Screening Overview

Purpose of Form

This form will help determine whether HDEC review is required and if so, what review pathway the study will go through. The questions are based on the rules from section three of the Standard Operating Procedures (SOP) for Health and Disability Ethics Committees (HDEC). You can find a copy of the SOP at https://ethics.health.govt.nz/operating-procedures

Guidance is provided to help answer the questions. If you answer the questions correctly and you do not require HDEC review, the system will generate and send you an 'out of scope' letter from HDEC that states why HDEC review is not required.

If you answer the questions correctly and require HDEC review, the form will direct you to the appropriate review form to complete.

Please note the following:

- The screening overview is not considered an HDEC application and can only determine whether a potential application should be submitted to HDEC for review. If an application requires review the answers in the screening form will automatically be added to the application form.
- A letter stating the study is not in scope for HDEC review is not ethical approval. It is only evidence that the proposed study does not meet the conditions for HDEC review.
- Your institution may have additional ethical review policies, please check with your institution.
- If your study involves a Te Whatu ora locality, you must contact the locality's research office before you begin a study.
- If your study involves a university or polytechnic, you must contact its institutional ethics committee before you begin a study.

Health and disability research

HDEC only review health and disability research. Health and disability research is research that aims to generate knowledge for the purpose of improving health and independence outcomes. The knowledge must be expected to improve health and independence outcomes. Broadly speaking, health and disability research should:

- aim to answer a question or solve a problem and therefore generate new knowledge to prevent, identify and treat illness and disease
- have the ultimate purpose of maintaining and improving people's health – in the sense of a state of physical, mental and spiritual wellbeing, rather than simply the absence of disease or infirmity
- support disabled people to be included, participate more, exercise choice and control, and be more independent
- address health and disability disparities
- contribute to whānau ora.

S1. Is your study health or disability research?

- (●) Yes
- ( ) No

S2. Will your study involve the creation or use of a human gamete, a human embryo or a hybrid embryo?

- ( ) Yes
- (●) No

Category

S3. Which category best describes your study?

- ☐ Intervention Study

In intervention studies, the investigator controls and studies the preventive, diagnostic or therapeutic intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of the intervention(s). Many intervention studies are clinical trials.

☐ Observational Study

All health and disability research that is not an intervention study is an observational study. In an observational study, in contrast to an interventional (or experimental) study, the researcher does not influence the assignment of any variable. Instead, the researcher observes and analyses natural relationships between variables and outcomes, and records them.

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).

☑ Audit or Related Activity

Please see below table for assistance in determining what an activity is.

There is inconsistency in the terminology used between the HDEC's Standard Operating Procedure and the National Ethical Standards. For the purposes of this form 'Human Participant Research' in the table refers to Health and Disability Research and 'Quality Improvement Activities' refers to Audits and Related Activities.

Human Participant Research:	**Quality Improvement Activities:**
• Activities which attempt to create new generalisable knowledge in response to an acknowledged information gap.	• Activities which aim to improve healthcare by assessing current situation and systematically implementing/testing evidence -based knowledge within a local organisation.
Goal: **Quantitative research** • Acceptance or rejection of a hypothesis in relation to treatment, cause, risk or diagnosis of a health problem. Small differences may represent a significant finding. **Qualitative research** • Description and interpretation of something in its natural setting. May address how treatments and relationships are experienced.	• Ensure healthcare delivered by organisations are effective, safe, and equitable through the applications of improvement science methodology.
Setting: • May be conducted within a healthcare setting or primary research setting. **Methods:** **Quantitative research** • Emphasis on prespecified aims, clearly protocolised methods, high precision measures, careful bias control, sample size calculations and statistical analysis. • May involve random allocation and blinding to intervention. • Attempts to remove/minimise contextual influences. **Qualitative research** • Obtains information from interviews, focus groups, observations, or documents or other materials	• May be conducted within a health and care or community setting • Uses established, structured quality improvement methodologies to evaluate baseline performance, implement change and retest for sustained improvement. • Approaches include diagnosing and understanding the issue, followed by testing an intervention (usually a known intervention) to ascertain if it results in an improvement in the local context prior to full implementation. Small samples are often adequate. • Tools to understand the issue may be similar to those used for research such as auditing against a standard and qualitative experience capture through interviews /focus groups/observations. Tests of change are undertaken through PDSA cycles. Methods such as Lean Thinking and Six Sigma are used to identify and remove waste and unjustified variation. • Group randomisation may occur in cluster or step-wedge designs.
Data collection: • Usually collects data additional to that collected for routine healthcare, sometimes by invasive diagnostic techniques. May also repurpose healthcare data for research.	• Uses existing healthcare data but may require additional data gathering.
Outcomes from Activity: • Results published /presented beyond the immediate environment in which they were collected. May be applicable elsewhere. • Dissemination may be slow. No presumption that local practice will alter quickly.	• Primary audience is the organisation in which the activity was conducted.

S3.1. Does your audit or related activity involve 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 and Right 7(10)(c) of the Code of Health and Disability Services Consumers' Rights 1996)?

Statutory exemptions:

- a professionally recognised quality assurance programme
- an external audit of services
- an external evaluation of services

- ○ Yes, my audit involves the use, collection or storage of human tissue without consent (other than in accordance with a statutory exception)
- ◉ No, my audit does not involve the use, collection or storage of human tissue without consent

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 and Right 7(10)(c) of the Code of Health and Disability Services Consumers' Rights 1996).

Please proceed to the end of the form.

Inclusions

S18. Research funded by Health Research Council of New Zealand

Is your study 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)?

A list of HRCIECs can be found here.

- ○ Yes
- ◉ No

S19. New Zealand's Newborn Metabolic Screening Programme

Does your study involve the use of human tissue samples taken as part of New Zealand's Newborn Metabolic Screening Programme (known as 'Guthrie cards')?

- ○ Yes
- ◉ No

Disclaimer

S20. **Please ensure all questions above are answered in full.**

I agree that:

- ***I have read the EthicsRM Terms and Conditions***
- ***I have provided accurate information in describing my study and acknowledge that if an out of scope letter has been issued it is automated, based on the information provided by me.***

Regardless of whether HDEC approval is required, researchers in such studies will still be required to comply with the National Ethical Standards for Health and Disability Research and Quality Improvement.

- (•) Yes
- ( ) No

Review Pathway (If more than one displays please email ethicsrm@health.govt.nz)

If more than one or no review pathway displays please export the application as a PDF (using the 'view as PDF' button on the action menu to the left) and email it to ethicsrm@health.govt.nz.

An HDEC advisor will contact you and advise which pathway to proceed with. We will fix the screening algorithm in a future update.

OOS *Based on your answers your study is exempt from HDEC review* and does not require HDEC approval.

*Note this does **NOT*** mean the study does not require ethics review and you may still require locality approval. Please check with your locality. *If your study involves a Te Whatu ora locality, you must contact the local research office before you begin. If your study involves a university or polytechnic, you must contact its institutional ethics committee before you begin.*

Please proceed with the form to generate an 'out of HDEC scope' exemption letter.

- (•) Proceed

You may now submit the form using the action menu to the left.