S. Screening Section

Screening Section Overview Page 1

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 DHB, you must contact the DHB'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.

Dependents: 3

S1. Is your study health or disability research?

- ○ Yes
- ○ No

Depends on S1. Is your study health or disability research?

Your study is not health and disability research and does not need to be submitted for HDEC review.

Dependents: 3

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

- ○ Yes
- ○ No

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

Your study must be reviewed by the Ethics Committee on Assisted Reproductive Technology, rather than by an HDEC.

Depends on S1. Is your study health or disability research?, S2. Will your study involve the creation or use of a human gamete, a human embryo or a hybrid embryo?

Please proceed with the screening form on the next page.

Screening Section Page 2

Category

Dependents: 47

Depends on S1. Is your study health or disability research?, S2. Will your study involve the creation or use of a human gamete, a human embryo or a hybrid embryo?

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	• May be conducted within a health and care or community setting

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	• 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.

Dependents: 3 Depends on S3. Study category

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

Depends on S3. Study category, S3.1. Use of Human Tissue in Audit

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 atsection 20(f) of the Human Tissue Act 2008and Right 7(10)(c) of the Code of Health and Disability Services Consumers' Rights 1996).

Please proceed to the end of the form.

Participants

Dependents: 7 Depends on S3. Study category

S4. Does your study involve the *active participation* of any human participants recruited in their capacity as consumers of, or relatives or caregivers of consumers of, health or disability support services, or volunteers in clinical trials? Please select all that apply.

- [ ] Consumers of health or disability support services
- [ ] Relatives or caregivers of consumers of health or disability support services
- [ ] Volunteers in clinical trials (including, for the avoidance of doubt, bioequivalence and bioavailability studies)
- [ ] None of the above

Dependents: 1 Depends on S4. Study Participants

S5. Will your study involve any of the below human participants? Please select all that will apply.

- [ ] One or more human participants who will not have given informed consent to participate

*Note this refers to active participants enrolled into the study and **NOT** the use of identified health information without consent.*

- [ ] One or more human participants who have a restricted ability to make independent decisions about their participation (e.g. children)
- [ ] None of the above

Health Information

Depends on S3. Study category, S4. Study Participants

Health information is defined in section 4(1) of the Health Information Privacy Code 2020 as:

- *information about the health of that individual, including his or her medical history;*
- *information about any disabilities that individual has, or has had;*
- *information about any health services or disability services that are being provided, or have been provided, to that individual;*
- *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*
- *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.*

Dependents: 5 Depends on S3. Study category, S4. Study Participants

S6. Will any identifiable health data be accessed, reviewed, collected or analysed at any point during your study?

- ○ Yes
- ○ No

Data from which it can reasonably be assumed that it is possible to identify a specific individual involved in the study:

Direct identifiers:

Indirect identifiers:

- NHI
- Name
- Street address
- Phone number
- Online identity (e.g., email, twitter name)
- Identification numbers (e.g., community services card, driver's licence)
- Date of birth
- Identification of relatives
- Identification of employers
- Clinical notes
- Any other direct or indirect identifiers that carry significant risk of re-identification

Dependents: 4 Depends on S3. Study category, S4. Study Participants, S6. Identified health information

S7. Has consent for accessing health information for the purpose of this study already been provided from participants for this use?

- Yes
- No

Dependents: 2 Depends on S3. Study category, S4. Study Participants, S7. Consent for use of identified health informatoin

S8. Will all health information be disclosed to researchers in a **deidentified** form (i.e. without any direct or indirect identifiers)?

(n.b. an NHI number is **identifiable**).

- Yes
- No

Human Tissue

S9. Will your study use human tissue?

Dependents: 39 Depends on S3. Study category

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).

S9. Will your study use human tissue?

- Yes
- No

Dependents: 7 Depends on S9. Use of Human Tissue.

S10. Has informed consent for this use already been obtained?

- Yes
- No

Dependents: 7 Depends on S10. Consent for tissue

S11. Will the tissue be provided to researchers in a **deidentified** form (i.e. without any direct or indirect identifiers)?

- Yes

- ○ No

Dependents: 4 Depends on S9. Use of Human Tissue., S11. Identifiability of tissue

S12. Do you meet one of the exemptions for ethical review, under *statute (see section 20(f) of the Human Tissue Act 2008 and Right 7(10)(c) of the Code of Health and Disability Services Consumer' Rights 1996):*

Statutory exemptions:

(i) a professionally recognised quality assurance programme:

(ii) an external audit of services:

(iii) an external evaluation of services

- ○ Yes
- ○ No

Dependents: 5 Depends on S9. Use of Human Tissue., S11. Identifiability of tissue, S12. Statutory exemptions for ethical review

S13. Will you be storing, preserving or using human tissue without consent?

- ○ Yes
- ○ No

Dependents: 1
Depends on S9. Use of Human Tissue., S11. Identifiability of tissue, S12. Statutory exemptions for ethical review , S13. Will you be storing, preserving or using human tissue without consent?

S14. Will you be banking the tissue for future research and seeking a future unspecified consent?

Note if the biobank is in New Zealand this must be an HDEC approved biobank.

- ○ Yes
- ○ No

Study Features

Dependents: 11 Depends on S3. Study category

S15. Does your study have any of the following features?

Please select all that apply from the list below.

- ☐ A new medicine
- ☐ An approved medicine being used for a new indication or through a new mode of administration
- ☐ A new medical device that is or would be classified as a class IIb, class III, or active implantable medical device by the Therapeutic Goods Administration (TGA guidance https://www.tga.gov.au/sme-assist/what-classification-my-medical-device)
- ☐ A new surgical intervention
- ☐ A change to standard treatment / care
- ☐ None of the above

Exemptions

Exemptions from HDEC review

Dependents: 1 Depends on S3. Study category

S16. Does your study primarily involve evaluating a low-risk (class I) medical device?

- Yes
- No

Dependents: 1 Depends on S3. Study category

S17. HDEC does not review observational research that is conducted principally for the attainment of an educational qualification of Masters or below. Does this apply to your study?

