



**THE LAW REFORM COMMISSION
OF WESTERN AUSTRALIA**

Project No 65 – Part II

**Confidentiality of Medical Records
And Medical Research**

DISCUSSION PAPER

MARCH 1989

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PREFACE

The Commission has been asked to consider and report on the question of confidentiality as it applies to the use of medical records for research purposes.

The Commission has not formed a final view on the issues raised in this discussion paper and welcomes the comment of those interested in the topic. It would help the Commission if views were supported by reasons.

Comments should be sent to the Commission by 26 May 1989.

Unless advised to the contrary, the Commission will assume that comments received are not confidential and that commentators agree to the Commission quoting from or referring to their comments, in whole or part, and to the comments being attributed to them. The Commission emphasises, however, that any desire for confidentiality or anonymity will be respected.

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ABBREVIATIONS

Bravender-Coyle	P Bravender-Coyle “The Law Relating to Confidentiality of Data Acquired by Researchers in the Bio-medical and Social Sciences” (1986) 8 <i>Uni of Tas LR</i> 333.
ALRC Privacy Report	The Australian Law Reform Commission <i>Privacy</i> (Report No 22 1983).
Law Commission Report	The English Law Commission <i>Breach of Confidence</i> (Report No 110 1981).
NHMRC	The National Health and Medical Research Council.
NHMRC Report	The National Health and Medical Research Council <i>Report on Ethics in Epidemiological Research</i> (1985)
NHMRC Epidemiological Unit	The National Health and Medical Research Council Unit in Epidemiology and Preventive Medicine

Chapter 1

INTRODUCTION

1. TERMS OF REFERENCE

1.1 The Commission has been asked to review the law relating to the use of patients' medical records for the purposes of medical research. The purpose of this paper is to discuss the issue of confidentiality and medical research and to give the public an opportunity to comment before the Commission makes its recommendations.

1.2 The Commission also has a general reference on privacy¹ and would normally have dealt with the above issue as part of that reference. However, with the approval of the Attorney General, it decided to deal with the issue separately because the State Health Department and other research organisations² have become increasingly concerned that development of the law of confidentiality could unduly inhibit medical - especially epidemiological³ - research in Western Australia or even stop large areas of it altogether.

1.3 Although the matter has not been the subject of a definitive legal ruling, a substantial body of legal opinion holds that the disclosure by a doctor or a hospital to a researcher of a patient's medical records, in a form which identifies the patient, is a breach of the legal duty of confidence, unless the patient has consented to the disclosure.⁴

1.4 The Commission understands that the use of confidential information with name identifiers is widespread in Western Australia. It appears that a large number of research projects are undertaken every year which use medical information without patient consent. Since 1979 the NHMRC Epidemiological Unit has produced many epidemiological studies based on name identified medical records. The Health Department has informed the Commission that other organizations, including the Health Department itself, also make extensive use of them. Unlike some other Australian jurisdictions, there is no legislative

¹ Project No 65.

² Including the NHMRC Epidemiological Unit.

³ Epidemiological research may broadly be defined as research into (a) the incidence or distribution of disease or death within the population and (b) the factors responsible for such incidence or death. In the nineteenth century it was mainly concerned with infectious diseases such as typhoid and cholera. Now it includes non-communicable diseases as well.

⁴ See ch 3 below.

exemption from the general law of confidentiality in favour of medical research. Hence researchers' concerns.

1.5 The Health Department has no quarrel with the broad thrust of the law of confidentiality. The general requirement of consent helps safeguard a patient's medical record from unwanted public exposure or disclosure to a person who may use it in a way adverse to the patient. But it is the Department's view that disclosure for the purpose of medical research should be governed by a less restrictive rule. It argues that since the community as a whole readily accepts the benefits of medical research,⁵ we should also be prepared to accept that degree of loss of privacy involved in the disclosure of our medical records for the purposes of that research.⁶

1.6 It is important to emphasize -

- (a) That the difficulty which the law of confidentiality places in the way of medical research concerns the disclosure without the patient's consent of a patient's medical records in a way which can identify the patient. Disclosure of medical information from which individual patients cannot be identified presents no problem: no breach of confidence is thereby involved. Likewise, where a patient consents to the use of his or her medical records problems are unlikely to arise unless the records are misused or misapplied.
- (b) That the broad issue discussed in this paper is whether doctors or other record-keepers should be authorised to disclose a patient's record without patient consent for medical research purposes without breaching the legal duty of confidence. The issue is not whether they should be *required* to do so. Whether there should be a requirement to disclose would continue to be dealt with on a subject by subject basis, as at present, through specific statutory provision.⁷

⁵ An obvious example of the benefits of medical research is the dramatic drop in developed countries in the incidence of major epidemic diseases such as cholera and tuberculosis. Benefits can be expected from the substantial research effort being directed towards the causes, prevention, and cure of cancer and AIDS.

⁶ See also L Gordis and E Gold "Privacy, Confidentiality and the Use of Medical Records in Research" (1980) 207 *Science* 153; Bravender-Coyle 356-357.

⁷ See, for example, the provisions referred to in footnote 20 to ch 3 below.

2. LAYOUT OF PAPER

1.7 The remainder of the paper is divided into 5 chapters. Chapter 2 lists the questions upon which comment is specifically invited. Chapter 3 reviews the law relating to privacy and confidentiality and considers the impact of this law on medical research. Chapter 4 discusses the nature and methodology of medical research, particularly epidemiological research, and the need from the researcher's point of view to have access to patient identifiable medical records without the patient's consent. Chapter 5 reviews several legislative initiatives in the area of confidentiality and medical research. The final chapter raises a number of salient issues and summarizes the Commission's approach.

Chapter 2

QUESTIONS AT ISSUE

2.1 The Commission welcomes comment on any matter arising out of the terms of reference and in particular on the following. (Chapter 6 below - "Options for Reform" - discusses what the Commission regards as the important issues.)

Disclosure of confidential information

1. Should doctors be authorised by statute to disclose patient-identifiable information relating to their patients, without the patients' consent, for the purpose of approved medical research?

Scope of medical research

2. If so, is it desirable to define the type of medical research for which disclosure may be made? Should it be confined to epidemiological research or should it encompass other forms of medical research? Should the legislation even include "social research" (cf the *Victorian Health Services Act 1988*)?¹

Approval

3. If the answer to 1 is yes, should approval of research be granted by -
 - (a) Government officer (Governor, Minister for Health or Commissioner of Health -please stipulate);
 - (b) an institutional ethics committee; or
 - (c) some other person or body?
4. If the answer to Question 3 is an institutional ethics committee, how should the committee be constituted and to whom should it be responsible?

¹ Para 5.19 below.

5. Should regulations be promulgated listing the factors to which the approving body (whether Government officer, ethics committee or other) must have regard in approving the disclosure of patients' records?

Protection of information disclosed for medical research

6. Assuming confidential medical information has been obtained by a person for the purpose of approved medical research, should the unauthorised disclosure of that information to a third party give rise to civil remedies or be an offence?

Chapter 3

LEGAL ASPECTS OF CONFIDENTIALITY

1. INTRODUCTION

3.1 The law relating to breach of confidence has been described as uncertain and inadequate¹ although there are signs that the law has recently been developing in a "reasonably consistent, yet flexible, fashion."² An action for breach of confidence may lie in contract or in equity for breach of a fiduciary duty.³ Specific statutes may also restrict or prohibit the release of information.⁴

3.2 Privacy and confidentiality have been the subject of quite a number of Committee and Commission papers, both in Australia and elsewhere.⁵ The specific question of research and confidentiality has been dealt with by a number of academic writers⁶ and was touched upon in the ALRC Privacy Report. The following is a brief outline of the law concerning confidentiality in the medical context as gleaned from current materials. It deals with the situation where there is a contract between doctor and patient and where there is not.

¹ Law Commission Report para 6.1.

² ALRC Privacy Report Vol 1 para 862.

³ There is little to support the existence of a separate and distinct tort of breach of confidence: see *Malone v Metropolitan Police Commissioner* [1979] Ch 344, 360 per Megarry V-C; The Law Commission Report paras 4.74-4.77; PM North "Breach of Confidence: Is there a New Tort?" (1972) 12 *JSPTL* 149; R Goff and G Jones *The Law of Restitution* (2nd ed 1978); 518, 519; J Kearney *The Action for Breach of Confidence in Australia* (1985) 30; H Street *The Law of Torts* (6th ed 1976) 377. The proposal in the Law Commission Report for the creation of a statutory tort of breach of confidence has not yet been acted upon.

