



**THE LAW REFORM COMMISSION
OF WESTERN AUSTRALIA**

Project No 65 – Part II

**Confidentiality of Medical Records
and Medical Research**

REPORT

AUGUST 1990

To: **HON J M BERINSON QC MLC**
ATTORNEY GENERAL

In accordance with the provisions of section 13 of the *Law Reform Commission Act 1972*, I am pleased to present the Commission's report on Confidentiality of Medical Records and Medical Research.

J A THOMSON, *Chairman*

18 September 1990

The Law Reform Commission of Western Australia was established by the *Law Reform Commission Act 1972*.

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Contents

	Paragraph
1. TERMS OF REFERENCE	1.1
2. DISCUSSION PAPER	2.1
3. THE PRESENT LAW	3.1
4. MEDICAL RESEARCH INVOLVING THE USE OF PATIENT-IDENTIFIABLE INFORMATION	4.1
5. THE COMMISSION'S VIEW	5.1
6. SAFEGUARDS	
(a) Approval by a prescribed IEC	6.1
(b) Prescribed IEC's	6.2
(c) Criteria for approval	6.4
(d) Scope of research	6.6
7. IMPLICATIONS	
(a) Effect of approval by a prescribed IEC	7.1
(b) Institutions without a prescribed IEC: unaffiliated researchers	7.3
8. PROFESSIONAL ETHICS	8.1
9. PROTECTION OF INFORMATION SUPPLIED TO A RESEARCHER	9.1
10. HEALTH DEPARTMENT RECORDS	10.1
11. OTHER RESEARCH	11.1
12. STATE ARCHIVES	12.1
13. COMMONWEALTH PRIVACY ACT	13.1
14. SUMMARY OF RECOMMENDATIONS	14.1
APPENDIX I - LIST OF THOSE WHO COMMENTED ON THE DISCUSSION PAPER	
APPENDIX II - CHAPTER 3 OF THE DISCUSSION PAPER	
APPENDIX III - CHAPTER 5 OF THE DISCUSSION PAPER	

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 purpose of medical research. The Commission has a general reference on privacy¹ and would normally have dealt with this 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 had come to recognise that the law of confidentiality could unduly inhibit medical - especially epidemiological - research or even stop large areas of it altogether.

2. DISCUSSION PAPER

2.1 The Commission published a Discussion Paper on the reference in March 1989. Thirty-two individuals, associations or departments responded. Their names are listed in Appendix I. The Commission thanks them for the time and trouble they took.

3. THE PRESENT LAW

3.1 Put simply,³ doctors and other health professionals are under a legal duty to keep secret information about their patients' condition and treatment and not to disclose that information - in a form which identifies the patient⁴ - unless they have a "just excuse" to do so. The duty can arise either in contract or in equity. Breach of the duty is actionable by the patient concerned, the court being empowered to grant an injunction or award damages, as appropriate.

3.2 It is of course a just excuse if the patient has expressly or implied consented to the disclosure. It is also a just excuse where legislation authorises or requires disclosure.⁵ The

¹ Project No 65.

² Including the National Health and Medical Research Council's (NHMRC) Epidemiological Unit.

³ A detailed account of the law of confidentiality in its application to medical records is set out in ch 3 of the Discussion Paper. The chapter is reproduced as Appendix II below.

⁴ Disclosure of medical information in a form from which a patient's identity cannot be inferred is obviously not a breach of confidence.

⁵ For example, hospitals are required by law to supply information in patient-identifiable form to the State Health Department about the condition and treatment of their patients: see para 10.2 below. Another example - not so far of great importance in the medical research context (but see para 9.3 below) - is where the doctor is called as a witness in legal proceedings. The doctor cannot refuse to answer a question on the ground that to do so would disclose confidential information about a patient. The

law also permits disclosure "in the public interest", but this category seemingly is limited to cases involving a patient's criminal or illegal activity or the prevention of harm to innocent people and so (although the matter has not been the subject of a definitive legal ruling) not include disclosure for research purposes.⁶ Accordingly, in the absence of authorising legislation, a doctor or hospital that made available patient records to a researcher may be held to have breached the legal duty of confidence, no matter how beneficial to the community the outcome of the research was likely to be.

3.3 Although it is usual to speak of a patient's "medical record" it is important to emphasise that the legal duty of confidence applies to **information** and it makes no legal difference that the doctor or hospital, as the case may be, owns the document or computer disc on which the information is recorded.⁷ Contrary to the assumption of some commentators on the Discussion Paper, ownership of the document or disc, or authorship of the writing, does not of itself exempt the doctor or hospital from the duty of confidence as regards the information so recorded.⁸

question whether there should be a relaxation of this rule is being considered by the Commission in its reference on Project No 90: *Privilege for Confidential Communications*.

