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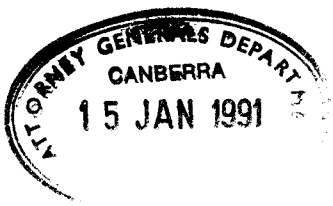
PERIODIC

These guidelines are in force until 30 June 1991

GUIDELINES FOR THE PROTECTION OF PRIVACY IN THE CONDUCT OF MEDICAL RESEARCH

in which any aspect of health is involved and includes epidemiological research.

As approved by the Privacy Commissioner under Section 95 of the Privacy Act 1988 (Commonwealth).



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COMMONWEALTH OF AUSTRALIA

SECTION 95 OF THE PRIVACY ACT 1988

MEDICAL RESEARCH GUIDELINES

Pursuant to subsections 95(2) and (3) of the Privacy Act 1988, the National Health and Medical Research Council, as resolved at its meeting of 7-8 November 1990, and with the approval of the Privacy Commissioner given on 17 December 1990, hereby publishes and issues the following medical research guidelines, being guidelines the same in form as those presently in force, to have effect during the period 1 January 1991 to 30 June 1991.

Professor John Phillip Chalmers
Chairman
National Health and Medical Research Council

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I

INTRODUCTION

The *Privacy Act 1988* (the Act) sets out eleven Information Privacy Principles (IPPs) that govern agencies of the Commonwealth in their collection, management and use of data containing personal information. The IPPs do not provide any general permission for the use of personal information for research and statistical purposes.

Where, for the purpose of medical research, a Commonwealth agency collects, manages or discloses data containing personal information, it is possible for an infringement of an IPP to occur.

Section 95 of the Act provides that the National Health and Medical Research Council (NHMRC) may, with the approval of the Privacy Commissioner, who is appointed under the Act, issue guidelines for the protection of privacy in the conduct of medical research.

There was an urgent need to establish guidelines for the conduct of medical research projects for which funding would be sought in 1990. To meet this need, these guidelines were developed as an interim measure. In the light of the experience of their use, the NHMRC will develop further guidelines for the Commissioner's approval.

In giving his approval to these guidelines, the Privacy Commissioner is satisfied that the public interest in the promotion of the type of research covered by them outweighs to a substantial degree the public interest in maintaining adherence to the IPPs.

In October 1982, the NHMRC established the Medical Research Ethics Committee (MREC) to advise on ethical matters relating to medical research. The MREC has prepared these guidelines which have been considered and endorsed by the NHMRC.

Failure to comply with the guidelines would be a ground for the application of appropriate sanctions. Medical research conducted in conformity with these guidelines cannot be regarded as an infringement of an IPP.

II

KEY TERMS

The following explanations are given to assist in understanding the meaning of some key terms used in these guidelines.

Breach —refers to an act of collection, management, use or disclosure of personal information by an agency that does not conform to an IPP.

Commonwealth Agency —a Commonwealth body that collects information and keeps records and means Commonwealth Ministers and Commonwealth government departments (other than the Commonwealth Parliamentary departments), bodies or persons established and performing functions under Commonwealth laws.

Consent —means explicit consent, arrived at in accordance with paragraphs 4.11–4.15 of these guidelines.

Health —includes good health which means a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity (World Health Organisation definition).

Medical Research —means systematic investigations for the purpose of adding to generalised knowledge pertaining to human health and includes epidemiological research.

Personal Information —means information or an opinion, whether true or not, about an individual who could be identified from the information or opinion.

Record —means a document, a data base (however kept) or a photograph. It does not include information publicly available in a library, gallery, museum or government archive.

III

OPERATION AND SCOPE

These guidelines are designed to achieve their purpose of protecting privacy in the conduct of medical research in three ways. First, they prohibit all medical research that might involve an unlawful interference with privacy from proceeding unless and until a decision has been made by an Institutional Ethics Committee (IEC) that the public interest in the research outweighs to a substantial degree the public interest in the protection of privacy.

Second, they determine who is to make that decision and set out the procedures that are to be followed in reaching that decision and in monitoring the conduct of research.

Third, they state the principles and matters that are to be considered and the reasons used in reaching that decision.

In short, the guidelines require approval of a project by an IEC, specify how that decision is to be made, and state the matters that are to be considered in making that decision and describe means of ensuring compliance in the conduct of the research.

These guidelines are in force until 31 December 1990.

MEDICAL RESEARCH INVOLVING PERSONAL INFORMATION HELD BY A COMMONWEALTH AGENCY

These guidelines apply to all medical research (not only that research supported by the NHMRC) which involves collection, storage, access to or use of personal information from a Commonwealth agency, where that research may involve a breach of an IPP.