- Yes
- No

Inclusions

Dependents: 9 Depends on S3. Study category

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

Dependents: 9 Depends on S3. Study category

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

Dependents: 22

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

Depends on S20. Declaration

You must agree to the above in order to submit the form.

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

Dependents: 96

Depends on S15. Features of studies that require review by full review pathway, S20. Declaration, S5. Non consenting or vulnerable participants. , S20. Declaration, S13. Will you be storing, preserving or using human tissue without consent? , S20. Declaration, S3. Study category, S3.1. Use of Human Tissue in Audit, S20. Declaration

*Your study will be reviewed by the **full review*** pathway described at section 5 of the Standard Operating Procedures for Health and Disability Ethics Committees.

Proceed

Depends on Full Review

Please proceed on the next page.

Dependents: 93

Depends on S4. Study Participants, S10. Consent for tissue , S15. Features of studies that require review by full review pathway, S20. Declaration, S15. Features of studies that require review by full review pathway, S18. HRC Funding, S20. Declaration, S15. Features of studies that require review by full review pathway, S19. New Zealand's Newborn Metabolic Screening Programme, S20. Declaration, S3. Study category, S12. Statutory exemptions for ethical review , S13. Will you be storing, preserving or using human tissue without consent? , S14. Biobanking and FUR, S10. Consent for tissue , S11. Identifiability of tissue, S9. Use of Human Tissue., S15. Features of studies that require review by full review pathway, S20. Declaration, S13. Will you be storing, preserving or using human tissue without consent?

*Your study will be reviewed by the **expedited review** pathway described at section 6 of the Standard Operating Procedures for Health and Disability Ethics Committees.*

Proceed

Depends on Expedited Review

Please proceed on the next page.

Dependents: 43

Depends on S3. Study category, S7. Consent for use of identified health informatoin, S8. Disclosure of identified health information, S6. Identified health information , S9. Use of Human Tissue., S20. Declaration, S15. Features of studies that require review by full review pathway

*As a data-only project that does **not** involve active participants, your study will be reviewed by the **expedited review** pathway described at section 6 of the Standard Operating Procedures for Health and Disability Ethics Committees.*

Proceed

Depends on Data only expedited

Please proceed on the next page.

Dependents: 1

Depends on S3. Study category, S3.1. Use of Human Tissue in Audit, S18. HRC Funding, S19. New Zealand's Newborn Metabolic Screening Programme, S20. Declaration, S3. Study category, S9. Use of Human Tissue., S15. Features of studies that require review by full review pathway, S17. Masters exemption, S18. HRC Funding, S19. New Zealand's Newborn Metabolic Screening Programme, S20. Declaration, S3. Study category, S10. Consent for tissue , S11. Identifiability of tissue, S15. Features of studies that require review by full review pathway, S16. Low-Risk Class I device, S18. HRC Funding, S19. New Zealand's Newborn Metabolic Screening Programme, S20. Declaration, S3. Study category, S6. Identified health information , S9. Use of Human Tissue., S15. Features of studies that require review by full review pathway, S18. HRC Funding, S19. New Zealand's Newborn Metabolic Screening Programme, S20. Declaration, S3. Study category, S7. Consent for use of identified health informatoin, S6. Identified health information , S9. Use of Human Tissue., S18. HRC Funding, S19. New Zealand's Newborn Metabolic Screening Programme, S20. Declaration, S3. Study category, S7. Consent for use of identified health informatoin, S8. Disclosure of identified health information, S6. Identified health information , S9. Use of Human Tissue., S18. HRC Funding, S19. New Zealand's Newborn Metabolic Screening Programme, S20.

Declaration, S3. Study category, S10. Consent for tissue , S11. Identifiability of tissue, S9. Use of Human Tissue., S15. Features of studies that require review by full review pathway, S18. HRC Funding, S19. New Zealand's Newborn Metabolic Screening Programme, S20. Declaration, S3. Study category, S12. Statutory exemptions for ethical review , S10. Consent for tissue , S11. Identifiability of tissue, S15. Features of studies that require review by full review pathway, S18. HRC Funding, S19. New Zealand's Newborn Metabolic Screening Programme, S20. Declaration, S4. Study Participants

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 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 before you begin.*

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

Proceed

Depends on OOS Out of Scope

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

A. Study overview

Title, summary and overview

Title and Summary

Depends on Full Review, Expedited Review, Data only expedited

A1. Short study title:

This is a simple lay-language title that should be used to head any PISCFs used for the study.

Depends on Full Review, Expedited Review, Data only expedited

A2. Formal study title:

Depends on Full Review, Expedited Review, Data only expedited

A3. Protocol number (if applicable):

If this protocol has a unique identifier, please enter this below.

Depends on Full Review, Expedited Review, Data only expedited

Upload Protocol document.

Upload Document

Depends on Full Review, Expedited Review, Data only expedited

A4 Please provide the dates on which you plan to commence and conclude your study in New Zealand.

Planned commencement date: Depends on Full Review, Expedited Review, Data only expedited

Planned conclusion date: Depends on Full Review, Expedited Review, Data only expedited

HDEC review preference

Dependents: 2 Depends on Full Review, Expedited Review, Data only expedited

A5. Please indicate your review preference.

- I request that this application be reviewed as soon as possible.
- I request that this application be reviewed by a specific HDEC.

Depends on A5. Please indicate your review preference.

A5.1. The preferred HDEC is:

- CEN
- NTA
- NTB
- STH

Depends on A5. Please indicate your review preference.

A5.2. Please explain why you wish this HDEC to review your study (e.g. resubmission of a previously declined study).

Dependents: 1 Depends on Full Review, Expedited Review, Data only expedited

A6. *HDECs are public administrative bodies, and their meetings are open to the public. Your study may be reviewed in a closed meeting only if grounds may exist to withhold information about it under the Official Information Act 1982.*

Do you wish to request your application be considered in a closed meeting?

- Yes
- No

Depends on A6. Closed meeting request.

A6.1. Please provide reasons, and specify the grounds that you consider may exist under the Official Information Act 1982 to withhold information about your study.