⁶ But see the recent English case of *W v Egdell* [1990] 2 WLR 471 (CA). Although not a case involving disclosure for research purposes, the court had regard to the British Medical Council's guidelines on professional conduct in determining whether an actionable breach of confidence had taken place. One item in those guidelines states that doctors may disclose patient information for the purpose of a medical research project approved by a recognised ethics committee. If disclosure for medical research was ever to be directly in issue in legal proceedings the courts in England may be guided by that item, as may an Australian court as regards the NHMRC guidelines: see footnote 15 below. However, the matter remains in doubt and should be clarified by statute as recommended below.

⁷ It is the generally held legal view that a record made of a patient's treatment is created for the use of the patient's doctor and not for the patient's use and as such is the property of the doctor or the clinic or hospital in which the treatment is provided: *Australian Health and Medical Law Reporter* (CCH) 27-860. See also *Lamothe v Mogleby* (1979) 106 DLR (3rd) 233, 234 and *Leicestershire County Council v Michael Faraday and Partners Ltd* [1941] 2 All ER 483. X-rays and pathology reports obtained by the doctor and paid for by the patient or his or her health fund may however be the property of the patient: *Australian Health and Medical Law Reporter* (CCH) 27-860.

⁸ The obligation of confidence also of course applies to information not recorded in any form, but merely in the doctor's memory.

The issue of access to records, including patient records, by the **subject** of the record was addressed in the Australian Law Reform Commission's report *Privacy* (Report No 22 1983 98-124). That Commission concluded that it was in the interests of personal autonomy that the subject of a record should in general be given a right of access to that record and to have any inaccuracies in it corrected. These recommendations were given effect to in Information Privacy Principles 6 and 7 of the *Privacy Act 1988* (Cth) insofar as Commonwealth departments and agencies are concerned. The question of subject access to records is outside the scope of this report.

4. MEDICAL RESEARCH INVOLVING THE USE OF PATIENT-IDENTIFIABLE INFORMATION

4.1 Research projects are often undertaken - in Western Australia and elsewhere - involving access to patient-identifiable records without the patient's consent.⁹ The need for access to patient-identifiable information is, depending on the aim of the study, to avoid double counting of individuals with a disease or condition, to trace their subsequent health history from various sources (other hospitals, death certificates) or to obtain further information directly from them (for example as to their smoking or drinking habits or occupation). There would in many cases be practical difficulties in tracing the whereabouts of many former patients to seek their consent to disclosure of their records. Research results could be skewed if patients could not be traced to seek their consent or if consent was withheld. In some sorts of research it would be impossible for a researcher to seek the patient's consent in advance.¹⁰ A more detailed account of the need from a researcher's point of view for obtaining access to patient-identifiable information without obtaining the patient's consent is set out in the Discussion Paper.¹¹

4.2 The main sources of patient-identifiable information in Western Australia are the Health Department's system of databases¹² and the teaching hospitals.¹³ A researcher is usually not given access to these records unless he or she has obtained the approval of the relevant Institutional Ethics Committee (IEC)¹⁴ to undertake the study. The committee requires the researcher to submit details of the proposed study (a "protocol"), including the research methods to be used, the reason why name-identifiable information is needed and why

⁹ The Commission is not here speaking of research described as "planned experimentation on human beings", for example as to the effectiveness of a particular form of treatment or drug. In these cases the consent of the participants to the experiment necessarily involves their consent to the medical records compiled in the course of the experiment being used for research. These were referred to in the Discussion Paper as "self-standing" records: para 4.1.

¹⁰ A researcher who wished to obtain information from former patients about their occupational history could not approach them for the information unless the researcher had obtained their names from the hospital beforehand.

Some commentators suggested to the Commission that it was not a breach of confidence for a hospital merely to disclose names. This is incorrect. For example a list of names of women who had been patients in a hospital's maternity wing would impliedly disclose information about their condition and would thus be a breach of confidence.

¹¹ Ch 4, especially paras 4.7 to 4.9. See also the report of the NHMRC *Ethics in Epidemiological Research* (1985).

¹² Para 10.1 below.

¹³ Sometimes other records are studied, eg the records of the Silver Chain Nursing Association, community health centres and Aboriginal Medical Services.

¹⁴ One impetus for the establishment of IEC's in institutions throughout Australia was that the NHMRC will not grant research funds for a project unless it has been approved by an IEC and the institution in which the research is to be conducted has an IEC.

patient consent is not being sought. As its name implies, the IEC determines whether the study is acceptable on ethical grounds. In doing so the committee has regard to the guidelines promulgated by the NHMRC.¹⁵

5. THE COMMISSION'S VIEW

5.1 The Commission acknowledges that the law of confidentiality is one of the most important mechanisms evolved by the courts for the protection of individual privacy. The full potential of that law to protect personal information has only recently been recognised.¹⁶

5.2 In the medical context the obligation of confidence underpins the bond of trust between health professional and patient which is so important for proper medical care. The bond is essential not only from the individual patient's point of view but also from that of the general community which has an interest in the health of each its members.

