

HBDHB provides the locality review and approval for all research within the public health system in Hawke's Bay.

INFORMATION

This information sheet provides guidance for obtaining ethical approval, locality authorisation & Maori Health consultation for research activities.

Ethical Review

All health research proposals will require ethical review. The level of review and approval required is to be determined by the researcher, and advice regarding this is available on <http://ethics.health.govt.nz/>. There is an online application process, which allows applicants to answer questions in the HDEC application form, upload documents, request electronic signatures from other parties involved in your research, and track the progress of applications.

Completion of the Health and Disability Ethics Committee (HDEC) ethical review screening questionnaire will:

- Allow researchers to ascertain whether projects are within the scope of the HDEC review process requiring formal application to HDEC for ethics approval or just require local HBDHB locality approval. If a researcher has ethical concerns about a project deemed of minimal risk and not requiring ethical review via the online screening process, further advice should be sought
- Allocate applications requiring ethical approval to a full or expedited approval pathway.

Locality Authorisation

For Projects Requiring HDEC Approval

The HDEC online submission process includes locality authorisation to the HBDHB Research Coordinator as delegated by HBDHB Chief Executive Officer and Chief Medical Officer. For HBDHB locality approval through the Online Forms process you must utilise the research@hbdhb.govt.nz email address.

For Projects Not requiring HDEC Approval

- Completion of the HBDHB Research Application form for **all research activities / projects** (excluding clinical trials) to gain institutional / locality approval AND
- Institutional Ethics Committee approval if being undertaken to fulfil the requirements of completion of an academic qualification

Notes:

1. For information and documentation regarding clinical trials within HBDHB email clinicaltrials@hbdhb.govt.nz.
2. Research cannot commence within HBDHB without institutional / locality approval being granted.

Māori Consultation

The Health Research Council has prepared guidelines for researchers on Health Research involving Māori, <http://www.hrc.govt.nz/news-and-publications/publications/maori>. Although written for applicants for HRC funding the intent is “to establish research practices which ensure that research outcomes contribute as much as possible to improving Māori health and well-being, while the research process maintains or enhances mana Māori.” Considerations should be made as to how Māori are involved, the impact the research will have on Māori health, which Māori will be involved and how can Māori be involved in the research team. Consultation is required early in the research process and on its completion prior to dissemination of results. This can be obtained via the HBDHB Māori Health Service, who have a specific application form.

DEFINITIONS

Research

Any health and disability activity which is methodologically sound and which systematically seeks to gain new knowledge, relevant to individual and public health in all sectors of the population. The activity will contribute to the improvement and maintenance of individual and public health and/or advances the prevention, diagnosis and treatment of disease.

Clinical Trial

A study in which an investigator controls and studies the interventions which are provided to participants for the purpose of adding to the knowledge of health effects of the intervention.

Ethical Review/Approval

A review and approval provided by the New Zealand Health and Disability Ethics Committees or Institutional Ethics Committees for student research where patients are not involved.

Audit

Audit determines whether existing clinical knowledge, skills and resources are being properly and effectively used. In contrast research is concerned with generating new knowledge which will have general application.

References

1. Health Research Council Act 1990
2. Health & Disability Ethics Committees Operating Procedures <http://ethics.health.govt.nz/operating-procedures>.
3. National Ethics Advisory Committee Ethical Guidelines for Intervention Studies and Ethical Guidelines for Observational Studies: Observational Research, Audits & Related Activities <http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research>
4. Towards Clinical Excellence – An Introduction to Clinical Audit, Peer Review and Other Clinical Practice Improvement Activities, Ministry of Health, April 2002 http://www.health.govt.nz/system/files/documents/publications/moh_tce_2002.pdf
5. Health and Disability Commissioner Act 1994
6. Code of Health and Disability Services Consumer Rights
7. Privacy Act 1993

PROCESS FOR APPROVAL