Prior HDEC Review

Dependents: 2 Depends on Full Review, Expedited Review, Data only expedited

A7. Is this application related to one or more previous applications for HDEC review?

- Yes
- No

Depends on A7. Is this application related to one or more previous applications for HDEC review?

A7.1. Please give the reference number(s) for all related HDEC applications.

Dependents: 2 Depends on A7. Is this application related to one or more previous applications for HDEC review?

A7.2. Has an application for this study (or a substantially similar study) previously been declined approval by an ethics committee in New Zealand?

- Yes, by an HDEC
- Yes, by an institutional / university ethics committee
- No

Depends on A7.2. Has an application for this study (or a substantially similar study) previously been declined approval by an HDEC in New

Zealand?

A7.3. Please give the reference number of the previously declined study(s).

Depends on A7.2. Has an application for this study (or a substantially similar study) previously been declined approval by an HDEC in New Zealand?

Please upload a copy of the declined letter for the previous study.

Upload Document

Study Aims

Depends on Full Review, Expedited Review, Data only expedited

A8. Please briefly summarise the scientific basis for your study (including, where appropriate, brief discussion of previous research)

Depends on Full Review, Expedited Review, Data only expedited

A9. Briefly and in plain English, state the principal aims / objectives of your study.

Depends on Full Review, Expedited Review, Data only expedited

A10. Briefly explain how your study will contribute to new knowledge and improve health outcomes.

B. Study design

Design and Type of Study

Therapeutic study

Dependents: 13 Depends on S3. Study category, Full Review, S3. Study category, Expedited Review

B1. Does your study hold the **prospect of direct benefit** (diagnostic, therapeutic or preventative) for **individual participants.**

This does not include potential future benefit from the information gained from the study.

○ Yes ○ No

Depends on B1. Is your intervention study a therapeutic study?

B1.1. Please briefly describe the direct diagnostic, therapeutic or preventative benefits that your intervention study may have for participants

Type of study

Dependents: 4 Depends on S3. Study category, Full Review, S3. Study category, Expedited Review

B2. Which of the following options best describes the area in which your study aims to improve knowledge?

- ☐ diagnosis
- ☐ early detection/screening
- ☐ prevention
- ☐ treatment
- ☐ rehabilitation
- ☐ lifestyle/behaviour
- ☐ other

Dependents: 7 Depends on B2. Which of the following options best describes the area in which your study aims to improve knowledge?

B2.1. Please specify:

- ☐ medicines
- ☐ devices / medical technologies
- ☐ surgery
- ☐ radiotherapy
- ☐ gene technologies / stem cells or reprogrammed cells
- ☐ other

Depends on B2.1. Area in which study aims to improve knowledge

Please note GTAC approval may be required.

Depends on B2. Which of the following options best describes the area in which your study aims to improve knowledge?, B2.1. Area in which study aims to improve knowledge

Please specify 'other':

Please upload an investigator's brochure for the medicine.

Depends on B2.1. Area in which study aims to improve knowledge

Please upload an investigator's brochure for the medicine.

Upload Document

Add Another

Dependents: 6

Depends on B2. Which of the following options best describes the area in which your study aims to improve knowledge?, B2.1. Area in which study aims to improve knowledge, S3. Study category, Full Review, B2. Which of the following options best describes the area in which your study aims to improve knowledge?, B2.1. Area in which study aims to improve knowledge, S3. Study category, Expedited Review

B3. Please select the following that apply to your study:

- ☐ Phase
- ☐ Randomisation
- ☐ Blinding
- ☐ Control
- ☐ Design Type
- ☐ Arms

Depends on B3. Intervention attributes

Phase:

- ☐ Pilot study / feasibility study
- ☐ Phase 1
- ☐ Phase 2
- ☐ Phase 3
- ☐ Phase 4 / Post-approval

Depends on B3. Intervention attributes

Randomisation:

- ☐ Randomised
- ☐ Non-randomised

Depends on B3. Intervention attributes

Blinding:

- ☐ Open-label
- ☐ Single-blind
- ☐ Double-blind

Dependents: 1 Depends on B3. Intervention attributes

Control:

- [ ] Uncontrolled
- [ ] Placebo controlled
- [ ] Active controlled

Dependents: 1 Depends on B3. Intervention attributes

Design type:

- [ ] Single ascending dose
- [ ] Multiple ascending dose
- [ ] Food effect
- [ ] Drug interaction
- [ ] Bioequivalence / biosimilarity
- [ ] Renal impairment
- [ ] Hepatic impairment
- [ ] Dose ranging
- [ ] Proof of concept
- [ ] Efficacy
- [ ] Long term extension
- [ ] Other

Depends on Intervention design

Please specify other:

Depends on B3. Intervention attributes

Arms:

- [ ] Single arm
- [ ] Two arm
- [ ] Multiple arm

Depends on Intervention control

B4. Please explain why the use of placebo is justified in your study.

Depends on S3. Study category, Full Review, S3. Study category, Expedited Review

B5. Please justify the design of your study.

Dependents: 1 Depends on B2.1. Area in which study aims to improve knowledge

B5.1. Is your study a 'First in Human' trial of a medicine or device?

- ○ Yes
- ○ No

Dependents: 2 Depends on B5.1. First in Human Trial

B5.2. Will sentinel dosing / sentinel exposure be used?

- Yes
- No

Depends on B5.2. Sentinel dosing

B5.3. Please briefly describe the sentinel design.

Depends on B5.2. Sentinel dosing

B5.4. Please provide a justification for not using a sentinel exposure design in this first-in-human study.

Depends on S3. Study category, Full Review, S3. Study category, Expedited Review

B6. **Best intervention standard**

An intervention study meets the best intervention standard if the intervention(s) in the study are tested against the best proven intervention(s) available outside the study. Please explain how your study meets the "best intervention standard".

Dependents: 1 Depends on S3. Study category, Full Review, S3. Study category, Expedited Review

B7. Will your study involve withholding standard treatment from participants?

