# HDEC – Scope of Review Form

**Introduction:**

This form will help determine whether HDEC review is required, and if not, will result in an ‘out of scope’ letter from HDEC. This letter will not include an HDEC reference number but can be used as evidence of HDEC review not being required.

This form is not considered a HDEC application and can only determine whether a potential application should be submitted to HDEC for review.

**Please note**: your locality may have additional ethical review policies, please check with your locality. If your study involves a DHB, you must contact the DHB’s research office before you begin. If your study involves a university or polytechnic, you must contact its [institutional ethics committee](http://ethics.health.govt.nz/applying-review/research-contacts) before you begin.

**Submission Process:** Once you have completed the form please email it to [HDECS@moh.govt.nz](mailto:HDECS@moh.govt.nz)

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| --- | --- | --- |
| Study title |  | |
| Title  (e.g. Dr, Ms, Mr, Mrs) |  |
| First Name |  |
| Last Name |  |
| Address |  |
| Organisation |  |
| Email |  |
| Phone |  |

# Health and Disability Research

## Is your study Health and Disability Research?

Health and disability research is research that aims to generate knowledge for the purpose of improving health and independence outcomes. Consider whether your study is health research, or some other kind of research.

**Only health research is reviewed by HDECs.**

# Student- led research

## Is this study being conducted principally for the attainment of an educational qualification?

If yes, please detail the level of this qualification (e.g. Master’s or PhD)

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# Research funded by the Health Research Council of New Zealand

## Is your project funded by the Health Research Council (HRC)? If yes please state which HRC-approved ethics committee will review your project in the event that it is outside the scope of HDEC review. A list can be found here: [http://www.hrc.govt.nz/ethics-committee-approval-and-annual-reporting](http://www.hrc.govt.nz/ethics-committee-approval-and-annual-reporting%20)

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# Summary of study

## Briefly explain your study using lay language.

This explanation should include:

* your participant population
* study aims
* study question(s)

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# Health information:

Is any identifiable health information involved in your study, at any point in time?   
(E.g. identifiable when the information is accessed, recorded, stored).

Health Information is defined in section 4(1) of the Health Information Privacy Code 1994 as:

1. *information about the health of that individual, including his or her medical history;*
2. *information about any disabilities that individual has, or has had;*
3. *information about any health services or disability services that are being provided, or have been provided, to that individual;*
4. *information provided by that individual in connection with the donation, by that individual, of any body part or any bodily substance of that individual or derived from the testing or examination of any body part, or any bodily substance of that individual; or*
5. *information about that individual which is collected before or in the course of, and incidental to, the provision of any health service or disability service to that individual.*

Please explain what information is accessed for the project, and comment on its identifiability at each stage of the study.

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## Has consent for accessing health information for the purpose of this project been sought from patients?

Please explain your answer.

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## Is the access and use of health information for this project directly related to the purpose it was collected for?

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# Type of Study

## Is your study an intervention study, observational study, or an audit and related activity?

Please review Appendix 1 of this application, select a type of study and **justify your answer.**

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## Is this project conducted at your own organisation or does it involve multiple agencies?

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Does your project have a hypothesis?

Please explain your answer

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Will the study produce any generalisable information?

Generalisability relates to the extent to which the findings of a clinical study can be reliably extrapolated from the participants to a broader patient population and a broader range of clinical settings.

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# Human tissue

Will your study use human tissue?

Section 7(1) of the Human Tissue Act 2008 defines tissue as material that is:

*(a) is, or is derived from, a body, or material collected from a living individual or from a body; and*

*(b) is or includes human cells; and*

*(c) is not excluded, for the purposes of some or all of the provisions of this Act, by subsection (2) or (3).*

Please explain the proposed use of tissue in your study, including:

* where the tissue is collected from,
* how it will be used, and
* whether consent has already been obtained.

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## **Participants**

Does your study involve any participants?

If yes, please include information on:

* how participants will be identified and approached for consent,
* what participation in the study will involve for participants (e.g. any procedures), and
* any risks to participants.

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Are any of your participants vulnerable?

Please explain your answer.