The Act contains provisions allowing agencies to release personal information in certain circumstances which could include medical research. An agency should attempt to meet those provisions when it releases information for the purposes of medical research. Where those provisions of the Act cannot be met and release of personal information may involve a breach of an IPP, it will be necessary for that medical research to be conducted in accordance with these guidelines.

MEDICAL RESEARCH UNDERTAKEN BY A COMMONWEALTH AGENCY

Where a Commonwealth agency conducts activities that are within the definition of medical research, those activities should be conducted in conformity with the Act. This conformity can be achieved by conducting those activities in accordance with the IPPs, a Public Interest Determination or these guidelines.

IV

PROCEDURES AND PRINCIPLES

This section sets out guidelines for researchers and IECs to assist their preparation and consideration of research proposals. The attention of IECs is drawn to considerations of the public interests that are the subjects of paragraph 4.26 of the guidelines.

PRESENTATION BY RESEARCHERS

4.1 No medical research may proceed without prior consideration and approval (in accordance with these guidelines) of a written protocol by an IEC composed and functioning in accordance with Supplementary Note 1, entitled Institutional Ethics Committees, as published from time to time in association with the NHMRC Statement on Human Experimentation.

4.2 The written protocol for the conduct of each medical research project shall state the aims of the study, the data needed, the reasons why personal information is needed and the way in which the data will be collected, used and protected.

4.3 When a proposal for medical research would or might be thought to involve a breach of an IPP or IPPs, this must be stated in the written protocol and reasons must be there given for believing that the public interest in the research outweighs to a substantial degree the public interest in adhering to that Principle or Principles.

CONSIDERATION BY INSTITUTIONAL ETHICS COMMITTEES

4.4 When considering a proposal for medical research that involves an act that would or might be thought to breach an IPP, no decision is to be taken without a meeting of the IEC involving at least one representative of each of the categories set out in paragraph 3 of Supplementary Note 1.

4.5 The decision of an IEC on such a proposal shall involve all of the following:

4.5.1 the identification of the purposes of the research and the manner in which personal information will be used in achieving those purposes;

4.5.2 the identification and consideration of the IPP or IPPs that might be breached in the course of the proposed research;

4.5.3 the identification and consideration of the matters, to which the guidelines refer, that show that the proposed research is in the public interest;

4.5.4 the determination that the public interest in the proposed research outweighs, or does not outweigh, to a substantial degree the public interest in the protection of privacy;

4.5.5 the determination whether the research is, or is not, acceptable on ethical grounds;

4.5.6 notification, to the Commonwealth agency providing the information, that the proposal for medical research is under active consideration.

RECORDING OF DECISIONS

4.6 The IEC shall make and keep a written record of its decisions and the reasons for those decisions.

MONITORING OF COMPLIANCE

It is a function of IECs to maintain registers of all proposed research projects. The registers include among other things the reason for ethical approval or non-approval of each proposed project. The NHMRC through the MREC has access, upon request, to information in these registers maintained by IECs. The NHMRC will publish in its November Session Report the number of medical research projects to which these guidelines applied and the decisions made as a result of the guidelines.

4.7 IECs must maintain a separate register of all research proposals that involve consideration of the public interest in privacy as specified in these guidelines. The register shall contain the following information:

- the name of the researcher;
- the name of the institution;
- the title and a brief description of the research;
- the agency from which the information will be sought; and
- an indication of the approval or non-approval of the research protocol.

4.8 In the months of March and September, IECs shall provide the MREC with a copy of the register referred to in paragraph 4.7 above.

4.9 It is a function of IECs to provide for surveillance of research projects until completion so that the committee can be satisfied that the projects continue to conform with approved ethical standards. IECs shall maintain a similar surveillance of research projects to which these guidelines apply in order to be satisfied that those projects continue to conform with these guidelines.

4.10 IECs shall report periodically to the NHMRC on the reports received by them from researchers on the conduct of research that involves privacy considerations.

OTHER RELEVANT PRINCIPLES

Subjects

4.11 In the conduct of research, the investigator must at all times respect the personality, rights, wishes, beliefs, consent and freedom of the individual subject.

Research Requiring Direct Involvement of Subjects

4.12 Before research is undertaken the free consent of the subject should be obtained. To this end the investigator is responsible for providing the subject at his or her level of comprehension with sufficient written information about the purpose, methods, demands, risks, inconveniences and discomforts of the study. Consent should be obtained in writing unless there are good reasons to the contrary. If consent is not obtained in writing, the reasons for not so doing and the circumstances under which it is obtained should be recorded.

4.13 The subject must be free at any time to withdraw consent to further participation and thereupon the records of that subjects' participation are to be destroyed.