- Yes
- No

Depends on B7. Will your study involve withholding standard treatment from participants?

B7.1. Please briefly explain why it is appropriate to withhold standard treatment from participants.

Depends on B1. Is your intervention study a therapeutic study? , S3. Study category

B8. Will all participants have continued access to the study treatment(s) after the end of your intervention study?

- Yes
- No

You need to explain this clearly to participants.

Depends on S3. Study category, B1. Is your intervention study a therapeutic study?

B9. **Equipoise Standard**

An intervention study meets the equipoise standard if the evidence is 'equally poised' as to the overall balance of risks and benefits of each of the interventions offered in the study, so that it cannot be determined in advance which of the groups in a proposed study will be better off.

Please briefly explain how your intervention study meets the equipoise standard.

Dependents: 1 Depends on B1. Is your intervention study a therapeutic study?

B10. Will you use public health care resources in the conduct of your study?

- Yes
- No

Depends on B10. Will you use public health care resources in the conduct of your study?

B10.1. May this adversely impact on the provision of healthcare services for non-participants?

Independent Scientific Peer Review

Dependents: 1 Depends on B2.1. Area in which study aims to improve knowledge, S3. Study category

B11. Is your study being submitted for SCOTT review

- Yes
- No

Depends on B1. Is your intervention study a therapeutic study? , B11. Is your study being submitted for SCOTT review?, B1. Is your intervention study a therapeutic study?

B12 Please briefly describe the peer review process that has been carried out for your study.

Please upload evidence of independent peer review

Depends on B1. Is your intervention study a therapeutic study? , Full Review, Expedited Review, Data only expedited

Please upload evidence of independent peer review

Upload Document

Add Another

AI and machine learning

Dependents: 1 Depends on B1. Is your intervention study a therapeutic study?

B13. Will the study involve the use of artificial intelligence or machine learning?

- Yes

- [ ] No

Please note you are required to comply with all relevant sections in *Chapter 13 of the National Ethical Standards for Health and Disability Research.*

If you have supporting documents relevant to the AI or machine learning technology used you may upload them here.

Depends on B13. Will the study involve the use of artificial intelligence or machine learning?

Please note you are required to comply with all relevant sections in *Chapter 13 of the National Ethical Standards for Health and Disability Research.*

If you have supporting documents relevant to the AI or machine learning technology used you may upload them here.

Upload Document

Add Another

Number of participants

Dependents: 4 Depends on B1. Is your intervention study a therapeutic study?

B14. Please select locations the study will occur in

- [ ] New Zealand only
- [ ] International (including New Zealand)

Depends on B14. participant numbers

B14.1. Approximately how many participants do you intend to recruit in New Zealand?

Depends on B14. participant numbers

B14.2. Will your study involve multiple sites in New Zealand?

- [ ] Yes
- [ ] No

Dependents: 2 Depends on B14. participant numbers

B14.3. At which type(s) of locality do you intend to conduct your study?

- [ ] District Health Board
- [ ] Tertiary Education Institution
- [ ] Primary Health Care Centre
- [ ] Private Organisation
- [ ] Other

Depends on B14.3. Study localities

Please specify other

Depends on B14. participant numbers

B14.4. Please enter the number of participants to be recruited worldwide.

Publishing of Results

Depends on Full Review, Expedited Review, Data only expedited

B15. Please describe how the results of the study may be published (e.g. peer-reviewed journal, internal distribution within institution, website).

Dependents: 1 Depends on Full Review, Expedited Review, Data only expedited

B15.1 Are there any possible restrictions that may be placed on publication? (e.g. by a Sponsor or authorising institution).

- Yes
- No

Depends on B15.1 Restriction of publication

B15.2 Please explain what possible restrictions there are on publication and by whom.

Dependents: 1 Depends on Full Review, Expedited Review, Data only expedited

B16. Will the results be published in a form that identifies (or could reasonably be expected to identify) any individual participants?

- Yes
- No

Dependents: 2

Depends on B16. Will the results be published in a form that identifies (or could reasonably be expected to identify) any individual participants?

B17. Can participants request a copy of their own individual study test and procedure results?

- Yes
- No

Depends on B17. Can participants request a copy of their own individual study test and procedure results?

B17.1. Please explain and justify why participants may not request their own results.

Dependents: 1 Depends on B17. Can participants request a copy of their own individual study test and procedure results?

B17.2. Can participants request a summary of the overall findings of the research?

- Yes
- No

Depends on B17.2. Can participants request a summary of the overall findings of the research?

B17.3. Please explain and justify why participants may not request a summary of the study's findings.

Conflicts of interest

Funding and remuneration

Depends on S20. Declaration, Full Review, S20. Declaration, Expedited Review

B18. Please briefly describe the main source(s) of funding for your study.

Dependents: 2 Depends on S20. Declaration, Full Review, Expedited Review, S20. Declaration

B19. Does the Coordinating Investigator, any other investigator, or any direct member of their families have any commercial interest in the intervention(s) to be studied, or any financial relationship to the study sponsor or funder(s), that may inappropriately influence their conduct in the study?

- Yes
- No

Depends on B19. CI financial interest

B19.1. Please briefly describe the nature of this interest or relationship, and how the risk of a conflict of interest will be minimised and managed.

Dependents: 1 Depends on B19. CI financial interest

B20. Will the Coordinating Investigator or any other investigator be remunerated for their involvement in the study in a way that may inappropriately influence their conduct in the study (for instance, bonuses for favourable results or high recruitment rates)?

- Yes
- No

Depends on B20. Investigator Remuneration

B20.1. Please briefly describe the nature of this remuneration (or any other valuable consideration), and how the risk of a conflict of interest will be minimised and managed.

Health or disability support service providers

Dependents: 3 Depends on Full Review, Expedited Review

B21. Will the Coordinating Investigator or any investigator also provide non-research related clinical care or health / disability support for one or more participants in your study?

- ○ Yes
- ○ No

Depends on B21. Will the Coordinating Investigator or any other investigator also provide non-research related clinical care or health / disability support for one or more participants in your study?