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# Appendix 1 – HDEC Scope from Standard Operating Procedures

## When does a study require HDEC review?

## *Main criteria*

1. Health and disability research requires HDEC review only if it involves one or more of the following:
   1. **human participants** recruited in their capacity as:
      1. consumers of health or disability support services, or
      2. relatives or caregivers of consumers of health or disability support services, or
      3. volunteers in clinical trials (including, for the avoidance of doubt, bioequivalence and bioavailability studies)
   2. theuse, collection or storage of **human tissue** (as defined by the [Human Tissue Act 2008](http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html)), unless:
      1. informed consent (which may include informed consent to future unspecified research) has been obtained for such use, and tissue will not be made available to researchers in a form that could reasonably be expected to identify the individual(s) concerned, or
      2. one or more of the statutory exceptions to the need to gain informed consent set out at section 20(f) of the [Human Tissue Act 2008](http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html) (or Right 7(10)(c) of the [Code of Health and Disability Services Consumers’ Rights 1996](http://www.hdc.org.nz/the-act--code/the-code-of-rights)) applies
   3. the use or disclosure of **health information** (as defined by the [Health Information Privacy Code 1994](http://privacy.org.nz/health-information-privacy-code)), unless:
      1. this use or disclosure has been authorised by the individual(s) concerned, or
      2. health information will not be disclosed to researchers in a form that:
      3. could identify, or could reasonably be expected to identify, the individual(s) concerned, or
      4. would allow for the information to be matched with other data sets (for example, through the use of non-encrypted identifiers such as National Health Index numbers).

## *Exemptions to main criteria*

1. **Studies on low-risk devices:** A study involving a medical device does not require HDEC review if the device is (or would be) classified as a low-risk (class I) medical device by Australia’s Therapeutic Goods Administration (TGA).[[1]](#footnote-1)
2. **Minimal-risk observational studies:** An observational study requires HDEC review only if the study involves more than minimal risk (that is, potential participants could reasonably be expected to regard the probability and magnitude of possible harms resulting from their participation in the study to be greater than those encountered in those aspects of their everyday life that relate to the study).
3. For the avoidance of doubt, an observational study always involves more than minimal risk if it involves one or more of the following:
   1. one or more participants who will not have given informed consent to participate, or
   2. one or more participants who are vulnerable (that is, who have restricted capability to make independent decisions about their participation in the study),[[2]](#footnote-2) or
   3. standard treatment being withheld from one or more participants, or
   4. the storage, preservation or use of human tissue without consent, or
   5. the disclosure of health information without authorisation.
4. **Audits and related activities:** An audit or related activity requires HDEC review only if it involves the use, collection or storage of human tissue without consent, other than in accordance with a statutory exception (set out at section 20(f) of the [Human Tissue Act 2008](http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html) and Right 7(10)(c) of the [Code of Health and Disability Services Consumers’ Rights 1996](http://www.hdc.org.nz/the-act--code/the-code-of-rights)).
5. **Student-led research:** From 1 January 2013, a study conducted wholly or principally for the purposes of an educational qualification requires HDEC review only if it:
   1. is an intervention study, or
   2. is not conducted at or below Master’s level.

## *Inclusions*

1. Regardless of the exemptions to the main criteria outlined above, a study requires HDEC review if it:
   1. involves the use of human tissue samples taken as part of New Zealand’s Newborn Metabolic Screening Programme (known as ‘Guthrie cards’), or
   2. is funded by the Health Research Council of New Zealand (HRC) and is not able to be reviewed by an institutional ethics committee approved by the HRC’s Ethics Committee (HRCEC).
   3. involves the establishment or maintenance of a tissue bank (see section 13).

# Appendix 2 – Definitions of types of research

For more information please see <http://ethics.health.govt.nz/ethical-standards-health-and-disability-research>

## Intervention study

## An intervention study is a study in which the investigator controls and studies the intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of the intervention(s). The term ‘intervention study’ is often used interchangeably with ‘experimental study’. Many intervention studies are clinical trials.

## Observational study:

The primary purpose or justification for observational research is to add to generalisable knowledge about a health or disability issue. The six main types of observational research are summarised below.

