Ethical Conduct in Human Research and Related Activities Regulations

Appendix 6

Referring Human Ethics Applications to a Health and Disability Ethics Committee

Section 22(3) of the Ethical Conduct in Human Research and Related Activities Regulations states as follows:

(3) Each School of Studies and Faculty has one or more committees with responsibility at the School, Faculty or departmental level, delegated by the University of Waikato Human Research Ethics Committee, for:
(a) the approval of research and/or related activities with human participants in the School, Faculty or department (health and disability research involving human participants must also be approved by a health and disability ethics committee see Appendix 6 of these regulations);

Researchers must ensure that all proposed health and disability research investigations which involve human participants, whether health or disability service consumers, healthy volunteers or members of the community at large, are submitted for review by a Health and Disability Ethics Committee. Health and disability research means research that:

- compares an established procedure, whether therapeutic, non-therapeutic or diagnostic, with other procedures that are not recognised as established, either by virtue of their recent development, discovery or use in a new or unfamiliar way
- ii. involves access to personal information for purposes other than direct consumer care or clinical audit (ethical review is required if it is intended, as part of an audit, to seek additional information from patients other than that collected during the provision of patient care; any access to health information must be in accordance with the provisions of the Privacy Act 1993 and the Health Information Privacy Code 1994)
- iii. seeks to further scientific or professional knowledge by means of questionnaires, interviews or other techniques of information gathering, or by means of laboratory analysis of human blood, tissues, etc, of living people, cadavers or discarded body tissues (for example, placenta)
- iv. is conducted by government departments unless they have a statutory exclusion (for example, Statistics New Zealand)
- v. is observational clinical research or is a physiological study
- vi. is a clinical trial
- vii. involves the use of any form of irradiation, organ imaging or surgical technique
- viii. involves innovative practice in health and disability services
- ix. involves a new treatment or intervention that uses pain or deprivation of basic food or drink as a means to change behaviours
- x. is a study that requires ethics committee review, in accordance with the National Ethics Advisory Committee's Ethical Guidelines for Observational Studies.

Exceptions to these requirements can be found in the *Operational Standard for Ethics Committees* Section 4 http://www.ethicscommittees.health.govt.nz/moh.nsf/pagescm/6777/\$File/OperationalStandard2006.pdf

University of Waikato applications involving health and disability research must be submitted to the **Northern Y Regional Ethics Committee.** Contact details, the application form and guidelines for completing the application are available from the following website: http://www.ethicscommittees.health.govt.nz/moh.nsf/indexcm/ethics-about-northern?Open&m_id=2.2

Where applications are made to a Health and Disability Ethics Committee an application would normally be made to and approved by the relevant delegated ethics committee within the University prior to any application to a Health and Disability Ethics Committee