B21.1. Please briefly describe how the risk of a conflict of interest between the research and clinical roles of such Investigators will be minimised and managed.

Please briefly describe how the participant feeling undue influence to participate will be mitigated.

Dependents: 1

Depends on B21. Will the Coordinating Investigator or any other investigator also provide non-research related clinical care or health / disability support for one or more participants in your study?

B21.2. Will the usual health or disability service provider for one or more participants in your study receive any remuneration (or any other valuable consideration) for referring potential participants to the research team in your study?

- ○ Yes
- ○ No

Depends on B21.2. Will the usual health or disability service provider for one or more participants in your study receive any remuneration (or any other valuable consideration) for referring potential participants to the research team in your study?

B21.3 Please explain your answer:

Other potential conflicts of interest

Depends on B21. Will the Coordinating Investigator or any other investigator also provide non-research related clinical care or health / disability support for one or more participants in your study?

B22. Please briefly describe how any other potential conflicts of interest will be minimised and managed.

(For guidance on what constitutes a conflict of interest please click the help button).

C. Value of Research

Value for Māori

Relevance for Māori

Dependents: 4 Depends on Full Review, Expedited Review

C1. Might Māori be involved as participants in this study, or does the project relate to a health issue of importance to Māori?

- Yes
- No

Depends on C1. Relevance for Māori

C2. Please explain why Māori are being excluded from this study, or why the health issue studied is not of importance to Māori.

Dependents: 3 Depends on C1. Relevance for Māori

C3. Are any of the research staff involved in the study Māori?

- Yes
- No
- Unknown

Depends on C3. Māori researcher

C3.1. Please describe what role Māori staff will have in the study.

Depends on C3. Māori researcher

C3.2. Are the Māori staff able to advise on tikanga?

- Yes
- No

Depends on C3. Māori researcher

C3.3. Does the study use Kaupapa Māori methodology?

- Yes
- No

Risks and benefits for Māori

Depends on C1. Relevance for Māori

C4. Please describe whether and how your study may benefit Māori.

Please include information on the incidence of the disease or condition in Māori (if known) and any useful statistics. If these are not known please state so.

Please do not cite Te Tiriti o Waitangi / the Treaty of Waitangi as a health benefit. Equal access to participation in clinical research is not a health benefit but rather the default expectation.

Depends on C1. Relevance for Māori

C5. Please identify the main cultural issues (including issues of data sovereignty) that may arise for Māori who may participate in your study, and explain how these issues will be managed.

Māori Consultation

Depends on Full Review, Expedited Review

C6. Please describe the consultation process for the study.

Depends on Full Review, Expedited Review

Please upload evidence of Māori consultation, if available.

Consultation with Māori does not need to be complete before HDEC approval but must happen prior to the beginning of the study.

Upload Document

Value for Pacific peoples

Value for Pacific peoples

Depends on Full Review, Expedited Review

C7. Please describe whether and how your study may benefit Pacific peoples.

Depends on Full Review, Expedited Review

C8. Are Pacific people being specifically targeted for recruitment in your study?

- ○ Yes
- ○ No

Dependents: 1 Depends on Full Review, Expedited Review

C9. Are any of the research staff Pasifika?

- ○ Yes
- ○ No

Depends on C9. Are any of the research staff Pacific?

C9.1. Please describe what role Pacific staff will have in the study.

Depends on Full Review, Expedited Review

C10. Please identify the main cultural issues that may arise for Pacific people who participate in your study and explain how these issues will be managed.

Pacific consultation

Depends on Full Review, Expedited Review

C11. Please describe the consultation process for the study.

Value for other population groups

Value for other population groups

Depends on Full Review, Expedited Review

C12. Please briefly indicate whether the results of your study may risk stigmatising individuals or population groups, and if so, how this risk will be minimised and managed

Dependents: 2 Depends on Full Review, Expedited Review

C13. Will your study specifically target any other ethnic group, gender or demographic (e.g. disabled people)

- Yes
- No

Depends on C13. Will your study specifically target any other ethnic group, gender or demographic (e.g. disabled people)

C14. Please discuss the planned or undertaken consultation process with relevant stakeholders to ensure appropriate practices are followed.

Please upload any relevant documentation (if any) on the consultation process.

Depends on C13. Will your study specifically target any other ethnic group, gender or demographic (e.g. disabled people)

Please upload any relevant documentation (if any) on the consultation process.

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Equity

Where possible, research should reduce health inequalities

Dependents: 1 Depends on Full Review, Expedited Review

C15. Might your intervention study contribute to reducing health inequalities in health outcomes between different populations, and particularly between Māori, Pacific Peoples and other New Zealanders?

- Yes
- No

Depends on C15. health inequalities

Please explain your answer

D. Recruitment of participants

Inclusion and exclusion criteria

Inclusion and exclusion criteria

Depends on Full Review, Expedited Review

D1. Please briefly describe the important inclusion and exclusion criteria for your study (e.g. age, gender, condition).

Dependents: 1 Depends on Full Review, Expedited Review

D2. Will any genders or ethnicities be specifically excluded from participation?

- Yes
- No

Depends on D2. Will any genders or ethnicities be specifically excluded from participation?

D2.1. Please specify the group to be excluded and provide a justification.

Depends on Full Review, Expedited Review

D3. Please explain how these inclusion and exclusion criteria ensure that the risks and benefits of your study are distributed fairly.

Recruitment and Advertising

Recruitment

Depends on Full Review, Expedited Review

D4. Please describe how potential participants in the study will be identified.

Depends on Full Review, Expedited Review

D5. Please describe how potential participants in the study will be approached.

Dependents: 1 Depends on Full Review, Expedited Review

D6. Will initial permission to be approached by the research team be obtained from a member of the potential participant's clinical care team / health provider?

This approach may be brief and does not need to be formally recorded.

- ○ Yes
- ○ No
- ○ n/a - this is a healthy participant study
- ○ n/a - participants will approach the study team (e.g. self referral from advertisements)

Depends on D6. Approach by healthcare provider?

D6.1. Please provide a justification for the research team approaching participants directly.