Exceptionally, some breaches of doctor/patient confidentiality may give rise to liability in negligence: *Furniss v Fitchett* [1958] NZLR 396. In that case the doctor was approached by a distraught Mr Furniss for a medical report on his wife's mental condition to give to his solicitors. Relations between Mr Furniss and his wife were extremely strained. Later the doctor's report was introduced by the husband's solicitor in separation proceedings. The revelation to Mrs Furniss of her doctor's opinion of her condition caused her to suffer nervous shock. The Court held that the doctor should have foreseen that the disclosure in the report was likely to harm the patient's health and accordingly awarded damages in negligence.

Exceptionally also an action for defamation may lie.

⁴ For example, *Health Act 1911* ss 314(1) and 340AK(5b); *The Criminal Code* s 81; *Crimes Act 1914* (Cth) s 70; *Epidemiological Studies (Confidentiality) Act 1981* (Cth) s 4.

⁵ For example, ALRC Privacy Report; ALRC *Privacy and Personal Information* (DP No 14 1980); *The Committee on Privacy and Data Banks in Western Australia* (1976), the "Mann Committee"; New South Wales Privacy Committee *Research and Confidential Data: Guidelines for Access* (1985); The Law Commission Report.

⁶ For example, Bravender-Coyle 336; J N Gray and G B Melton "The Law and Ethics of Psychosocial Research on AIDS" (1985) 64 *Nebraska LR* 637; W J Winslade and J W Ross "Privacy, Confidentiality, and Autonomy in Psychotherapy" (1985) 64 *Nebraska LR* 578.

2. CONTRACT

3.3 An obligation to maintain confidentiality may be imposed by contract, express or implied. There seems little doubt that, where there is a contract between a doctor and his or her patient,⁷ it is an implied term of that contract that the doctor will maintain confidentiality as regards the patient's medical condition.⁸ Where the right of confidentiality is contractual the patient may obtain damages for breach. Damage may cover mental distress caused by the breach provided that the possibility of such damage was contemplated by the parties.⁹ An injunction may lie to restrain a threatened breach of confidence. If the breach of contract was induced by a third party an action in tort may also lie against that party.¹⁰

3.4 If, in a contractual situation, it is the doctor's nurse or other employee, and not the doctor, who breaches the confidence, the patient would probably be able to take proceedings against the doctor under an implied warranty that his or her employee would maintain secrecy. The patient may also be able to proceed directly against the nurse for breach of the fiduciary duty the nurse personally owes the patient.¹¹

3. EQUITABLE OBLIGATIONS

3.5 Contract law may provide an inadequate remedy for breach of confidence. The nature of modern medical practice is such that there is often no contractual relationship between the

⁷ There would usually be a contract where a person consults a doctor at a suburban surgery or clinic. See para 3.5 for non-contractual situations.

⁸ *Tournier v National Provincial and Union Bank of England* [1924] 1 KB 461; *Parry-Jones v Law Society* [1969] 1 Ch 1: In the latter case Lord Denning said (at 7): "The law implies a term in the contract whereby a professional man is to keep his client's affairs secret." This dictum would cover the case of a doctor.

Such an implied term satisfies the conditions referred to by the Privy Council in *BP Refinery (Westernport) Pty Ltd v Hastings Shire Council* (1911) 52 ALJR 20. The term implied is reasonable and equitable and is necessary to give "business efficacy" to the contract. The term is so obvious that it "goes without saying". The Hippocratic Oath and its modern derivatives (see Part A of Appendix I below) reinforces this view.

⁹ *Heywood v Wellers* [1976] QB 446, 461 per James LJ; Law Commission Report paras 4.80 and 4.82.

¹⁰ Thus, assuming the doctor was in breach of contract in disclosing the patient's medical records to a researcher, and that the researcher had persuaded the doctor to do so, the researcher may be liable in tort to the patient for procuring a breach of contract.

¹¹ A person who has acquired personal information and who knows or ought to know the confidential nature of the information is subject to the same obligation of confidence as the original confidant: Law Commission Report paras 4.11 and 4.12. S 92 of the *Privacy Act 1988* (Cth) gives a confider a statutory right of action in such circumstances as against the persons to whom the Act applies (Commonwealth officers and agencies and persons subject to the law of the Australian Capital Territory).

For a discussion (not in the medical context) of the rights and obligations under the general law of a confider, employer, employee, subcontractor and other parties see P D Finn *Fiduciary Obligations* (1977) 152-156. See also the ALRC Privacy Report Vol 1 paras 903-921.

doctor and the patient, for example, where a doctor employed by a public hospital provides medical services to a patient admitted to the hospital.

3.6 In such a case the patient can look to equity for protection. Certain relationships are characterised by an equitable duty of confidentiality; the doctor-patient relationship is clearly recognised as giving rise to such a duty.¹² The duty applies not only to information actually imparted by the patient to the doctor but also to information derived by observation, examination and testing and from consultants' reports. It subsists after the relationship has ceased.¹³

3.7 Since the duty is equitable, the normal equitable remedies apply. The court may grant an injunction to prevent anticipated breaches of confidentiality and where an injunction is not appropriate, for example post-disclosure, damages may lie. Although the law is not completely settled, it appears that these remedies would be available even where the patient could not point to any positive detriment suffered by the disclosure,¹⁴ though in the absence of such detriment any damages awarded would be nominal.

3.8 As part of the investigation and treatment of a patient's condition the clinician for the time being in charge of the patient will usually need to consult, or direct, other health professionals and pass on confidential information for this purpose. In large hospitals many persons may need to be told of the patient's condition for a purpose connected with the patient's treatment or the running of the hospital: radiologists, pathologists, nurses, dieticians, physiotherapists, welfare officers, orderlies and administrative personnel may all be included.¹⁵ The law would no doubt regard disclosure to these people as being implicitly authorised by the patient. However, as with the nurse in the simple example given in paragraph 3.4 above, they would likewise be subject to an equitable duty of confidence as

¹² *AG v Guardian Newspapers (No 2)* [1988] 8 WLR 776, 781 per Lord Keith. Other relationships giving rise to inequitable duty of confidentiality include solicitor and client and banker and customer: *ibid*.

¹³ The scope of the duty implied by contract is similar.

¹⁴ F Gurry *Breach of Confidence*, *Essays in Equity* (1985 ed P D Finn) 110, 112; *AG v Guardian Newspapers (No 2)* [1988] 3 WLR 776 at 782 per Lord Keith. For a contrary view see that of Lord Griffiths in the same case at 795.

¹⁵ Information about the patient may of course flow from them to the clinician; eg a pathologist's report containing the results of a biopsy. The clinician is as much bound by the equitable duty of confidence in respect of that information as if he or she had conducted the biopsy personally: para 3.6 above.

regards the information entrusted to them.¹⁶ This duty cannot legally be overridden merely on the instructions of the confidant's superior.¹⁷

4. EXCEPTIONS TO CONFIDENCE

3.9 The duty of confidence is not absolute. There are circumstances in which confidential information may, or even must, be disclosed. Confidential information may of course, be disclosed with the consent of the patient provided the disclosure is in accordance with the terms of the consent.¹⁸ A doctor may also disclose confidential information where the doctor's interests require disclosure, for example in order to defend a legal action brought by the patient or to enforce a debt against the patient.¹⁹ Sometimes the doctor *must* disclose the information, for example where the doctor is a witness in court proceedings and is asked a question about the patient's condition. There are also a number of provisions in the *Health Act 1911*, or in regulations made thereunder, which impose mandatory reporting requirements for certain diseases or conditions.²⁰

3.10 The law of confidentiality also recognises the defence of disclosure "in the public interest", and it is this category which might be thought to be the most relevant for medical research. However the cases where disclosure has been held to be so justified concerned criminal or illegal activity, or the prevention of harm to innocent people.²¹ As far as the Commission is aware, no reported case has involved disclosure for medical research so that this issue has not been determined judicially. But no judge has, in attempting to illustrate the bounds of the public interest category, suggested medical research as an example of justified

¹⁶ The duty of confidence is of course not confined to the duty not to disclose any written document and extends to any confidential information whether on paper, in a computer or merely in the confidant's head.

¹⁷ *Slater v Bissett and Another* (1986) 85 FLR 118, a decision of the Supreme Court of the Australian Capital Territory.

¹⁸ Strictly speaking, disclosure with consent is not an exception to the duty of confidence since the quality of confidentiality no longer applies to the information.

¹⁹ ALRC Privacy Report Vol 1 para 915.

²⁰ For example, ss 300 and 301 of the *Health Act 1911* (venereal diseases). The *Health (Notification of Cancer) Regulations 1981*, which require notification to the Health Department in patient identifiable form of a patient's cancer, were introduced to facilitate epidemiological research.