5.3 Nevertheless, the Commission agrees with the views of health bodies both in Australia and overseas¹⁷ that the benefits to be derived from medical research justify disclosure of name-identified records without patient consent for that purpose, provided strict safeguards are maintained. Accordingly, as foreshadowed in the Discussion Paper, the Commission recommends the enactment of a statutory regime expressly to permit this. Almost all the commentators were of the same view. The Commission's approach is broadly in line with the position elsewhere in Australia where legislation exists in one form or another relaxing confidentiality requirements for the purposes of medical research.¹⁸

5.4 To avoid any misconception, the Commission emphasises that its proposal is simply intended to free a record-keeper from the legal **duty** of confidence which would

¹⁵ *NHMRC Statement on Human Experimentation and Supplementary Notes*; Supplementary Note 6 (Epidemiological research). The phrase "epidemiological research" is used in the Note in a wide sense to cover not only research into the incidence and distribution of disease or death but also research on the success or otherwise of various forms of treatment. An IEC's "jurisdiction" normally covers all projects involving human experimentation carried on at that institution and is not confined to the single issue of access to patient-identifiable information, which is the subject of this report.

¹⁶ Among the first to recognise the potential of the law of confidentiality in this regard was the UK Privacy Committee under the chairmanship of the Rt Hon Kenneth Younger: *Report of the Committee on Privacy* (Cmnd 5012 1972) para 630.

¹⁷ Discussion Paper Appendix I Part B. The NHMRC's *Report on Ethics in Epidemiological Research* (1985) contains a full discussion of the issues.

¹⁸ Discussion Paper ch 5 reproduced as Appendix III below.

otherwise¹⁹ apply. It would not create a legal duty to disclose, even if all the statutory safeguards proposed below were complied with. Under the legislation the record-keeper would remain as free as before to refuse access if he or she thought fit.

6. SAFEGUARDS

(a) Approval by a prescribed IEC

6.1 The Commission recommends that it be a condition of avoiding the legal duty of confidence which would otherwise apply that the research project in respect of which access to patient-identifiable information without patient consent is sought has been approved by a prescribed²⁰ IEC. IECs have been set up by institutions which conduct research involving human beings to ensure that the research is ethically acceptable generally and are accordingly appropriate bodies to deal with one aspect, namely the balancing of confidentiality against research needs.²¹

(b) Prescribed IECs

6.2 The Commission regards it as important that the IECs to be involved in the proposed scheme should not be left at large. They should consist of the IECs of institutions which are associated with significant research projects of benefit to the community and which can also be expected to be keenly aware of the need to pay proper regard to patient confidentiality. The Commission accordingly recommends that the legislation should

- (a) directly prescribe IECs of the teaching hospitals,²² universities set up by Western Australian legislation and the State Health Department;²³

¹⁹ There may be other legislation which would authorise or require disclosure in particular circumstances, eg see paras 10.1 and 10.2 below.

²⁰ Paras 6.2 and 6.3 below.

²¹ As well as canvassing the IEC approach, the Discussion Paper invited comment on the alternative of requiring approval by a Government officer. The overwhelming majority of commentators were opposed to this option, seeing it as unacceptably bureaucratic. The Commission agrees.

A third possible approach - to give a Government officer jurisdiction over the confidentiality aspects of a research project, while leaving other aspects to an IEC - would be a recipe for confusion.

²² Teaching hospitals are those appointed as such by the Minister for Health under s 3(4) of the *Hospitals Act 1927*. They are the Royal Perth Hospital, Sir Charles Gairdner Hospital, Princess Margaret Hospital for Children, King Edward Memorial Hospital for Women and the Fremantle Hospital: *Government Gazette* 4 August 1972, 2933. Sir Charles Gairdner Hospital in fact has no IEC of its own and instead is advised by the Human Rights Committee of the University of Western Australia as regards research projects undertaken within the hospital, or which involve access to the hospital's medical records.

- (b) empower the Minister for Health, by notice in the *Gazette*, to prescribe the IEC of any other body if satisfied of the suitability of that body and its IEC, having regard to the purpose of the legislation.

The world of medicine will continue to develop. New institutions will be established and existing ones regrouped. (b) above will enable such changes to be accommodated without the need to amend the legislation.