4.14 Special care must be taken in relation to consent, and to safeguarding individual rights and welfare where the research involves children, the mentally ill and those in dependent relationships or comparable situations.

Research Requiring Access to Records of Personal Information

4.15 Consent of subjects should generally be obtained for the use of their records for medical research, but in certain circumstances an ethics committee may approve of the granting of access to records without consent.

Dispensing With Consent

4.16 An IEC may, in special circumstances, and with considerable caution, approve the conduct of medical research, whether requiring personal involvement or access to records, without the consent of subjects. Before granting such approval, the IEC must consider any prejudice to the scientific value that would result from obtaining consent and any unnecessary distress likely to be caused to subjects by seeking consent. The necessity of a very large subject group may also make it difficult to seek individual consent. The IEC must be satisfied that such approval will not be to the lasting disadvantage of subjects.

Research Goals

4.17 When an IEC is considering a proposal for medical research it shall be satisfied that:

4.17.1 the research is likely to contribute to the acquisition of knowledge that may improve the health of the community, and

4.17.2 the investigators have the necessary skills and the facilities for the research.

Resource Implications

4.18 The researcher must inform the IEC that the agency has consented to grant access to, and has indicated that it has the resources to provide the information.

Confidentiality

4.19 Information that is confidential or personal, obtained for medical research, must not be used for purposes other than those specified in the approved protocol. On completion of those purposes the personal information is to be either destroyed or returned to its original confidential source.

4.20 Investigators and their associates must preserve the confidentiality of information about research subjects. The confidentiality of records used in medical research, both in the short and long term, must be at least as secure as it was in the sources from which the records were obtained.

4.21 The investigator must maximise the security of identifying data. The research protocol shall contain a description of the ways of separating personal information from the medically relevant data. This could involve removing identifying data from records at the earliest possible time or, if the data needs to be retained, utilising coding procedures and separate storage.

4.22 Results of medical research must not be published in a form that permits identification of the individual subject.

4.23 Subject to maintenance of confidentiality in respect of subjects, members of research groups should have access to such information as is relevant to their role in the project.

4.24 Access to other relevant records should be restricted to investigators recognised as appropriate by an IEC.

4.25 The use or disclosure in medical research, of confidential or personal information should not be allowed to cause material, emotional or other disadvantage to any individual.

THE PUBLIC INTEREST IN PRIVACY

The purpose of the *Privacy Act (1988)* is to protect the privacy of an individual. The public interest in privacy of personal information includes both the freedom from unauthorised interference with, or use of, personal information and also freedom from authorised practices which are unduly embarrassing, intrusive or prejudicial. For the purposes of medical research, an unlawful interference with privacy is an act of an agency that breaches an IPP.

The eleven IPPs can be grouped into three categories. The first category (IPPs 1,2 and 3) is concerned with the collection of personal information and impose obligations on collectors of that information. The second category (IPPs 4,5,6,7 and 8) is concerned with the management of personal information. The third category (IPPs 9, 10 and 11) is concerned with the usage of personal information.

THE PUBLIC INTEREST IN MEDICAL RESEARCH

Properly conducted medical research advances the community's understanding of disease and improves its capacity to prevent or treat disease. For this reason the public interest in medical research may be seen as outweighing the public interest in privacy.

The public interest in medical research is delineated in the NHMRC document entitled 'Report on Ethics in Epidemiological Research'.

WEIGHING OF THE PUBLIC INTERESTS

4.26 The need for an IEC to weigh the public interest in medical research and the public interest in privacy arises where medical research might involve an agency acting in breach of an IPP. Such a breach would be justifiable if, in the opinion of the IEC, the public interest in that medical research would outweigh to a substantial degree the public interest in privacy.

In reaching this decision an IEC is to consider the following matters:

4.26.1 the public importance of the study;

4.26.2 the extent to which the data being sought is ordinarily available to the public from the agency from which it is to be sought;

4.26.3 the weight that was given by the community and by relevant areas of expertise to similar previous studies;

4.26.4 the standards of propriety that have been observed in the conduct of similar previous studies; and

4.26.5 the standards of conduct that are to be observed in the study under consideration, including:

4.26.5.1 the size of the population to be affected or involved in the study;

4.26.5.2 the degree of intrusiveness of the questions to be asked or the procedures to be employed;

4.26.5.3 the procedures or controls that will apply to researchers to ensure confidentiality and tact in the treatment of research subjects;

4.26.5.4 the risk that an individual could be identified in the published results even where the data are presented in aggregate form;

4.26.5.5 the procedures that are to be followed to ensure that, at the completion of the approved research, all data containing personal information will be destroyed or returned to the original confidential source;

4.26.5.6 the sanctions that will follow a failure to comply with the above standards.

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