²¹ There is an interesting discussion by M Neave in "AIDS - Confidentiality and the Duty to Warn" (1987) 9 *Uni of Tas LR* 1 on whether there is a *duty* to disclose in certain circumstances, for example where the patient's condition poses a threat to the community.

disclosure.²² A passage in the judgment of Duff J in the leading Canadian case of *Halls v Mitchell*²³ sums up what appears to be the general position:

"It is not necessary, for the purposes of this appeal, to attempt to state with any sort of precision the limits of the obligation of secrecy which rests upon the medical practitioner in relation to professional secrets acquired by him in the course of his practice. Nobody would dispute that a secret so acquired is the secret of the patient, and, normally, is under his control, and not under that of the doctor. *Prima facie*, the patient has the right to require that the secret shall not be divulged; and that right is absolute, unless there is some paramount reason which overrides it. Such reasons may arise, no doubt, from the existence of facts which bring into play overpowering considerations connected with public justice; and there may be cases in which reasons connected with the safety of individuals or of the public, physical or moral, would be sufficiently cogent to supersede or qualify the obligations *prima facie* imposed by the confidential relation."

3.11 The ALRC's Privacy Report put the position in the form of a warning:

"There is undesirable uncertainty associated with the extent to which 'public interest' might be relied upon to justify an unauthorised disclosure of personal information. Those undertaking clinical data trials, epidemiological research projects and other projects dependent upon a large supply of personal information should not be encouraged to justify them by reference to an expansive concept of 'public interest', but through legislation specifically authorising a particular activity".²⁴

5. DISCIPLINARY PROCEEDINGS

3.12 So far this chapter has been concerned with the general law of confidentiality as it applies to medical records and the various legal remedies available to a patient for breach of confidence. A health professional who has breached a confidence without just excuse may also be subject to disciplinary proceedings. For example, a complaint may be made to the Medical Board which has authority to discipline or deregister a medical practitioner for

²² A summary of cases in the "public interest" category is contained in Bravender-Coyle. The author said (at 849): "[The] advice given by some lawyers that certain forms of research, such as epidemiological research, would come within the 'public interest' exception to the duty of confidentiality is probably not tenable in the light of judicial decisions".

²³ [1928] 2 DLR 97, 105. The case concerned an action for defamation by a former patient against a doctor. Halls had applied for compensation from the Canadian National Railways after he suffered an eye ailment which he ascribed to a blow from a swinging door. Mitchell, whom Halls had consulted some years before in a private capacity, was the medical officer for the Canadian Railways. He had given incorrect information that Halls had previously suffered from venereal disease to an army doctor from whom Mitchell was seeking Halls' army medical records and to an independent physician who was examining Halls for the purposes of the claim. The Court held that Mitchell's duty to ensure that the Workmen's Compensation Board received accurate information did not require him to betray professional confidences to third parties.

²⁴ Vol 1 para 859.

"infamous or improper conduct in a professional respect".²⁵ The Board would determine whether the disclosure of information in the circumstances constituted such conduct. A similar situation exists as regards nurses²⁶ and psychologists.²⁷

3.13 A successful complainant would, of course, derive no direct benefit from the Board's decision. In any event there may be a tension between the general law of confidentiality as laid down by the courts and the rules of "professional ethics" laid down by professional and other organisations. A number of such bodies have made policy statements indicating their view that disclosure of medical records for research purposes can be ethically justified.²⁸ It is an interesting question whether, in determining whether a health care professional had engaged in improper conduct by disclosing medical records, the controlling authority should have regard only to the general law or whether it could take into account the views of these bodies, or even treat them as paramount. A similar question would arise where the researcher who made use of the records was a health professional also subject to the jurisdiction of a controlling authority.

6. WHAT INTERESTS DOES THE PRESENT LAW STRIVE TO PROTECT?

3.14 In the medical field the right to have confidence respected is seen primarily as an aspect of privacy, something which belongs to the patient. Confidentiality may also be seen from a broader perspective as an essential element of an effective health care system without which patients may be less inclined to expose themselves to the scrutiny of health care professionals. This is particularly true in the fields of psychiatry and psychotherapy where confidentiality is especially important and fears of disclosure may fundamentally undermine the doctor-patient relationship.

3.15 The dual role of confidentiality in the therapeutic process has been noted by Siegler:

"In the first place it acknowledges respect for the patient's sense of individuality and privacy. The patient's most personal physical and psychological secrets are kept

²⁵ *Medical Act 1894* s 13(1)(a). See *Duncan v Medical Practitioners Disciplinary Committee* [1986] 1 NZLR 513, 521-522.

²⁶ The Nurses Board may discipline or deregister a nurse who has been guilty of "malpractice, impropriety or misconduct in respect of her calling as a nurse": *Nurses Act 1968* s 29(1)(c).

²⁷ The Psychologists Board may discipline or deregister a psychologist for improper conduct in a professional respect by reason of carelessness, incompetence, impropriety or infamous behaviour: *Psychologists Registration Act 1976* s 39.

²⁸ Their statements are reproduced in Part B of Appendix I below.

confidential in order to decrease a sense of shame and vulnerability. Secondly, confidentiality is important in improving the patient's health care - a basic goal of medicine. The promise of confidentiality permits people to trust (ie have confidence) that information revealed to a physician in the course of a medical encounter will not be disseminated further. In this way, patients are encouraged to communicate honestly and forthrightly with doctors. This bond of trust between patient and doctor is vitally important both in the diagnostic process...and subsequently in the treatment phase, which often depends as much on the patient's trust of the physician as it does on medications and surgery.²⁹

Confidentiality may thus be seen both as a means to an end (the provision of effective health care) and as an end in itself (protection of privacy).

3.16 Whether one takes the first or the second basis, it must be acknowledged that there are occasions when research needs cannot be harmonised with a strict requirement of confidentiality. As indicated above,³⁰ a number of authoritative bodies have recognised the need for the use of name identified records without patient consent and have attempted to set out the circumstances in which this is ethically justified. Such bodies overseas include the United States Department of Health and Human Services, the General Medical Council of the United Kingdom, the Medical Research Council of the United Kingdom, the United States Privacy Protection Commission and the Commission of Inquiry into the Confidentiality of Health Information in Canada.³¹ A similar approach has been taken in Australia by the NHMRC.³²

3.17 The following chapter elaborates the reasons given for these views.

²⁹ [1982] *New Eng Journal of Medicine* 1519-1520.

³⁰ Para 3.13.

³¹ For statements by some of these bodies, see Part B of Appendix I.

³² *Report on Ethics in Epidemiological Research* (1985) Supplementary Note on Epidemiological Research.

Chapter 4

THE NATURE AND METHODOLOGY OF MEDICAL RESEARCH - A PUBLIC HEALTH PERSPECTIVE

1. THE USE OF MEDICAL RECORDS

4.1 Some medical research projects generate self-standing records but many depend on access to pre-existing records, for example where -

1. **The research necessitates the identification of all cases of a particular disease occurring in a group of people exposed to a potentially harmful (or beneficial) substance.** Thus to determine if Vietnam veterans exposed to Agent Orange had an increased risk of birth defects in their offspring, it was necessary to identify from medical records all cases of birth defects occurring in veterans' children.¹
2. **The research necessitates the identification of all cases of a particular disease occurring in a population living in a defined geographic area and time period, or attending a particular clinic or hospital.** For example, to examine the effect of sun exposure on the risk of developing melanoma skin cancer, the sun exposure histories of all patients with melanoma occurring in a two year period and a random sample of people from the general population were compared.²
3. **The research necessitates the identification of all patients exposed to a particular type of treatment or medical technology.** Thus, to find out if babies conceived through artificial procedures such as in vitro fertilization suffer any increased risk of disease or disability compared with naturally

¹ J W Donovan, R MacLennan and M Adena "Vietnam Service and the Risk of Congenital Anomalies - A Case-Control Study" (1984) 140 *Medical Journal of Australia* 394-397.

² C D J Holman, B K Armstrong, P J Heenan, J B Blackwell, F J Cumming, D R English, S Holland, G R H Kelsall, L R Matz, I L Rouse, A Singh, R E J Ten Seldam, J D Watt and Z Xu *The Causes of Malignant Melanoma: Results of the West Australia Lions Melanoma Research Project* (1986) 102 Recent Results in Cancer Research 18-37.