6.3 The Commission's proposals do not in terms place any legal obligation on an IEC (the legislation is simply intended to free a record-keeper from the duty of confidence **if** the IEC grants approval in accordance with the statutory criteria below). Nevertheless not all IECs may wish to participate in the scheme, either because an IEC feared that it might come under judicial scrutiny if legal proceedings ever eventuated or that it might be faced with an increased number of applications for project approval or for some other reason. The Commission accordingly recommends that an IEC should only be deemed to be prescribed if it has consented to be included. The consent should be notified in the *Gazette*.

(c) Criteria for approval

6.4 In giving its approval in terms of paragraph 6.1 above, the IEC should be required to be satisfied²⁴ that -

- (a) the project has as its purpose the advancement of medical knowledge or the improvement of health services in Western Australia;
- (b) access to patient-identifiable information is necessary for the scientific validity of the project;
- (c) access to that information without subject consent is justified having regard to the factors listed below; and that

²³ The Health Department has two IECs; one dealing with researchers' access to general health information held by the Department and the other with psychiatric information so held.

²⁴ The practice would be for the researcher in his or her protocol to include reasons supporting the claim that the proposed research complied with these conditions.

- (d) the public interest in undertaking the project outweighs the public interest in maintaining confidentiality.

In deciding whether access to patient-identifiable information without subject consent is justified the IEC should take into account -

- (i) the cost or delay likely to be involved in seeking consent;²⁵
- (ii) whether the nature of the project is such that consent cannot be obtained beforehand;²⁶
- (iii) the degree of sensitivity of the information being sought;
- (iv) the extent to which refusal of consent of some subjects would vitiate the scientific value of the project; and
- (v) such other factors as the IEC considers relevant in the circumstances.

6.5 As a further condition of approval the researcher²⁷ should be required to give an undertaking in writing to the IEC to comply with the prescribed code of conduct for the security of name-identified data and any further conditions the IEC imposes in the case of that project.²⁸ The Commission has not attempted to draft such a code but the relevant parts of the Health Department's Code would provide a suitable model.²⁹

²⁵ For example the present whereabouts of the subjects may be difficult to ascertain where the information being sought relates to an episode a considerable time ago.

²⁶ Footnote 10 above.

²⁷ If the research is to be undertaken by a team, the person in charge of the team would give the undertaking. In such a case the head researcher should be required to obtain a similar undertaking from the others.

²⁸ The IEC might require the researcher to destroy particularly sensitive information after a certain time.

²⁹ Code of Practice issued by the Health Department for the use of name-identified data from *Health Statistical Data Collections* (1986): see Appendix II of the Discussion Paper which reproduces the Code.

(d) Scope of research

6.6 The reference in paragraph 6.4 above to the "improvement of health services in Western Australia" is necessary because such research may not fall within the category of "advancement of medical knowledge". Clearly it should be included within the scheme.

6.7 Some commentators suggested that social research should also be included. While there is undoubtedly an argument in favour of doing so, the Commission considers that the scheme should not extend so far. A patient or former patient who would readily accept that his or her records could justifiably be disclosed to help improve the health of the community might be more reluctant if the research had for example a historical or political purpose.

7. IMPLICATIONS

(a) Effect of approval by a prescribed IEC

7.1 Under the Commission's proposals it would only be necessary for **one** such IEC to give approval for the statutory exemption to apply in respect of all medical records wherever held. However this is not as wide a concession as first appears. Each teaching hospital, and the Health Department, has its own IEC and under present practice would not approve access to medical records held by it unless the researcher's project had been approved on ethical grounds by its own IEC. Whether some rationalisation of IECs may be possible is a matter for the institutions concerned and is outside the scope of this report.

7.2 The proposed legislation would not override any specific legislation which prohibited disclosure of name-identified information in particular areas.³⁰ Its aim is simply to exempt a record-keeper from the legal³¹ duty of confidence which would otherwise apply, on condition that an IEC had approved the research project in accordance with the criteria specified above. The record-keeper would therefore need to be sure that the IEC had in fact done so. To simplify the position from the record-keeper's point of view, the Commission accordingly recommends that he or she should be entitled to act on a certificate of the secretary of the IEC that it was satisfied that the project met the statutory requirements.

³⁰ An example (in a slightly different context) is the prohibition placed on a doctor from disclosing to the Health Department the identity of a patient suffering from venereal disease: *Health Act 1911* s 300. This prohibition ceases to apply if the patient fails to continue the treatment: id s 301.

³¹ That is, contractual and equitable duties, as distinct from statutory duties.