Advertisements

Dependents: 1 Depends on Full Review, Expedited Review

D7. Will any advertisements (e.g. flyers, digital media / social media platforms) be used to promote the study?

- ○ Yes
- ○ No

Please upload all advertisements that may be used.

Note if the advertisements are not available and/or have not been created yet these may not be used without HDEC approval. Please submit these as an amendment following approval of the main study.

Depends on D7. Advertisements

Please upload all advertisements that may be used.

*Note if the advertisements are not available and/or have not been created yet these may **not** be used without HDEC approval. Please submit these as an amendment following approval of the main study.*

Upload Document

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Informed Consent Process

Informed Consent

Dependents: 9 Depends on Full Review, Expedited Review

D8. Will **all** participants in your study give their informed consent to participate?

- ☐ yes, all participants will give informed consent
- ☐ yes, but one or more participants will require decision making support
- ☐ no, one or more participants will not give informed consent
- ☐ no participants will give informed consent

Depends on D8. Will all participants in your study give their informed consent to participate?

D9. Briefly explain the process by which potential participants in your study will be provided with information on the study, have the opportunity to ask questions, and asked to give their informed consent.

Depends on D8. Will all participants in your study give their informed consent to participate?

D9.1 Please describe the supported decision making process that will be used in your study.

(For guidance on a person-centred, supported decision-making model please click the help button).

PIS/CF

D10. Please upload a generic version of the main participant information sheet(s) and consent form(s) (PIS/CF) that you will provide to potential participants. You don't need to submit information sheets specific to each study locality.

Depends on D8. Will all participants in your study give their informed consent to participate?

D10. Please upload a generic version of the **main** participant information sheet(s) and consent form(s) (PIS/CF) that you will provide to potential participants. You don't need to submit information sheets specific to each study locality.

Upload Document

Add Another

Depends on D8. Will all participants in your study give their informed consent to participate?

D10.1 How have you checked that the participant information sheet is appropriate for your study population?

Studies involving non-consenting participants

Dependents: 3 Depends on D8. Will all participants in your study give their informed consent to participate?

D11. *New Zealand law – particularly the New Zealand Bill of Rights Act 1990, the Protection of Personal and Property Rights Act 1988, the Code of Health and Disability Services Consumers' Rights ('the Code'), and the Care of Children Act 2004 – substantially limits the powers of health practitioners to offer treatment without consent in the context of research. It is the Coordinating Investigator's responsibility to ensure that all applicable legal standards are met in non-consensual studies.*

Please indicate the groups to which non-consenting participants in your study belong, and provide

brief details.

- ☐ children and young people (under the age of 16) who are not competent to give informed consent
- ☐ unconscious adults
- ☐ adults with serious mental illness
- ☐ adults with serious intellectual disability
- ☐ other

Depends on D11. Please indicate the groups to which non-consenting participants in your study belong, and provide brief details.

Details:

Depends on D8. Will all participants in your study give their informed consent to participate?

D12. Please briefly explain why it is appropriate that your study involves non-consenting participants.

Dependents: 4 Depends on D8. Will all participants in your study give their informed consent to participate?

D13. For studies involving adults who lack the capacity to provide informed consent will you ascertain the views of relatives or other persons who interested in the welfare of the non-consenting participant?

- ☐ yes
- ☐ no

Depends on D13. For studies involving adults who lack the capacity to provide informed consent will you ascertain the views of relatives or other persons who are able to advise on the presumed wishes of non-consenting participants?

D13.1. Please briefly describe the process for seeking these views.

Depends on D13. For studies involving adults who lack the capacity to provide informed consent will you ascertain the views of relatives or other persons who are able to advise on the presumed wishes of non-consenting participants?

D13.2. Please justify why these will not be sought.

Please upload a generic version of the information sheet that will be provided to relatives or other persons whose views will be ascertained.

Depends on D13. For studies involving adults who lack the capacity to provide informed consent will you ascertain the views of relatives or other persons who are able to advise on the presumed wishes of non-consenting participants?

Please upload a generic version of the information sheet that will be provided to relatives or other persons whose views will be ascertained.

Upload Document

Add Another

Dependents: 2 Depends on D8. Will all participants in your study give their informed consent to participate?

D14. Will your study include participants to whom Right 7(4) of the Code applies?

(i.e. participation is in the best interests of the participant; AND reasonable steps have been undertaken to ascertain the views of the participant; AND if views have been ascertained, having regard to those views the provider believes the service is consistent with the choice the consumer would make if competent OR if views not ascertained the provider must take into account the views

of other suitable persons).

- Yes
- No

Depends on D14. Right 7 4

D14.1. Who will be ascertaining the best interest of the participant and how will this be recorded?

Depends on D14. Right 7 4

D14.2 Please describe the process for enrolling non-consenting adult participants into this study and provide a justification.

Dependents: 1 Depends on D8. Will all participants in your study give their informed consent to participate?

D15. Is it possible that non-consenting participants' ability to give informed consent could change during your study?

- yes
- no

Depends on D15. Is it possible that non-consenting participants' ability to give informed consent could change during your study?

Please upload a copy of the PIS/CF to be given to participants who regain the capacity to give informed consent to inform them they were enrolled without their consent and to consent them for ongoing participation and/or the ongoing use of previously recorded data.

Upload Document

Studies involving minors (children under 16)

Dependents: 2 Depends on D11. Please indicate the groups to which non-consenting participants in your study belong, and provide brief details.

D16. Will you seek the consent of a parent or guardian?

- Yes
- No

Depends on D16. Parent / Guardian Consent

D16.1. Please briefly explain why this will not be sought.

Please upload the parent / guardian consent form.

Depends on D16. Parent / Guardian Consent

Please upload the parent / guardian consent form.

Upload Document

Add Another

Dependents: 2

Depends on D13. For studies involving adults who lack the capacity to provide informed consent will you ascertain the views of relatives or other persons who are able to advise on the presumed wishes of non-consenting participants?

D17 Will assent for participation be sought from the minor?