Access to medical records in the two types of study described in 1 and 2 of para 4.1 enables identification or verification of the diagnosis, as well as providing information that allows different variants of the disease to be studied on an individual basis. In the second example review of pathology records and tissue specimens showed that the importance of sun exposure during the teenage and young adult years applied mainly to one sub-type of melanoma skin cancer.

conceived babies, it was necessary to identify from medical records the mothers whose babies were artificially conceived, and then using other medical records to examine the medical histories of the babies during early childhood.³

4. **The research necessitates the collection of other medical information that is only available in medical records.** For example, in a study of the Pap smear histories of women with cancer of the uterine cervix, based on medical records, it was found that one in every eleven women with cervical cancer had at least one abnormal Pap smear during the five years before diagnosis, but appropriate medical action had not been taken when the abnormality was first reported.⁴

2. THE USE OF PATIENT IDENTIFIABLE MEDICAL RECORDS

4.2 It is usual for each page of a patient's medical record to be headed by the patient's name and other basic identifying details such as sex and date of birth. The purpose is to minimise the risk of patients' test results being confused or the wrong treatment given.

4.3 Although it is theoretically possible to remove patient names from medical records prior to access by researchers, to do so would not only add to the administrative cost but, more importantly, increase the probability of error arising from the administration of duplicate medical record systems side by side, one for use in patient management and one for use in research.

4.4 There are, however, more fundamental reasons why patient identifiers should be preserved. Linkage between different sources of patient information is essential for many types of medical research. For example, if the health effects of exposure to a potentially dangerous chemical in the workplace or environment are to be assessed accurately, it is necessary for the researcher to work from a list of the people who have been exposed, and often a corresponding control group of unexposed persons. The object is to gain access to the

³ S Webb *In Vitro Fertilization and Related Procedures in Western Australia 1983-1987: A Demographic Clinical and Economic Evaluation*, a study by the Health Department of Western Australia (1988).

⁴ C D J Holman, A J McCartney, K L Hyde and B K Armstrong "Cervical Cytology Histories of 100 Women with Invasive Carcinoma of the Cervix" [1981] 2 *Medical Journal of Australia* 597-598. This example illustrates the value of using medical records to enable the medical profession to review and improve its standard of treatment and care.

correct medical records so that instances of disease can be documented and linked statistically with the corresponding information on level of exposure to the chemical concerned. This is particularly important in epidemiological research.⁵

4.5 Often, in order to determine the relative benefits and disadvantages of different forms of treatment for a particular illness, it is necessary for the researcher, having identified the appropriate group of patients, to have access to later medical information on the apparent success or otherwise of each treatment. Patients may have moved or changed doctors, and the information must then be sought from a source other than the original. Some patients may be dead, in which case the researcher will usually need to check the patient's death certificate for the cause of death. These secondary sources of follow-up information cannot be used unless the researcher has a record of the patients' identities.

4.6 Finally, under the case-control study method, the researcher may (with the agreement of the patient's doctor) wish to obtain further information directly from the patient, for example, on smoking habits, diet, exposure to drugs or chemicals, alcohol intake, and so on.⁶ Such information is often necessary so that data obtained from patients' records can be accurately interpreted. Access to patients for this purpose would be impossible if their identities were unknown.

3. USE OF PATIENT IDENTIFIABLE MEDICAL RECORDS WITHOUT PATIENT CONSENT

4.7 As previously noted, a considerable body of legal opinion supports the view that the use of patient identifiable confidential information for medical research purposes without patient consent is not authorised by law.⁷

4.8 One solution would be to ensure that informed consent is obtained from the patient at the time of seeking health care, at least in relation to disclosure for medical research.⁸ But epidemiologists submit that this approach is unrealistic for the following reasons -

⁵ "Privacy, Epidemiology, and Record Linkage" (1979) *British Medical Journal* 1018.

⁶ For guidelines concerning access to patients identified from medical records, see the NHMRC Report paras 9.5-9.12.

⁷ See ch 3.

⁸ This suggestion was put forward in the ALRC Privacy Report Vol 2 para 1298.

- (a) Doctors and hospital staff lack the resources to implement an effective informed consent programme;⁹
- (b) Many patients will be too ill to address the issue of informed consent, and may never recover sufficiently to do so;
- (c) The vast bulk of existing medical data collected on previous patients would remain locked away - many of the record-subjects would be untraceable or dead;
- (d) Many valuable records are compiled under circumstances where there is no opportunity for the record-subject to express or withhold consent.¹⁰

4.9 Epidemiological studies seek to demonstrate a statistical association between the condition under investigation and an exposure or risk factor. A requirement of consent may diminish the size of the sample, or skew it by eliminating those who withhold consent or who cannot be traced, and to that extent may undermine the validity of the study. This argument supports usage of subject-identified medical records without patient consent in some cases, but does not go so far as to demonstrate the need for access to records complete with subject identifiers in all situations.

4. CONCLUSION

4.10 The nature and methodology of much epidemiological research seems incompatible with a total ban on the use of name-identified patient information in the absence of patient consent. Studies based upon large population samples using linkage techniques (where name identifiers must be used as the common link) would be drastically affected by such a ban.

⁹ Hospital doctors and nurses engaged in the treatment of patients may not be the best people to explain the benefits of research and to allay any fears that patients may have about breaches of confidentiality.

¹⁰ B K Armstrong "Privacy and Medical Research" (1984) 141 *Medical Journal of Australia* 620 gives the following reasons for rejecting the proposed solution: "First, because it is unlikely to be implemented at the point of collection of *all* medical records, and completeness is the essence of validity and generalisation of much medical research. Second, because it would prevent the use of historical information or information collected outside the health system where this practice does not apply (for example, information on industrial exposure to chemical hazards). Third, because it is not at all certain that this prospective, and essentially uninformed, consent would, in the event of legal challenge, prove to be adequate."

See also the NHMRC Report paras 6.2-6.6.

4.11 Present research practice, which regularly uses medical records with subject identifiers in the absence of subject consent, stands in opposition to the law as perceived by the Australian Law Reform Commission and others.¹¹ The question is whether the law should be amended so as clearly to authorise the practice and, if so, what the limits and safeguards should be.

¹¹ Ch 3 above.

Chapter 5

THE LAW ELSEWHERE

1. GENERAL

5.1 The importance of privacy and confidentiality in the therapeutic process has been noted above.¹ But privacy is also important in the conduct of medical research. Doctors and other record keepers are less likely to release confidential information in patient identifiable form for that purpose unless satisfied that the safeguards against misuse or disclosure - whether deliberate or inadvertent - by the researcher are adequate. This comment applies equally where the researcher seeks information directly from patients, whose voluntary co-operation is important for medical research, especially epidemiological research.²

5.2 The following quotations illustrate the importance of privacy in medical research, and the need to pay proper regard to that interest in conducting it:

- (a) "The first principle in use of medical records for research, as in medicine generally, is to do no harm. As regards privacy, this will be best achieved if disclosure of confidential information is the least required to achieve research objectives."³
- (b) "The importance of confidentiality of any patient's record is paramount. If patients' records are to be used for clinical or epidemiological research, it is incumbent on the medical practitioner to ensure that the patient's identity is safeguarded" Information should be disclosed only for worthwhile medical research conducted according to a written protocol approved by a recognised ethical committee. The disclosure should be the minimum necessary to the research and the protocol should make explicit provision for maintaining the confidentiality of any individually identified or identifiable data."⁴

5.3 The *Code of Practice for Use of Name-Identified Data from Health Statistical Data Collections*, issued by the Health Department of Western Australia in 1986, also emphasises the role of privacy in medical research. The Code is reproduced in Appendix II.

¹ Paras 3.14 and 3.15.

² As noted by Dr Blewett, in debate on the Epidemiological Studies (Confidentiality) Bill 1981 (Cth) "[I]f such studies are to be successful the participants in the studies must have complete confidence that in no way will the personally identifiable material be released": Commonwealth Parliamentary Debates (House of Representatives) 8 September 1981 p 1032.

³ B K Armstrong "Privacy and medical research" (1984) *The Medical Journal of Australia* 620, 621.

⁴ Australian Medical Association: see Part B of Appendix I below.

5.4 The issue of confidentiality assumes particular importance in the fields of psychiatry and psychology, as noted above, and in the case of patients who seek advice or treatment for AIDS and sexually transmitted diseases. The adverse social, legal and economic consequences which may result from a breach of confidentiality in these cases are obvious.

5.5 The following outlines the various legislative initiatives taken by other Australasian jurisdictions in their attempts to strike a proper balance.