(b) Institutions without a prescribed IEC: unaffiliated researchers

7.3 Under the Commission's proposals a body which did not have a prescribed IEC, for example a private hospital or health clinic, would have to require a researcher to obtain the approval of a prescribed IEC if it wished to obtain exemption from the duty of confidence in disclosing its records to the researcher. This is in line with the general approach taken by the NHMRC which stated that if no institution with a qualified ethics committee is involved the researcher "should secure ethical approval from a properly constituted ethics committee of an institution that is appropriate to the subjects or community concerned".³² This would not of course present a difficulty if the researcher wished also to obtain access to the records of an institution which had a prescribed IEC. Approval of the research project by that IEC would automatically carry with it immunity from proceedings for breach of confidence for any disclosure of patient records by bodies without an IEC.

7.4 However there could be practical difficulties in the way of the researcher who was not affiliated to an institution with a prescribed IEC. An IEC may be reluctant to accept an outside researcher's protocol for consideration on jurisdictional³³ or policy³⁴ grounds. The Commission suggests that if such a case arose the Health Department's Confidentiality of Health Information Committee should undertake to consider it, on the basis that that department should generally encourage research for the benefit of the community's health.

8. PROFESSIONAL ETHICS

8.1 The above paragraphs have focused on the legal duty of confidence, but as the Discussion Paper pointed out³⁵ disclosure of patient-identifiable medical records to a researcher may also pose a problem for professional ethics. Is breach of the legal duty of confidence also a breach of the rules of professional ethics? Conversely, does immunity from legal proceedings for breach of confidence *ipso facto* give immunity from disciplinary proceedings for a breach of professional ethics? It is clearly inconsistent to give a record-keeper protection from legal proceedings and not give similar protection against disciplinary

³² NHMRC *Statement on Human Experimentation and Supplementary Notes*: Supplementary Note 6 para 5.

³³ Eg that its governing statute did not permit it to do so.

³⁴ Eg that it would unduly stretch its resources to do so.

³⁵ Paras 3.12 and 3.13. See Appendix II below.

proceedings before a controlling board. The Commission recommends that, following South Australia,³⁶ statutory protection be given accordingly.

9. PROTECTION OF INFORMATION SUPPLIED TO A RESEARCHER

9.1 In paragraph 6.5 above the Commission recommended that, as a condition of obtaining project approval from an IEC, the researcher should be required to give an undertaking to comply with a prescribed code of conduct.³⁷ The Commission also recommends that the statute should expressly place the researcher under an equitable duty of confidence to each patient whose record is in the researcher's³⁸ hands. Although the general law would probably imply such a duty it is desirable to place the matter beyond doubt. The Commission further recommends placing a similar obligation on any third party to whom patient-identifiable information had been given in breach of confidence and who knew, or ought to have known, that the information was given him or her in breach.

9.2 These proposals would give a patient a civil remedy against defaulting researchers and third parties. However, in view of the importance of maintaining confidentiality in respect of medical information, the Commission recommends that it be made a criminal offence for a researcher, without lawful excuse, to disclose patient-identifiable information to a third party. It should similarly be a criminal offence for the third party who knows or ought to have known that the disclosure was unauthorised, to disclose that information in his or her turn without lawful excuse. The penalty should be a maximum fine of, say, \$5000.

9.3 To complete the picture, the Commission recommends that patient-identifiable information in researchers' hands be made immune from disclosure in judicial proceedings, whether in response to a search warrant, a subpoena or a witness summons. Precedents exist in the Commonwealth *Epidemiological Studies (Confidentiality) Act 1981* and the New South Wales *Health Administration Act 1982*.³⁹ A person seeking disclosure in court proceedings

³⁶ *Health Commission Act 1976* (SA) s 64d(2).

³⁷ The researcher would normally be subject to the rules of professional ethics of his or her profession and so subject to disciplinary proceedings for a breach of the Code: see Discussion Paper, paras 3.12 and 3.13. There could also be other sanctions, depending on the circumstances, eg refusal of further NHMRC funding.

³⁸ Or researchers where a team is involved (including clerical and administrative assistants).

³⁹ S 8 and s 23(4) respectively.

may of course be able to obtain the information from other sources, but adoption of the Commission's proposal would help assure the public that the use of their records for medical research would not facilitate the process.

10. HEALTH DEPARTMENT RECORDS

10.1 The Health Department has an extensive system of data bases containing information about patients: the Hospital Morbidity Data System, the Cancer Registry, the Mental Health Register, the Midwives' Notification Data System, a Birth Defects Register, the Infectious Diseases Register, a mortality database and the drug-related death registry.⁴⁰ The information is mainly used by the Health Department to monitor and prevent the spread of infectious diseases, for the statistical evaluation of services provided by hospitals and for epidemiological research.