- Yes
- No

Depends on D17 Will assent for participation be sought from the minor?

D17.1. Please briefly explain why this will not be sought.

Please upload assent forms appropriate to the level of understanding of the minor participants.

Several forms may be required to meet different comprehension levels.

Depends on D17 Will assent for participation be sought from the minor?

Please upload assent forms appropriate to the level of understanding of the minor participants.

Several forms may be required to meet different comprehension levels.

Upload Document

Add Another

Dependents: 2 Depends on D11. Please indicate the groups to which non-consenting participants in your study belong, and provide brief details.

D18. Will any participants turn 16 or become competent to provide independent informed consent during the study?

- Yes
- No

Depends on D18. Will any participant turn 16

D18.1. Please briefly describe how consent for continued participation will be obtained.

Depends on D18. Will any participant turn 16

Please upload a PISCF to consent participants who turn 16 during the course of the study for their ongoing participation.

If participants will be consented using a standard PISCF for the study previously uploaded leave this blank and explain your answer above.

Upload Document

Study procedures

Study procedures

Depends on Full Review, Expedited Review

D19. Please describe the study:

- What is the expected study duration for each participant, and the estimated number of study visits?
- Briefly and in plain English, please describe the procedures to be undertaken by participants in your study.

Do not describe procedures that will be undertaken as part of normal clinical care regardless of participation in your study. If participation will involve a change to normal clinical care please explain these and provide a justification.

Ionising radiation not needed for normal clinical management

Depends on Full Review, B1. Is your intervention study a therapeutic study?

D20. Will your study involve the administration of ionising radiation that is not needed for participants' normal clinical management?

- ☐ Yes
- ☐ No

Dependents: 2 Depends on Full Review, B1. Is your intervention study a therapeutic study?

D20.1. Will your study involve the administration of ionising radiation for imaging purposes to screen for disease or monitor disease during the study?

- ☐ Yes
- ☐ No

Depends on D20.1. Will your study involve the administration of ionising radiation for imaging purposes to screen for disease or monitor disease during the study?

D20.2. Please briefly describe the imaging performed and its frequency, and whether this poses additional risk to participants.

Participants should be informed of the risks of ionising radiation above standard care in the PISCF.

Dependents: 2
Depends on D20.1. Will your study involve the administration of ionising radiation for imaging purposes to screen for disease or monitor disease during the study?

D20.3. Does your study involve the administration of ionising radiation for any other purpose?

- ○ Yes
- ○ No

Depends on D20.3. Does your study involve the administration of ionising radiation for any other purpose?

D20.4 Please summarise the procedures involving the administration of ionising radiation, and whether this poses additional risk to participants.

Depends on D20.3. Does your study involve the administration of ionising radiation for any other purpose?

D20.5. Has a medical physics expert verified that accurate effective doses have been calculated for this ionising radiation?

- ○ Yes
- ○ No

A medical physics expert must verify this aspect of your study before you apply to an HDEC. Localities at which ionising radiation is to be administered should be able to provide the contact details of a medical physics expert.

Participants' responsibilities

Participants' responsibilities

Depends on Full Review, Expedited Review

D21. What responsibilities do participants have specific to this study (e.g. avoiding pregnancy, certain foods or medication) and how will the investigators assist in achieving compliance with these requirements?

Participant Payments, Reimbursement, and Koha

Dependents: 1 Depends on Full Review, Expedited Review

D22. Will participants receive any payments, reimbursement of expenses, koha or any other benefits or incentives for taking part in your study?

- ☐ Yes
- ☐ No

Depends on D22. Will participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in your study?

D22.1. Please describe these, and explain why they are appropriate.

E. Risks to participants

Risks to participants

Risk of physical harm

Depends on Full Review, Expedited Review

E1. Briefly and in plain English, please describe **all** potential risks associated with participation in the study.

Do not *describe the risks of procedures that will be undertaken as part of normal clinical care regardless of participation in your study*

If your study involves use of a drug or device, the important risks associated with the drug / device should be explained.

If your study involves the use of quality of life surveys or potentially sensitive questions please include details of potential emotional, spiritual or cultural harm.

Notification to Participant's Primary Health Practitioner

Dependents: 1 Depends on Full Review, Expedited Review

E2. Will you seek consent from participants to inform health practitioners with responsibility for their health care that they are taking part in your study?

- Yes
- No

Depends on E2. Consent to Inform GP

E2.1. Please briefly explain why you will not do so.

Adverse Findings Requiring Clinical Action

Psychological Distress

Dependents: 2 Depends on Full Review, Expedited Review

E3. Does your study involve the use of any quality of life surveys or questionnaires involving mental health?

- Yes
- No

Depends on E3. Quality of Life Questoinaires

E3.1. Please describe how soon the study team will review any quality of life or mental health questionnaires completed by participants.

Depends on E3. Quality of Life Questoinaires

E3.2. Please describe the process for managing adverse findings if a participant indicates severe distress, depression, anxiety or suicidal ideation.

Details of this should be included in the Participant Information Sheet.

Abnormal Results of Clinical Significance

Depends on Full Review, Expedited Review

E4. Please describe how any abnormal findings of potential clinical significance will be managed.

Dependents: 2 Depends on Full Review, Expedited Review

E5. Will you inform the primary health care practitioner of any abnormal findings of potential clinical significance that arise during the study?

- Yes
- No

Depends on E5. Will you inform the primary health care practitioner of any abnormal findings of potential clinical significance that arise during the study?

E5.1. Please explain how the primary health care provider will be informed.

Depends on E5. Will you inform the primary health care practitioner of any abnormal findings of potential clinical significance that arise during the study?

E5.2. Please explain why the primary health care provider will not be informed of abnormal findings.

Monitoring Serious Adverse Events

Adverse Events

Dependents: 3

Depends on B1. Is your intervention study a therapeutic study? , Full Review, S3. Study category, S3. Study category, B1. Is your intervention study a therapeutic study? , Expedited Review

E6. How will safety and serious adverse events occurring in your study be monitored?