2. COMMONWEALTH LEGISLATION

(a) Epidemiological Studies (Confidentiality) Act 1981

5.6 The philosophy that underlines this legislation is that confidentiality is essential for effective epidemiological research. The Act was passed primarily to facilitate the Commonwealth study into the long-term side-effects of certain chemicals used during the war in Vietnam (the so-called Vietnam Veterans study) of which Agent Orange is the best known.⁵ The Act serves to facilitate epidemiological research by protecting information obtained in the course of certain prescribed studies. Data and records accumulated in such studies are protected against the demands of courts or persons empowered to require the production of documents or the answering of questions.⁶ The Act imposes penalties for breaches of confidentiality by persons working on a study proclaimed under the Act.⁷

5.7 There is no general provision under the legislation permitting disclosure by record-keepers (including doctors) to those conducting or assisting in the conduct of prescribed studies. Given the primary focus of the Commonwealth study, namely the Vietnam Veterans study, it was perhaps thought unnecessary to deal with the problem of consent, for the subjects were keen to participate in order to vindicate their claims against the Commonwealth for compensation. Other studies may evoke a lesser degree of subject co-operation.

5.8 Section 5 of the Act permits disclosure with Ministerial approval of documents prepared or obtained in the conduct of a prescribed study to persons assisting in the conduct

⁵ The Act permits other studies to be proclaimed. Recent studies which have been declared as "prescribed studies" are noted in Appendix III.

⁶ Ss 3 and 8.

⁷ Ss 4 and 6.

of another prescribed study. Section 7 permits disclosure of information to certain persons specified in that section.⁸ Section 11 affirms that the findings of any prescribed study "shall not be published in a manner that enables the identification of an individual person (including a deceased person)".

5.9 The Act does not contain any restriction upon publication of information obtained from a person conducting or assisting in the conduct of the study by a person not so involved. A journalist could publish information obtained from a person assisting in a study without breach of the Act.

(b) Privacy Act 1988

5.10 The Commonwealth *Privacy Act 1988* (not yet in force) was enacted to implement recommendations in the ALRC Privacy Report.⁹ The Act establishes rules of conduct, called Information Privacy Principles, for the collection, retention, access to, correction, use and disclosure of personal information about individuals. The Information Privacy Principles apply only to Commonwealth departments and agencies who are required to avoid doing any act which amounts to a breach of these Principles. The Act establishes the Office of Privacy Commissioner to investigate complaints that a department or agency has breached a Principle. If the Commissioner concludes that it has, he may make a declaration that the agency should not repeat the conduct and in any case may award damages to the complainant.

5.11 Of particular relevance to medical research is Principle No 11 which is as follows:

"Limits on disclosure of personal information

1. A record-keeper who has possession or control of a record that contains personal information shall not disclose the information to a person, body or agency (other than the individual concerned) unless:

⁸ By virtue of this section a person who has assisted, or is assisting, in the conduct of a prescribed study may give information concerning the affairs of another to: (a) the person who supplied the information; (b) where the information concerns the affairs of only one person - that person; (c) where the information concerns the affairs of two or more persons - any of those persons with the consent of the other person, or each other person, whose affairs that information concerns; or (d) a person nominated by a person to whom information may be given by virtue of (a), (b) or (c).

⁹ A previous Bill, the Privacy Bill 1986, was introduced as a companion piece to the Australia Card Bill 1986, but subsequently lapsed. It was reintroduced with modifications in 1988.

- (a) the individual concerned is reasonably likely to have been aware, or made aware under Principle 2,¹⁰ that information of that kind is usually passed to that person, body or agency;
- (b) the individual concerned has consented to the disclosure,
- (c) the record-keeper believes on reasonable grounds that the disclosure is necessary to prevent or lessen a serious and imminent threat to the life or health of the individual concerned or of another person;
- (d) the disclosure is required or authorised by or under law; or
- (e) the disclosure is reasonably necessary for the enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue."

5.12 Generally speaking, therefore, a record-keeper in a Commonwealth agency would breach this Principle if he or she disclosed a patient's medical record to a researcher without the patient's consent unless the record-keeper were protected by some other provision. Protection is provided by section 95 of the *Privacy Act* which empowers the NHMRC, with the approval of the Privacy Commissioner, to issue guidelines "for the protection of privacy in the conduct of medical research". The section provides that an act done in the course of medical research and in accordance with those guidelines is not to be regarded as breaching an Information Privacy Principle. Medical research is defined to include epidemiological research.

5.13 There is an important limitation to the Commissioner's power to approve the guidelines: he or she must be "satisfied that the public interest in the promotion of research of

¹⁰ Principle 2 is as follows:

"Where:

- (a) a collector collects personal information for inclusion in a record or in a generally available publication; and
 - (b) the information is solicited by the collector from the individual concerned;
- the collector shall take such steps (if any) as are, in the circumstances, reasonable to ensure that, before the information is collected or, if that is not practicable, as soon as practicable after the information is collected, the individual concerned is generally aware of:
- (c) the purpose for which the information is being collected;
 - (d) if the collection of the information is authorised or required by or under law - the fact that the collection of the information is so authorised or required; and
 - (e) any person to whom, or any body or agency to which, it is the collector's usual practice to disclose personal information of the kind so collected, and (if known by the collector) any person to whom, or any body or agency to which, it is the usual practice of that first-mentioned person, body or agency to pass on that information."

the kind to which the guidelines relate outweighs to a substantial degree the public interest in maintaining adherence to the Information Privacy Principles".¹¹

5.14 Acting in accordance with the guidelines would protect a record-keeper or researcher from an adverse determination by the Privacy Commissioner. But it is not clear whether the record-keeper would be free from liability under the general law for breach of confidence since the *Privacy Act* does not appear to abrogate the general legal duties of confidence in this respect. In fact by extending the general duties as regards personal information in Part VIII, the Act would seem to imply the converse.¹² The point could require judicial determination.

3. STATE LEGISLATION

(a) New South Wales

5.15 Section 23(1) of the *Health Administration Act 1982* provides that the Minister may authorise "any specified person or body, including a council, committee or advisory body" to conduct research or conduct investigations into "morbidity and mortality occurring within New South Wales". The authorisation may be of general application or be limited, for example, to a specific research project. The Act does not specifically provide any immunity to a doctor or other third party in relation to the disclosure of patient identifiable information to a researcher but the Minister's authorisation may impliedly carry with it that immunity. The legislation does, however, expressly protect the information while it is in the researcher's possession by making it an offence for a researcher to disclose that information without the consent of the person from whom the information was obtained or of the Minister. In addition, a person who has received information in connection with his or her research is neither "competent nor compellable in any proceedings to answer any question, or to produce any documents, relating to any such information...except with the approval of the Governor".¹³

¹¹ S 95. This section also provides a right of review to the Administrative Appeals Tribunal from the Commissioner's decision to refuse to approve the issue of guidelines.

¹² Thus s 92 expressly provides that third parties who acquire personal information which they know or ought to know is subject to an obligation of confidence are subject to the same obligation as the original confidant; s 93 gives a confider a right to recover damages for breach of confidence and also gives the same right of action against the confidant to the person *about whom* personal information is confided as the *confider* has. These sections apply only to an obligation of confidence to which a Commonwealth agency or officer is subject, or which arises under the law of the Australian Capital Territory.

¹³ S 23(4).

(b) Queensland

5.16 The legislation in this State is broadly similar to that of New South Wales, although its terms carry a stronger implication that a doctor or other record keeper disclosing confidential information in accordance with the legislation would not commit a breach of confidence. Section 154M of the *Health Act 1937* (inserted in 1964) permits the Governor in Council to authorise any person "to conduct scientific research and studies for the purpose of reducing morbidity and mortality in the State". Under section 154N, a person so authorised may "seek and obtain" information and reports directed towards the research or study, though there is no obligation on others to provide such information or reports to the researcher. Section 100E of the Act provides that the Director-General of Health is entitled to provide information "in any form" to a person authorised to conduct scientific research and studies under section 154N. This would seem to permit the Director-General to disclose information to the researcher in name-identifiable form, but since it appears in the Part of the Act setting up a cancer registry, the authorisation would appear to be limited to information about that disease.

5.17 Section 154N also imposes an obligation on a person receiving the information not to make use of or publish that information to any other person save in the course of the research and studies. Evidence of such information is inadmissible in legal proceedings except with the approval of the Governor in Council, and a witness cannot be compelled to answer any Question relating to information given by him to a researcher.

(c) South Australia

5.18 Under an amendment in 1987 to the South Australian *Health Commission Act 1976*, the Governor is empowered to authorise a person, or a class of person, to conduct research into the "causes of mortality and morbidity in the State".¹⁴ Unlike the legislation in New South Wales and Queensland, the South Australian provision specifically deals with the disclosure of patient identifiable records. It provides that confidential information relating to any patient may be disclosed to a person so authorized and, with the approval of the person authorized, to any person assisting in that research, "without breach of any law or any principle of professional ethics". Section 64d(3) creates an offence of divulging confidential

¹⁴ s 64d(1).

information obtained in the course of authorised research except to another person to whom information may be divulged under the section.