**A note from the HDEC Secretariat:** Generally speaking if health information is being accessed for research and the research is not directly related to the purpose for which the information was originally collected (e.g. quality audit) then it falls into the category of observational research.

**Case control studies** examine the relationship between an attribute and a disease by comparing those with and without the disease with respect to the presence of the attribute or level of exposure to it.

**Cohort studies** examine the relationship between exposure to a factor or factors and the probability of the occurrence of a disease (or other outcome) by observing large numbers of people over a period of time and comparing incidence rates of the disease (or outcome) in relation to exposure levels. A cohort study may be a clinical cohort study (for example, where a group of patients with a given disease is followed to examine the prognosis).

**Cross-sectional studies** examine the relationship between diseases (or other health-related characteristics) and other variables of interest in a defined population at one particular point in time, by collecting health and other information concerning members of the population. These include questionnaires or surveys done for research purposes.

**Case reports** are reports of cases from health or disability services or research settings.

**Case series** describe a set of cases of a disease (or similar problem). For example, a clinician may assemble a case series on a topic of interest, such as an unexpected adverse effect experienced by patients taking a particular medication.

**Descriptive studies** examine the existing distribution of variables in populations, for example, analyses of cancer registry data or emergency department data by person, place or time.

## Audit or related activity:

The primary purpose or justification for an audit or related activity is to improve delivery of the particular health or disability support service being studied or to control a threat to public health. (The results of audits and related activities should be disseminated at least to those able to take necessary action. Wider dissemination, including through publication in scientific journals, may sometimes be appropriate.) The 10 main types of audit and related activities are summarised below.

**A note from the HDEC Secretariat**: For the sake of clarity, the purpose of accessing identifiable health information for audit or related activity must be **closely connected** to the purpose for which the information was originally connected and can reasonably be assumed to be within the expectations of the person from whom it was collected.

**Audits** involve the systematic evaluation of aspects of health or disability support service delivery by considering measurable indicators of performance and/or quality.

**Programme evaluation** is a type of audit where a whole programme is evaluated, rather than specific interventions.

**Evaluation studies** aim to determine the relevance, effectiveness and impact of activities in the light of their objectives. Several types of evaluation are distinguished, including evaluation of the structure, process and outcome of an activity.

**Quality assurance activities** aim to improve health and disability support services by assessing the adequacy of existing practice against a standard.

**Outcome analyses** involve the assessment of health and disability support service quality by reviewing health care information to evaluate outcomes without comparing them against a standard. For example, clinicians may retrospectively examine health care notes and perform descriptive analyses to determine the outcome of medical treatment or course of a particular illness.

**Benchmarking** aims to improve practice through the comparison of two or more health and disability support services.

**Public health investigations** explore possible risks to public health, are often of an immediate or urgent nature, and are often required by legislation. Examples are investigations into outbreaks or clusters of disease, analyses of vaccine safety and effectiveness, and contact tracing of communicable conditions.

**Public health surveillance** involves the monitoring of risks to health by methods that include the systematic collection, analysis and dissemination of information about disease rates.

**Pharmacovigilance** (post-marketing surveillance) involves monitoring the adverse effects of pharmaceuticals after their introduction into the general population, by such methods as the spontaneous reporting of adverse events and the monitoring of all adverse events for a restricted group of medicines (prescription event monitoring).

**Resource utilisation reviews** evaluate the use of resources in a particular health or disability service activity, for example, by reviewing health records to determine health care inputs such as chest X-rays for patients with a particular diagnosis.

1. The TGA’s guidance on device classification can be found from page 77 of the Therapeutic Goods Administration’s 2011 *Australian regulatory guidelines for medical devices*, available from the TGA’s website at <http://tga.gov.au/pdf/devices-argmd.pdf>. [↑](#footnote-ref-1)
2. This term is defined more fully in the [*Ethical Guidelines for Intervention Studies*](http://www.neac.health.govt.nz/moh.nsf/pagescm/7654/$File/ethical-guidelines-intervention-studies-nov09.pdf). [↑](#footnote-ref-2)