10.2 Much of the information in these databases is collected under specific statutory authority.⁴¹ These provisions probably expressly or impliedly give the Department authority to use that information for purposes of departmental research but it is not clear whether the

Disclosure of information held by researchers in response to subpoenas has been noted as a problem in the United States of America: J N Gray and G B Melton *The Law and Ethics of Psychosocial Research on AIDS* (1985) 64 Neb LR 637, 665-666 and A R Holder *The Biomedical Researcher and Subpoenas: Judicial Protection of Confidential Medical Data* (1986) 12 American Journal of Law and Medicine 405. According to Holder (at 405): "In recent years, malpractice and product liability attorneys have become extremely interested in the results of epidemiological and biomedical research. Researchers and their records are now commonly subpoenaed in connection with lawsuits which relate to the subject of a study, but with which the researcher has no involvement."

The provision should be so drawn as not to apply to an action by the subject of the record against the researcher or third party for breach of confidence or to criminal proceedings against them for unjustified disclosure of patient-identifiable information.

⁴⁰ The Hospital Morbidity database contains information on all admissions and discharges from public and private hospitals in Western Australia. The information recorded includes the name and address of the patient, the purpose of stay and the treatment received. Information in the Cancer Registry includes the name and address of the subject and the major diagnosis. The Mental Health Register is similar to the hospital morbidity data system and is a record of psychiatric services provided to patients in this State. However, it is confined to patients who receive services from the Psychiatric Services Branch of the Department. It is compiled from records relating to services provided to patients and contains no information from private medical practitioners. The Midwives' Notification Data System contains information about outcomes of previous and current pregnancies, details of labour and delivery and details of babies.

⁴¹ For example, information about a patient's cancer must be given to the Health Department under the *Health (Notification of Cancer) Regulations 1981*. The authority to collect information from public hospitals is provided by s 18A of the *Hospitals Act 1927*. Private hospitals are required to provide the information as a condition of the grant of the hospital's licence. S 26D(2) of the *Hospitals Act 1927* provides that the Commissioner of Health may impose such terms and conditions as the Commissioner thinks fit on any licence granted to a private hospital. However it is not clear that a requirement to disclose information in patient-identifiable form to the Health Department as a condition of a licence would avoid the duty of confidence which would otherwise apply. The Commission suggests that the Health Department review the legal position on this matter.

legislation authorises disclosure to private researchers for their own purposes. The question is one of the scope of the Department's powers and the fact that the project had been approved by an IEC may not cure the defect. The Commission accordingly recommends that the matter be put beyond doubt by the enactment of a provision expressly empowering the Department to disclose patient-identifiable information to a private researcher on condition that the project has been approved by the Health Department's Confidentiality of Health Information Committee.⁴²

10.3 In his comments to the Commission, the Commissioner of Health submitted that there was a case for enacting a provision empowering the Governor in Council, on the recommendation of the Commissioner for Health, to exempt a record keeper from the duty of confidence without the researcher's project first being approved by an IEC. The power would be confined to emergency situations, for example an urgent study of the possible adverse effects of an environmental contaminant. Obliging the researcher to obtain the approval of an IEC may take too long in the circumstances.

10.4 The Commission considers that if this is a problem likely to arise in practice, the best way of dealing with it is not simply to **exempt** the record keeper from the duty of confidence in regard to the relevant records, thus leaving him free to withhold them if he chooses, but to **require** him to disclose them to the researcher. The urgency of the situation may justify this course. As pointed out above, there are a number of legislative provisions requiring record keepers to disclose patient identifiable information to the Health Department. But as also explained above the question of compulsory disclosure of records is outside the scope of this report and the Commission makes therefore no recommendation in this regard.

11. OTHER RESEARCH

11.1 One commentator expressed concern that an informal type of research, common in teaching hospitals, may fall foul of the duty of confidence. This involves a retrospective study of the course of treatment of a patient, or group of patients, by doctors practising at the

⁴² This is in fact the general practice at present. The Rev Colin Honey in his report to the Minister for Health *Review of Health Department Procedures for the Handling of Confidential Patient Data* (1989) made a number of recommendations to limit internal access to, and to improve the security of, medical records held by the Health Department. He also recommended that the release of data to private researchers be conditional upon an undertaking "to report outcomes to enable the Confidentiality of Health [Information] Committee to monitor their use of data". The Commission agrees with this recommendation.

hospital. The study not only enables assessment of the efficacy of the treatment on the patients concerned but also provides information for the treatment of other patients, present and future. This accords with good medical practice, and in the Commission's view such studies would have the implied consent of each of the patients concerned. No breach of confidence would be involved. Similarly, a study of patient records by hospital staff for the purpose of maintaining or improving the hospital's standard of delivery of services would also have implied patient consent.