(d) Victoria

5.19 Victoria has recently enacted legislation which bears on the issues discussed in this paper. Section 141 of the *Health Services Act 1988* (not yet in force) prohibits a hospital or like institution, or its employees, from disclosing to a third person patient-identifiable information except in specified circumstances. One specified circumstance is for the purposes of medical or social research if -

- (a) the use to which the information will be put, and the research methodology, have been approved by an institutional ethics committee; and
- (b) the giving of the information does not conflict with any prescribed requirements.¹⁵

The section also prohibits a person who *receives* information from giving that information to a third party unless the giving is approved by an ethics committee and does not conflict with any prescribed requirements.

5.20 The section does not in terms exempt the bodies or persons to which it applies from the requirements of the general law of confidence, so that a person who may be exempt from prosecution under the section may still be subject to legal action by the patient.

4. NEW ZEALAND

5.21 Section 50 of *the Area Health Boards Act 1983* prohibits employees (widely defined) of area health boards from disclosing or making use of information about patients except in specified circumstances. One such circumstance is the use or disclosure "for the purposes of the advancement of knowledge or research relating to any profession or activity associated with health services". Any resulting publication must not contain information about patients in identifiable form without the prior consent of the patient. Because the section expressly

¹⁵ s 141(3)(g).

authorises the use or disclosure of information about patients, it would seem impliedly to exempt any authorised use or disclosure from legal action by the patient.¹⁶

5. COMPARISON OF LEGISLATIVE INITIATIVES

5.22 The foregoing review of legislation in other jurisdictions does not disclose any uniform patterns or trends. The following points may be noted:

(a) **Type of research**

The Commonwealth *Epidemiological Studies (Confidentiality) Act* applies specifically to epidemiological research, whereas the Commonwealth *Privacy Act* applies more generally to medical research, which is defined to include epidemiological research. The New South Wales, Queensland and South Australian Acts apply to research into the causes of morbidity and mortality. The scope of the New Zealand and Victorian legislation is wider, the former including any research "associated with health services" and the latter including "social research".

(b) **Approval**

The Commonwealth *Epidemiological Studies (Confidentiality) Act* requires approval of specified projects whereas the Commonwealth *Privacy Act* relates to types of research. The New South Wales and Queensland Acts require authorisation of particular persons or bodies whereas the South Australian legislation would permit the authorisation of classes of persons. The Victorian legislation requires approval of a specific project by an ethics committee. The New Zealand legislation does not appear to require approval of either

¹⁶ s 139A(1) of the *Hospitals Act 1957* (NZ) provides that the Director-General of Health may request any licensed hospital or medical practitioner who attends patients at such a hospital to furnish him or her with medical information about the condition or treatment of patients in the hospital, "in order to obtain statistics for medical purposes or for the purposes of advancing medical knowledge, education, or research" and expressly absolves the hospital or medical practitioner from any civil or criminal liability for doing so. However the New Zealand Health Department has informed the Commission that the *Hospitals Act* will have no application when the area health board system becomes fully operational in 1989.

individuals or projects: it is sufficient if the research is of the sort authorised by the section.

(c) **Immunity for doctors and record-keepers co-operating with researchers**

The Commonwealth *Epidemiological Studies (Confidentiality) Act* does not specifically provide any immunity to doctors or record-keepers who divulge name-identified information to researchers in the absence of patient consent. The Commonwealth *Privacy Act* provides express immunity, although apparently only insofar as the Privacy Commissioner's jurisdiction is concerned. Although there is no specific immunity given in the New South Wales, Queensland and New Zealand Acts, the terms of the legislation probably carry that implication. The South Australian legislation however expressly provides that the disclosure of such information to an 'authorised' researcher does not involve the breach of any rule of law or professional ethics. The Victorian legislation is restrictive in form: it only exempts persons from a criminal charge which would otherwise apply under the section and thus leaves the question of civil immunity at large.

5.23 In answering the questions at issue in Chapter 2 above commentators are invited to indicate which, if any, of these legislative models or variations of them they prefer, assuming that disclosure of patients' medical records without patient consent is considered to be justified in some circumstances.

Chapter 6

OPTIONS FOR REFORM

1 THE DIRECTION OF REFORM

6.1 The Commission considers that the law should be clarified to allow disclosure of patient-identifiable confidential information without patient consent for at least some kinds of medical research, subject to the implementation of stringent privacy safeguards.¹ Some administrative machinery may be required to determine the circumstances in which confidential information may be released. Criminal sanctions may be required to secure the proper degree of protection of confidential information once released.

2. THE SCOPE OF APPROVED RESEARCH

6.2 A threshold question is whether the legislation should apply to all kinds of medical research. A difficulty in doing so is that the public interest factors which may justify the disclosure of patient identifiable information without consent do not apply with equal force across the entire spectrum of medical research. One solution would be to confine the legislation to epidemiological research,² as has been done in New South Wales, Queensland and South Australia, but this may be too limiting since it would probably exclude some other forms of worthwhile investigation. Another possible approach is to follow that taken in the Commonwealth *Privacy Act 1988* where the legislation covers medical research generally, but places an obligation on the approving authority to weigh the public interest involved in the research against the public interest involved in maintaining the patient's privacy.³ The Commission is provisionally of the view that the Commonwealth legislation satisfactorily deals with this issue but welcomes comment.

6.3 It might be asked whether even the concept of "medical research" is wide enough to cover all that is desirable. The Commission is of the opinion that confidential medical information could legitimately be used in the course of research into ways of improving the efficiency and effectiveness of the delivery of health services (for example, to help determine the desirable size or location of a hospital or clinic). It is difficult to assess to what extent

¹ See question 1, ch 2 above.

² Footnote 3 to ch 1.

³ Para 5.13 above.

confidential information would be relevant in such an enquiry, but it may be wise to allow for the possibility. In every case the question of the desirability of the research would be determined in accordance with the principle outlined in the previous paragraph.

3. APPROVING AUTHORITY

6.4 There seem to be basically two options -

- (a) Approval by a government officer (Governor, Minister, departmental head);
- (b) Approval by an institutional ethics committee.

6.5 Approval by a government officer has some advantages. Their actions are open to public scrutiny in that Parliament can obtain information about decisions made by them and can call the relevant Minister to account. Putting the decision-making power into the hands of one person could, theoretically, make for consistency of decision. On the other hand, such an approach may be seen as too "bureaucratic" (red tape, delays and possibly even decisions being made on party/political grounds).

6.6 Approval by institutional ethics committees also has advantages and disadvantages. Considerable experience has been gained in the operation of these committees in Western Australia and elsewhere. They are, or should be, free from political bias but are not accountable to Parliament. They can act quickly and informally and, provided their composition is appropriate, can reasonably be expected to weigh up the benefits of doing the research as against the interest in maintaining patient privacy. On the other hand, different ethics committees can come to different decisions on similar issues.

6.7 The Commission notes that the Victorian legislation⁴ opts for the ethics committee option, but requires that the disclosing of information about patients does not conflict with any prescribed requirements. The Commission suggests that the institutional ethics committee approach is to be preferred provided that -

⁴ Para 5.19 above.

- (a) The committee is constituted along the lines of that recommended by the NHMRC.⁵
- (b) Appropriate guidelines are statutorily promulgated, as in Victoria.

Here again, as on all the other issues canvassed in this paper, comment is welcomed.

4. CONTENT OF GUIDELINES

6.8 The Commission does not desire, by supporting limited disclosure for medical research, to undermine existing safeguards against unjustified disclosure of confidential information. Practices which protect patient privacy should be maintained and strengthened. For example, as a matter of proper medical or research practice, subject identifiers should always be removed from research data unless their removal is wholly impracticable or would seriously detract from the research value of the data.⁶ So, too, research data should not be processed in a subject identifiable form in the absence of consent unless the removal of identifiers is unrealistic.

6.9 Particularly sensitive projects might require compliance with additional restrictions. For example, a research protocol might be approved on condition that the research team dispose of information containing subject identifiers within a certain time or that information would only be made available to named persons and not to students, and so on. These are matters which could be dealt with in the prescribed guidelines suggested above.⁷

5. EXTENSION OF DUTY OF SECRECY: PROTECTING INFORMATION 'LEAKED' FROM THE STUDY

6.10 Assuming that a person holding confidential medical information has obtained it for purposes of medical research, should there be penalties associated with the unauthorised

⁵ See Appendix IV below.

