligation upon the Minister, nor upon IECs in Victoria, to have regard to the considerations which would tend to safeguard the privacy interests of research subjects under the section 95 guidelines. In Tasmania, Western Australia and the Northern Territory, there is no legislative mechanism for accessing name-identifying patient information without consent for epidemiological research.[72] In those states, this would presumably prevent researchers from accessing medical records in order to develop a database of factors associated with SIDS, as discussed in example iii above, without the consent of the mothers' concerned.

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68 See, however, the Privacy and Data Protection Bill 1994 (NSW).

69 *Health Administration Act* 1982 (NSW) s23; *Health Act* 1937 (Qld) s154M–154N; *South Australian Health Commission Act* 1976 (SA) s64d; cf *Health Act* 1993 (ACT) s7; see also *Epidemiological Studies (Confidentiality) Act* 1992 (ACT) ss4–6.

70 *Health Services Act* 1988 (Vic) s141(3)(g); *Mental Health Act* 1986 (Vic) s120A(3)(g). Subsection 4 of both sections extends the duty of confidentiality to the recipient (the researcher).

71 *Health Administration Act* 1982 (NSW) s22; *Health Services Act* 1988 (Vic) s141 (applies to a range of public and private organisations); *Mental Health Act* 1986 (Vic) s120A (applies to organisations providing psychiatric services); *Health Services Act* 1991 (Qld) s5.1; *South Australian Health Commission Act* 1976 (SA) s64.

72 Although in Tasmania, for example, HIV information may be disclosed "for the purpose of an epidemiological study or research authorised by the Secretary": *HIV/AIDS Preventive Measures Act* 1993 (Tas) s19(1)(h).

G. *What Should Be Done?*

In my view, the justification for authorising a breach of the confidential doctor/patient relationship in the interests of medical research, can only be determined on a case by case basis. IECs are a cost-effective and accessible mechanism for fulfilling this function, although it must be recognised that determinations by IECs under section 95-type guidelines represent a broadening of the functions of IECs beyond protecting the individual subjects of medical research. It is important that members of IECs should be aware of the novelty of their new role in balancing competing public interests, and that the guidelines themselves continue to ensure that the interests of research subjects are not thereby eroded, but continue to conform to the *NHMRC Statement*, which provides that the interests of subjects take precedence over medical research interests.[73]

In conclusion, therefore, Australian legislation authorising disclosure of name-identifying patient information for medical research is patchy and inappropriate. No such legislation exists in Western Australia, Tasmania or the Northern Territory, and one can only speculate as to the extent to which unauthorised disclosures of patient information to researchers occur anyway. In the other states, legislation needs updating to ensure that access will only be granted in accordance with guidelines which require the IEC (or other decision-maker) to have regard to appropriate and relevant considerations which also protect the interests of research subjects. Compliance with ethical and legal standards is likely to be improved if researchers are subject to an accessible mechanism for determining whether access to identifying information should be permitted in appropriate cases. As noted above, IECs are, on balance, probably the best mechanism for determining these issues. However, in providing a proper legislatively-based mechanism for providing researchers with access to identifying medical information, it is important that researchers themselves should continue to be immune from subpoena by private litigants pursuing litigation against individual doctors.[74]

4. *Conclusion*

Although various statutes do apply to medical research, patients' interests are, in practical terms, primarily protected by the ethical review process; that is, by IECs reviewing research protocols in accordance with the *NHMRC Statement on Human Experimentation* and Supplementary Notes. The issues of (i) consent to use of human tissue in research, and (ii) consent to use of confidential information in medical research demonstrate, however, that the legal regulation of medical research deserves more attention. The legality of non-consensual use of human tissue is uncertain, while the NHMRC guidelines on non-consensual use of confidential information in medical research may at times invite

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73 Above n2.

74 See *Epidemiological Studies (Confidentiality) Act* 1981 (Cth) s8; *Epidemiological Studies (Confidentiality) Act* 1992 (ACT) s8; *Health Administration Act* 1982 (NSW) s23(5); *Health Act* 1937 (Qld) s154N(2A)–(2B); *South Australian Health Commission Act* 1976 (SA) s64d(3)–(5).

IECs to act unlawfully. At the very least, IECs need to be aware of the existing, if deficient, framework of principles and legislation reviewed in this article, when either of the above-mentioned issues arise. Lawyers sitting on IECs sit on such committees by virtue of the expertise their profession can bring to reviewing the ethics of research protocols. At a time where the potential legal liability of IECs has arisen as an issue, however, it is important that ethical standards imposed upon researchers by IECs should be at least as strict as legal ones. Additional problems are caused by the fragmentation of relevant legislation at state level, particularly with respect to confidentiality. While, realistically, nothing is likely to be done about this in the short term, it is important for bodies like the AHEC to be aware of the potential problems facing IECs arising from legal uncertainties, and to provide clear guidelines to IECs in the meantime.