11.2 A further example of research which is not at present necessarily reviewed by an IEC is where medical and other health care students at tertiary institutions are given controlled access to patient-identifiable records at hospitals in order to complete a thesis as part of the requirements for a degree or other qualification.⁴³ The main purpose is not the advancement of medical knowledge or improvement of health services but the training of students in basic research techniques. The Commission considers that in the interest of patient confidentiality such student exercises should require approval by a prescribed IEC, in accordance with the proposed legislative scheme above, if the record-keeper wishes to avoid the duty of confidentiality otherwise applying. While this may mean that few student projects would qualify for approval, training could be provided in other ways. For example, as at present, students could assist in the conduct of research projects that had been approved by an IEC.

12. STATE ARCHIVES

12.1 Although not within its terms of reference on this project,⁴⁴ the Commission considers it desirable to draw attention to the law and practice regarding the deposit of medical records with the State archives.

12.2 Records of the Health Department and public hospitals containing patient identifiable information that are of no current interest are required to be transferred to the State archives.⁴⁵

⁴³ The Commission is here not referring to the long established system of "clerking" whereby a small group of students is attached to a medical team in a teaching hospital. The students accompanying the doctors on their rounds take notes about the patient's condition, sometimes assist in the completion of the patient's medical record and are given access to the reports of any specialist tests conducted on the patient. As in the case of the practices referred to in the previous paragraph, this practice would have the implied, and often the express, consent of the patient. The students are under a general duty of confidence in respect of the information they gain about particular patients and would be liable for breach of confidence for unjustified disclosure.

⁴⁴ Although it is within the terms of its general reference on privacy.

Although so long as the subject of the record is alive the general law of confidentiality applies to his or her record,⁴⁶ this law is subject to the provisions of the *Library Board of Western Australia Act 1951* which govern the State archives. Under that Act the Library Board has a statutory duty to provide public access to the State archives for study and research,⁴⁷ which of course would override any general duty of confidence otherwise applicable. There are certain safeguards in the Act, one being that the officer in charge of a department or instrumentality which transfers any record to the State archives may impose reasonable restrictions on public access to that record or any part of it.⁴⁸ The Health Department requires that access to medical records it has transferred is not to be given unless approval has been granted by its Confidentiality of Health Information Committee.

12.3 However health information in patient-identifiable form is sometimes contained in records of Government bodies other than the Health Department and instances have occurred where the transferring officer has not imposed restrictions on access to that material. Although the Library Board or its authorised officers have power to restrict access to records of such "private or personal nature that they should not be open for general public consultation",⁴⁹ the officers informed the Commission that they do not have the resources to search systematically transferred records for this purpose. Accordingly the Commission recommends that departments and instrumentalities be required to ensure that, before they transfer records to the State archives, they identify any patient identifiable information in them, impose restrictions on access to that material and inform the State archives accordingly.⁵⁰

13. COMMONWEALTH PRIVACY ACT

13.1 The Discussion Paper drew attention to section 95 of the Commonwealth *Privacy Act 1988* which empowers the NHMRC, with the approval of the Privacy Commissioner, to issue

⁴⁵ The records include general administrative records of the Health Department, admission registers, medical journals and day books of psychiatric hospitals and registers of outpatients.

⁴⁶ In the case of records held by a hospital or doctor, the duty of confidence subsists so long as the confider (the patient) is alive. Where the confider has died, his or her personal representative has no right of action for breach of confidence to protect the relations or friends of the deceased from distress resulting from the doctor's disclosure of the deceased patient's confidences. Disciplinary proceedings against the doctor for breach of professional ethics may however succeed.

⁴⁷ *Library Board of Western Australia Act 1951* s 28.

⁴⁸ Id s 32(3).

⁴⁹ Id s 32(5).

⁵⁰ The Commission understands that the legislation dealing with State archives is being reviewed and that the reviewers are aware of the need to give special protection to confidential information (such as medical records) by the most practical means.

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.⁵¹ Guidelines have now been issued by the NHMRC⁵² pursuant to section 95 which are broadly in line with the approach of this Commission (that is, the requirement of approval of the research by an IEC in accordance with specified criteria). However, the Commonwealth Act applies only to Commonwealth departments and agencies and, in any case, compliance with the guidelines only absolves a record keeper from an adverse determination of the Privacy Commissioner and not from liability under the general law of confidence. The need for State legislation remains.

14. SUMMARY OF RECOMMENDATIONS

14.1 The Commission recommends⁵³ that -

Disclosure of confidential information

1. The law should be clarified to ensure that the disclosure to researchers of patient-identifiable information without patient consent does not involve a breach of the legal duty of confidence, provided the research has been approved by a prescribed Institutional Ethics Committee (IEC) in accordance with specified criteria.

Paragraph 6.1

Approval

2. Prescribed IEC's should be those of the teaching hospitals, WA universities and the State Health Department and of any other body prescribed by the Minister for Health which have consented to being prescribed.

Paragraphs 6.2 and 6.3

⁵¹ That is, any of the eleven Principles set out in s 14 of the Commonwealth Act. See ch 5 of the Discussion Paper, reproduced as Appendix III below.