⁶ See New South Wales Privacy Committee Report *Research and Confidential Data: Guidelines for Access* (1985).

⁷ B K Armstrong in "Privacy and Medical Research" (1984) *Medical Journal of Australia* 620 at 621 sets out conditions laid down by the US Privacy Protection Commission for medical research, including safeguards against unauthorised use. The *Code of Practice for Use of Name Identified Data from Health Statistical Data Collections* issued by the Health Department of Western Australia contains conditions relating to the handling and storage of name identified records whether held in paper record form or on computer: Appendix II below.

release of that information to third persons. Should the recipient of that information in breach of a duty of confidence be fixed with a like obligation of confidence? For example, if a researcher breaches a secrecy obligation and passes information to a journalist who receives it knowing of the breach, should the journalist be liable for publishing the information? The first matter is dealt with in the Commonwealth *Epidemiological Studies (Confidentiality) Act 1981*, which creates offences of breach of secrecy.⁸ However, the second matter is not.

6.11 Assuming that a researcher engaged in approved medical research is subject to a strict duty of secrecy, it seems fair that a like duty should be imposed upon any person who acquires confidential information from the first person in breach of that duty. It may be necessary to create an offence in terms of the deliberate or reckless disclosure of confidential information obtained from a person who has breached a secrecy obligation in disclosing the information.

⁸

Sa 4 and 6.

Appendix I

STATEMENTS ON CONFIDENTIALITY AND MEDICAL RESEARCH

PART A

General statements on confidentiality as it applies to the doctor-patient relation:

The **Hippocratic Oath** states:

"Whatever, in connection with my professional practice, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret."

The **Declaration of Geneva** (as amended at Sydney, 1968) recommends the taking of the following vow at the time of being admitted as a member of the medical profession:

"I will respect the secrets which are confided in me, even after the patient has died."

The **International Code of Medical Ethics** states:

"A doctor shall preserve absolute secrecy on all he knows about his patients because of the confidence entrusted in him."

The **American Medical Association's Principles of Medical Ethics** states:

"A physician may not reveal the confidences entrusted to him in the course of medical attendance, or the deficiencies he may observe in the character of patients'; unless he is required to do so by law or unless it becomes necessary in order to protect the welfare of the individual or the community."

The **Australian Psychological Society Code of Professional Conduct and Advice to Members** 1970 contains the following provisions:

5. Where the client has been guaranteed, or can reasonably expect, that information given by him will be treated confidentially, the member must not divulge such information without the client's permission.
6. Before communicating any confidential information to another professional worker, the member must obtain the client's permission to do so, unless professional communication is already clearly implied by the nature of the consulting relationship or the setting in which it takes place.
7. A client is entitled to assume that a clinical or consulting relationship is confidential. A member must make clear the nature of his role or function if he can foresee that any departure may be required from this principle.
8. A member must not disclose information about criminal acts of a client unless there is some overriding legal or social obligation to do so.

14. A member must not convey confidential communications from related professions to a client without permission from the authors of such communications.
24. Test results or other confidential data obtained in a research study must never be disclosed in situations or circumstances which might lead to identification of the subjects, unless their permission has been obtained.
30. Confidential material about clients or subjects, which might lead to their identification, must not be published without their permission."

PART B

Specific statements on confidentiality and medical research include the following:

A recent policy statement (1986) by the **Australian Medical Association** states:

- 73 The Australian Medical Association holds that for the sound administration of medical care and for the protection of the confidence which exists between medical practitioner and patient, it should be established as a principle of public policy that medical records should be confidential. (1981)
- 74 The importance of confidentiality of any patient's record is paramount. If patients' records are to be used for clinical or epidemiological research, it is incumbent on the medical practitioner to ensure that the patient's identity is safeguarded. Information should be disclosed only for worthwhile medical research conducted according to a written protocol approved by a recognised ethical committee. The disclosure should be the minimum necessary to the research and the protocol should make explicit provision for maintaining the confidentiality of any individually identified or identifiable data. The medical practitioner should reserve the right not to disclose information when, in his or her opinion, disclosure would be contrary to the patient's interests (1985).
- 75 As a general principle clients of Government and other salaried medical officers should be entitled to expect the same degree of medical confidentiality as that enjoyed by patients of private medical practitioners. (1978)
- 76 In the absence of a patient's written consent to the contrary, any clinical information concerning a patient given by a private practitioner to a salaried medical officer should be on the understanding that the salaried medical officer is able to accept ultimate responsibility for confidentiality of the information. (1978)

The **New South Wales Privacy Committee** offered the following guidelines for consent:

1. Wherever data is sought from or concerning an individual for the purposes of research, prior to data collection, the person seeking the data should secure the informed consent of that individual to the collection of such data and to the method of its collection.

2. Wherever data is sought from or concerning an individual which would invade the privacy of other individuals, prior to data collection, the person seeking such data should secure the informed consent of all relevant parties to the collection of such data and to the method of its collection.
3. Subjects consenting to participate in 'double blind' experiments should, prior to the experiment, be fully informed of:
 - (a) what they may be asked to do or experience in the course of the experiment;
 - (b) what the likely dangers and effects of the experimental treatments are,
 - (c) what precautions have been taken by the experimenter to protect the subject; and, as soon as practicable
 - (d) what the purposes of the experiment are.
4. Where informed consent cannot be obtained the researcher should approach the Privacy Committee for advice before commencing any research.

Concerning de-identification of data by a researcher the Privacy Committee stated:

- (1) Wherever the de-identification of data by the researcher is possible and does not conflict with the purposes of the research or unduly impede its collection. data should be collected in de-identified form.
- (2) When de-identification of the data for the purposes of access is not possible. persons seeking access should ensure that standards of confidentiality are maintained which preserve the anonymity of data subjects.

In dealing with access to personal data held by third parties the Privacy Committee stated:

- (1) Wherever data sought by a person is in the possession of a record keeper and the de-identification of that data by the record keeper would not unduly interfere with his functions or responsibilities, or the purposes of the research, the record keeper should de-identify such data before providing it to the person seeking it.
- (2) Where the de-identification of data by a record keeper would unduly interfere with his functions or responsibilities or would unduly impede the collection of data, the person receiving such data should, as soon as practicable after receiving it, take all reasonable steps to effect its de-identification.

The **Declaration of Helsinki** (1975) provides a series of recommendations guiding doctors in biomedical research involving human subjects. Principle No 5 states:

"The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subjects physical and mental integrity and on the personality of the subject."

The **United States Department of Health and Human Services** declared:

"An Institutional Review Board (IRB) may approve a consent procedure which does not include or which alters some or all of the elements of informed consent set forth above *or waive the requirement to obtain informed consent* provided the IRB finds and documents that: (a) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation."

The **General Medical Council of the United Kingdom** declared:

"Information may also be disclosed if necessary for the purpose of a medical research project which has been approved by a recognised ethical committee."

The **Medical Research Council of the United Kingdom** stated:

"[S]ubject to certain safeguards, medical information obtained about individual patients should continue to be made available without their explicit consent for the purposes of medical research."

The Report on the Law of Privacy, which preceded the New South Wales *Privacy Committee Act, 1975*. stated that:

"[B]oth the European Convention for the Protection of Human Rights and Fundamental Freedoms and the Nordic Conference of International Jurists on the Right of Privacy (Stockholm, 1967) took the view that public health considerations could justify abridgement of the privacy of the individual and this clearly is taken to include research into the causation of disease".

Appendix II
**THE CODE OF PRACTICE (ISSUED BY THE HEALTH
DEPARTMENT OF WESTERN AUSTRALIA IN 1986) FOR USE
OF NAME-IDENTIFIED DATA FROM HEALTH STATISTICAL
DATA COLLECTIONS**

1. INTRODUCTION

Access to data from name-identified medical records is fundamental to epidemiology because of the need

- to identify multiple disease events suffered by a single individual in the past,
- to identify events occurring during the course of follow-up in patients under follow-up surveillance,
- to link records from various sources such as hospitals, forensic services, and death, employment and cancer registers,
- to avoid double-counting of cases in ascertaining the frequency of diseases.

While medical practitioners and trained nurses have a general duty under their professional codes of ethics to respect the confidentiality of information encountered in the course of their work, other research staff are not formally bound in this way. All types of staff need to be aware of the special obligations contingent upon the use for medical research of name-identified data that were originally collected for some other purpose.

