



CALVARY HEALTH CARE BETHLEHEM RESEARCH & ETHICS COMMITTEE

GUIDE FOR RESEARCHERS ON PRIVACY AND ETHICS APPROVAL

Calvary Health Care Bethlehem (CHCB) must comply with the privacy law requirements when considering requests to collect, use and/or disclose sensitive, health information for the purposes of research, the compilation of statistics or the management, funding or monitoring of a health service.

This document provides information about CHCB's privacy obligations and the circumstances in which you may need to submit an Application for Ethical Review to the CHCB Research and Ethics Committee (REC) and what would be required in such an application.

Privacy obligations

CHCB is required to comply with the following legislation:

- *Privacy Act 1988* (Cth), including the National Privacy Principles (NPPs) and the Information Privacy Principles (IPPs);
- Guidelines made under s 95A of the *Privacy Act 1988* (Guidelines); and

This document focuses on the NPPs and the Guidelines, as they are of particular importance. The NPPs are legal principles which must be complied with to safeguard information privacy. NPP 2 relates to the use and disclosure of personal information, which includes health information. NPP 10 relates to the collection, use and disclosure of sensitive information, which also includes health information.

Requirement for research approval

The overriding obligation for those who seek to collect, use or disclose health information is at all times to respect the dignity and privacy of the individual. CHCB bears a legal responsibility of ensuring that this respect is maintained, which it seeks to do by requiring researchers to submit an Application for Ethical Review to the REC.

For this reason, if you wish to collect, use and/or disclose health information for research relevant to public health or public safety, you may need to submit an Application for Ethical Review. If you propose to collect health information from which the individual may be identified without their consent, you will need REC approval.

The conduct of Quality Assurance activities can be an exception to this rule. We refer you to the National Health and Medical Research Council (NHMRC) document, *When does quality assurance in health care require independent ethical review?* Available at

<http://www.nhmrc.gov.au/publications/synopses/e46syn.htm>

In order to ensure that the criteria in the NHMRC document (above) are taken into account when considering a proposal relating to quality assurance, CHCB has prepared a Questions and Answers Checklist. The checklist can be accessed via <http://www.bethlehem.org.au/Research/RECQualityAssuranceChecklist.pdf> . It acts as a guide for researchers who are unsure whether their project requires REC approval.

If an Application for Ethical review is required, the process is set out below.

Application process

The purpose of an Application for Ethical Review is to provide the CHCB REC with enough information for it to determine whether or not the collection, use and/or disclosure of information involved in the project complies with the Guidelines, National Privacy Principle 2 and National Privacy Principle 10.

See guidelines to the National Privacy Principles at http://www.privacy.gov.au/publications/nppgl_01.html

REC consideration of the application

An awareness of the information that the REC needs in order to make a decision should assist you in determining what information to put in the Application for Ethical Review.

The REC must consider applications to determine whether the research proposal appears to satisfy privacy requirements. It does this by assessing the proposal against the Guidelines and the NPPs (in particular, NPP 2 and NPP 10).

Guidelines

The REC's main task is to assess whether the public interest in conducting the research substantially outweighs the public interest in protecting the privacy of individuals. Before engaging in this process, it must first find that the proposed collection, use or disclose of health information is necessary for:

- research relevant to public health or public safety;
- the compilation or analysis of statistics relevant to public health or public safety; or
- the management, funding or monitoring of a health service.

The REC must also be satisfied that the purpose of the research activity cannot be achieved by the collection, use or disclosure of de-identified data (that is, health information from which the individual it relates to cannot be identified), and that it would be impracticable to seek consent from the individual(s) to whom the information relates.

Being satisfied of these initial criteria, the REC must then determine whether the public interest in the proposed activity substantially outweighs the public interest in the

protection of privacy. To do this, it considers the factors set out in the Guidelines. There are numerous factors listed. Some examples are:

- the degree to which the proposed collection, use or disclosure is necessary to CHCB's functions or activities;
- any likely benefits to individuals or the wider community that will arise from the research; and
- the standards of conduct that are to be observed in the research, including the procedures or controls that will apply to ensure that participants are treated with integrity and sensitivity, and whether access to health information is adequately restricted to appropriate personnel involved in conducting the proposed study.

Once the REC has engaged in this balancing process, it will make a decision and notify you. For proposals that are approved and go ahead, the REC will monitor the conduct of the research project as required by NHMRC guidelines.