⁵² *Guidelines for the Protection of Privacy in the Conduct of Medical Research* (1990). The guidelines remain in force until 31 December 1990.

⁵³ What follows is intended as a summary only. Reference should be made to the relevant paragraphs of the Report for the details of each recommendation.

Criteria for approval

3. In giving its approval the IEC should be satisfied that -
- (a) the research project has as its purpose the advancement of medical knowledge or the improvement of health services in Western Australia;
 - (b) access to patient-identifiable information is necessary for the scientific validity of the project;
 - (c) access to that information without patient consent is justified having regard to specified factors; and that
 - (d) the public interest in undertaking the project outweighs the public interest in maintaining confidentiality.

Paragraph 6.4

5. As a further condition of the project being granted approval, the researcher should be required to undertake to comply with a prescribed code of conduct for the safeguarding of the information in his or her hands.

Paragraph 6.5

6. Record-keepers of patient-identifiable information should be entitled to act on a certificate of a prescribed IEC that the project conforms to the statutory criteria.

Paragraph 7.2

Protection of information supplied to a researcher

7. The researcher, and any other person who acquires patient-identifiable information directly or indirectly from the researcher, should be placed under an express duty of confidence towards the subject of the information.

Paragraph 9.1

8. It should be an offence for a researcher or third party, without lawful excuse, to communicate patient-identifiable information to any other person.

Paragraph 9.2

9. Patient-identifiable information in researchers' hands should be immune from disclosure in judicial proceedings.

Paragraph 9.3

Records of the Health Department

10. Legislation should be enacted so as expressly to authorise disclosure of Health Department records for research purposes, subject to specified safeguards.

Paragraph 10.2

State archives

11. Departments and agencies should be required to impose restrictions on access to any patient-identifiable information in their records when transferring those records to the State archives.

Paragraph 12.3

J THOMSON

Chairman

R LE MIERE

CHARLES OGILVIE

GEORGE SYROTA

18 September 1990

APPENDIX I

LIST OF THOSE WHO COMMENTED ON THE DISCUSSION PAPER

Australian Association of Social Workers (Western Australian Branch Inc)

Australian Medical Association (Western Australian Branch)

Bartlett H & Pennebaker D Dr, Clinical Nursing Research Unit, School of Nursing, Curtin University of Technology

Biggs E

Cancer Foundation of Western Australia Inc

Courtis A

Dawes D C Dr, Deputy Medical Superintendent, Royal Perth (Rehabilitation) Hospital

Dobbyn M & Massey C School of Nursing, Curtin University of Technology

Edwards B

Harper A C, Professor of Occupational Health Services, Curtin University of Technology

Health Advisory Network

Health Department of Western Australia

Jones N & Wilson S, Community Nursing Services

King Edward Memorial Hospital for Women, Institutional Ethics Committee

The Law Society of Western Australia

Medical Records Association of Australia, WA Branch

Medical Superintendents Group

Musk A W, Head, Department of Respiratory Medicine, Sir Charles Gairdner Hospital

Nursing Research Network of WA

O'Neill D F, Dr

Public Health Association of Australia

Roberts M

Robertson J, Nurse Researcher, Princess Margaret Hospital for Children

Segal N

Singer P, Professor

Sir Charles Gairdner Hospital, Director of Medical Services, Dr J Mulligan

Sir Charles Gairdner Hospital, Chief Executive Officer, Dr P T Southgate

Sivewright C W and Wallis A G

State Archivist of Western Australia

The Country Women's Association of Western Australia

University of Western Australia, Division of Public Health of the Department of Medicine

Western Australian AIDS Council (Inc)

Appendix II

CHAPTER 3 OF THE DISCUSSION PAPER

(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; P M 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

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 into 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* (1977) 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.

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 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

¹² *AG v Guardian Newspapers (No 2)* [1988] 3 WLR 776, 781 per Lord Keith. Other relationships giving rise to an equitable 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.

paragraph 3.4 above, they would likewise be subject to an equitable duty of confidence as 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 *s*, 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 349): "[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 (i.e. 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

....

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.

Appendix III

CHAPTER 5 OF THE DISCUSSION PAPER

(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

¹ Paras 3.14 and 3.15.

² As noted by Dr Blewett, in debate on the (Cth) Epidemiological Studies (Confidentiality) Bill 1981 "[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.

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.

95.4 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

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

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.

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 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* 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.

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.

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:
 - (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

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."

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 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

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.

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

(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

¹³ S 23(4).

¹⁴ S 64d(1).

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 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

¹⁵ S 141(3)(g).

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 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

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.

specific project by an ethics committee. The New Zealand legislation does not appear to require approval of either 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.

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