2. REQUIREMENT FOR WRITTEN PROTOCOL

Any person requesting access to name-identified medical data for research purposes should prepare a written protocol for the proposed study. This protocol should address ethical issues and be submitted to a properly constituted ethics committee in the institution where the research is to be based for approval.

3. WRITTEN DECLARATION

All persons who are to have access to name-identified data for research purposes in the course of their employment or studies shall complete a signed declaration binding them to respect the confidentiality of the information contained therein, and to follow this code of practice.

4. PAPER RECORDS BEARING NAME-IDENTIFIED INFORMATION

4.1 Creation and Maintenance

All paper records, including questionnaires and computer printouts, should be created and maintained in such a manner that identifying information is not juxtaposed with confidential medical or personal information unless that information is unintelligible. For example, identifying data should be physically separated from the main body of a

questionnaire immediately after the latter is completed, linkage at a later date being made possible by some sort of code common to both.

4.2 **Storage**

Paper records containing named data, especially master lists of codes assigned to name individuals, should be kept under lock and key when not in use. Master lists should be stored separately from the paper files to which they refer. Details of coding systems should be stored securely and separately from records containing information in coded form. These provisions should also apply to paper records containing named information that are removed from the institution in which the research is based for any purpose, for example, field work.

4.3 **Disposal**

Paper records containing named data should be disposed of by shredding or incineration, preferably on the research site, or under the supervision of a responsible member of the research team.

5. RECORDS HELD ON MICRO-COMPUTERS

5.1 **Creation and Maintenance**

All computer records should be created and maintained in such a manner that identifying information is not juxtaposed with confidential medical or personal information unless that information is unintelligible.

5.2 **Storage**

Master lists of codes assigned to named individuals should be sorted in files separate from data files. Access to name-identified records, especially master lists, which are not in use should be prevented by

- (a) Password - and/or read-access protection of computer files,

AND EITHER

- (b) Deletion of files held on hard discs and physical removal and storage under lock and key of floppy discs containing the information.

OR

- (c) Removal and safe storage of the enabling key of the micro-computer system (thereby preventing access to the hard disc), and storage of floppy discs under lock and key.

Name-identified data should not be stored on micro-computer systems unless the above requirements for security are met. Details of coding systems should be stored securely and separately from records containing information in coded form.

6. NAME-IDENTIFIED RECORDS HELD ON MAINFRAME COMPUTERS

6.1 Creation and Maintenance

All computer records should be created and maintained in such a manner that identifying information is not juxtaposed with confidential medical or personal information unless that information is unintelligible.

6.2 Storage

Master lists of codes assigned to named individuals should be stored in separate files from data files. Access to name-identified records, especially master lists, which are not in use should be prevented by password and/or read-access protection of computer files. Details of coding systems should be stored securely and separately from records containing information in coded form.

6.3 Deletion/Archiving/System Over-Ride

Individual users with computer files containing name-identified data should maintain their filestore in such a way that system programmers have minimal access to them, either during routing manipulation of files or in the course of archiving procedures initiated because of filestore overload, etc.

7. PUBLICATION

No publication or public presentation or discussion of results of research based on name-identified data shall include any information that could allow individual subjects to be identified unless the written consent of each such subject has first been obtained (see part 8).

8. CONTACT WITH INDIVIDUAL PATIENTS OR THEIR RELATIVES

From time to time a legitimate need arises to contact patients identified through named records, or their relatives, to obtain further information vital to a research study. In all cases, this contact may only be instigated after approval has been obtained from the doctor involved in the case at the time that the name-identified record was generated, an appropriate successor to that doctor, or the medical superintendent of the relevant hospital. This permission having been obtained, normal rules of consent would apply to the contact with the patient or relative; that is, verbal informed consent only is required if an interview, questionnaire or physical examination (by an appropriately qualified person) is involved, while written informed consent is required if the study requires that the patient undergo any additional technical, invasive, or therapeutic procedure that is not part of their routine medical care.

Appendix III
EPIDEMIOLOGICAL STUDIES (CONFIDENTIALITY)
REGULATIONS

The *Epidemiological Studies (Confidentiality) Regulations 1982* No 371 and amendments Nos 289/84, 164/87, 204/88 and 315/88 declare the following studies to be epidemiological studies for the purposes of the definition of "prescribed study" in section 3(1)(b) of the *Epidemiological Studies (Confidentiality) Act 1981* -

- (a) the Commonwealth epidemiological study that commenced in 1981 on those persons who were employed, whether in Australia or not, in relation to the Atomic Weapons Test Programme conducted by the United Kingdom in Australia at the Monte Bello Islands, Western Australia, and at the Emu Claypan and Maralinga, South Australia, between 1 January 1952 and 31 December 1967;
- (b) the epidemiological study in relation to Acquired Immune Deficiency Syndrome conducted on behalf of the Commonwealth by the National Health and Medical Research Council, being the study that commenced in 1983;
- (c) the epidemiological study in relation to motivations for illicit use of cocaine conducted on behalf of the Commonwealth by the Research into Drug Abuse Program of the National Campaign Against Drug Abuse, being the study that commenced in January 1986;
- (d) the epidemiological study in relation to drug indicators in the Australian Capital Territory conducted on behalf of the Commonwealth by the Research into Drug Abuse Program of the National Campaign Against Drug Abuse, being the study that commenced in 1986;
- (e) the epidemiological study in relation to heroin distribution conducted on behalf of the Commonwealth by the Research into Drug Abuse Program of the National Campaign Against Drug Abuse, being the study that commenced in February 1987;
- (f) the epidemiological study in relation to a survey of illicit drug users on patterns and predictors conducted on behalf of the Commonwealth by the Research into Drug Abuse Program of the National Campaign Against Drug Abuse, being the study that commenced in May 1987;
- (g) the epidemiological study in relation to cocaine usage evaluation in high-income groups conducted on behalf of the Commonwealth by the Research into Drug Abuse Program of the National Campaign Against Drug Abuse, being the study that commenced in July 1987;
- (h) the epidemiological study in relation to the extent and nature of cocaine use by illicit drug users and upper economic strata individuals and the assessment of recruitment and supply factors and attitudes of identified users conducted on behalf of the Commonwealth by the Research into Drug Abuse Program of the National Campaign Against Drug Abuse, being the study that commenced in July 1987;

- (i) the epidemiological study in relation to persons who have been charged in a court in the State of Western Australia with an offence relating to the use of illicit drugs, conducted on behalf of the Commonwealth by the National Centre for Research into Prevention of Drug Abuse of the National Campaign Against Drug Abuse, being the study that commenced in April 1986;
- (j) the epidemiological study in relation to Human Immunodeficiency Virus in intravenous drug users conducted on behalf of the Commonwealth by the Commonwealth AIDS Research Grants Committee Working Party on AIDS in Intravenous Drug Users, being the study that commenced in June 1988.

Appendix IV

ETHICS COMMITTEES

The NHMRC Report includes a supplementary note on institutional ethics committees. It states:

"In every institution in which human research is undertaken there should be an institutional ethics committee.

Following are the functions and composition suggested for such a committee:

(1) **Functions**

- (a) To consider ethical implications of all proposed research projects and to determine whether or not they are acceptable on ethical grounds.
- (b) To keep the progress of research projects under surveillance so as to be satisfied that they continue to conform with approved ethical standards.
- (c) To maintain a register of all proposed research projects, the register to include -
 - . institution's name
 - . project number
 - . principal investigator(s)
 - . short title of project
 - . reasons for ethical approval/non approval
 - . date of ethical approval
 - . comments (if any)
- (d) To establish and maintain communication with the national Medical Research Ethics Committee and provide access upon request, to information in the institutional ethics committee's register .

In carrying out these functions, institutional ethics committees should -

- (i) be guided by the principles outlined in the Declaration of Helsinki, 1975, and the NH & MRC Statement on Human Experimentation and Supplementary Notes on research in particular fields that may be published from time to time.
- (ii) take account of local, cultural and social attitudes in making decisions.
- (iii) ensure that the procedures relating to obtaining informed consent are observed.

- (iv) ensure that while accepting that doctors have a duty to advance knowledge by research, the rights of individual patients, or subjects of research take precedence over the expected benefits to human knowledge or to the community.

(2) **Composition**

Institutional ethics committees should be composed of men and women reflecting different age groups and include at least -

- . a person not associated with the institution;
- . a minister of religion;
- . a lawyer;
- . a medical graduate with research experience;
- . a laywoman;
- . a layman.

One person could reflect the interest of more than one of the above.

In institutions in which protocols are processed through two committees, e.g. a medical research committee, and an institutional ethics committee, the chairman (or his representative) of the medical research committee should attend meetings of the institutional ethics committee and vice versa."