- ☐ Independent data safety monitoring committee
- ☐ Internal data safety monitoring committee
- ☐ Other data safety monitoring arrangements
- ☐ No formal data safety monitoring arrangements

Depends on E6. How will SAEs be monitored.

E6.1. Please briefly explain either:

• The safety monitoring arrangements in place for your study, and explain why they are appropriate (including reference to your study's protocol where appropriate), *or*

• Why you consider formal monitoring arrangements unnecessary.

N.B. This does not refer to routine data monitoring (e.g. source data verification).

E7. Please upload the Terms of Reference / Charter for the Data Safety Monitoring Committee, if available.

Note this is not a mandatory document to submit.

Depends on E6. How will SAEs be monitored.

E7. Please upload the Terms of Reference / Charter for the Data Safety Monitoring Committee, if available.

Note this is not a mandatory document to submit.

Upload Document

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Depends on E6. How will SAEs be monitored.

E8. Please briefly outline the criteria (if any) for terminating your study, including reference to your study's protocol where appropriate.

N.B. Terminating a study solely for commercial benefit is not acceptable in New Zealand.

Please do not include detail about the withdrawal of a single participant as this is in regards to the study as a whole.

Compensation for Injury to Participants

ACC Eligibility

Dependents: 2 Depends on S3. Study category, Full Review, S3. Study category, Expedited Review

E9. Will any participants seek or be given treatment by or at the direction of a registered health professional (as defined in the Accident Compensation Act 2001) as part of your intervention study?

- Yes
- No

Depends on E9. ACC treatment

E9.1. Will any of these participants have given written consent to participate?

- Yes
- No

Dependents: 1 Depends on E9. ACC treatment

E9.2. Does your intervention study involve trialling an investigational or approved item (e.g. medicine, device, food product, natural remedy)?

- Yes
- No

Dependents: 5 Depends on E9.2. Trial of Medicine or Item

E10. Is your study commercially sponsored research?

- YES, my study is commercially sponsored
- NO, my study is investigator initiated

Dependents: 2 Depends on E10. Commercially sponsored research

E11. Is a sponsor, manufacturer or distributor of any medicine or item being trialled receiving the study data set and/or supplying the investigational product / device?

- Yes
- No

Depends on E11. Is a manufacturer or distributor of a medicine or item being trialled receiving the study data set?

E11.1 Please explain your answer.

Depends on E10. Commercially sponsored research, E11. Is a manufacturer or distributor of a medicine or item being trialled receiving the study data set?

*Subject to an HDEC being satisfied with your answer(s) above, participants injured a result of treatment given as part of your intervention study **may** be eligible for no-fault compensation through the Accident Compensation Corporation (ACC).*

Depends on E10. Commercially sponsored research

Participants injured as a result of treatment given as part of your intervention study may not be eligible for no-fault

compensation from the Accident Compensation Corporation (ACC). Researchers and sponsors must ensure that they have arrangements in place to ensure that at least ACC-equivalent compensation would be available in case of such injury.

E12. In the event of injury to a participant in your intervention study, will compensation potentially be available for all of the following entitlements, which would be available through ACC?

- rehabilitation (comprising treatment, social rehabilitation, and vocational rehabilitation)
- first week compensation
- weekly compensation
- lump sum compensation for permanent impairment
- funeral grants, survivors' grants, weekly compensation for the spouse or partner, children and other dependants of a deceased claimant, and child care payments

☐ Yes

☐ No

Depends on E10. Commercially sponsored research

The arrangements in place for your intervention study must ensure that compensation would be available for all of these entitlements, which would be available through ACC, in the event of injury to participants as a result of treatment given as part of the study.

Sponsor Insurance

Dependents: 2 Depends on E10. Commercially sponsored research

E13. Please confirm that:

- insurance cover will be in place for the duration of the study in New Zealand, and
- participation in the trial does not affect the right of participants to pursue legal remedies in respect of any injury alleged to have been suffered as a result of participation.

☐ Yes

☐ No

Depends on E13. Please confirm that:

Insurance cover must be available and a commercially-sponsored trial cannot be approved without it.

Depends on E13. Please confirm that:

Please upload a copy of the Sponsor's insurance certificate.

The certificate should specify New Zealand as the covered territory and cite the protocol number or study title of the study.

Upload Document

Professional Indemnity

Depends on S3. Study category, Full Review, S3. Study category, Expedited Review

Please upload evidence confirming the Coordinating Investigator is professionally indemnified, for

example through membership of the Medical Protection Society (MPS).

Upload Document

F. Tissue management

Collection and Use of Tissue

Use of Human Tissue

Depends on S9. Use of Human Tissue., Full Review, S9. Use of Human Tissue., Expedited Review

F1. Please describe the types of tissue (e.g. blood, urine, tumour tissue) that will be collected / used in this study.

Depends on S9. Use of Human Tissue., Full Review, S9. Use of Human Tissue., Expedited Review

F2. Please explain in plain English the mandatory uses of tissue collected / used in this study.

Dependents: 1 Depends on S9. Use of Human Tissue., Full Review, S9. Use of Human Tissue., Expedited Review

F3. Will consent be obtained for this use?

- Yes
- No

Depends on F3. Will consent be obtained for this use?

F3.1. Please justify why consent will not be sought.

Dependents: 1 Depends on S9. Use of Human Tissue., Full Review, S9. Use of Human Tissue., Expedited Review

Will tissue be sent overseas?

- Yes
- No

Depends on Tissue overseas

Please ensure the locations (city and country) that tissue will be sent to or stored in are stated in the Participant Information Sheet.

Mandatory genetic analysis

Dependents: 1 Depends on S9. Use of Human Tissue., Expedited Review, S9. Use of Human Tissue., Full Review

F4. Does your study involve mandatory genetic analysis (including the potential for mandatory genetic biomarker analysis)?

- Yes
- No

Depends on F4. Does your study involve mandatory genetic analysis?

F4.1. Please provide a justification for mandatory genetic analysis and why this is not optional.

Management of Tissue

Waiver for use of tissue without consent

Depends on Full Review, S9. Use of Human Tissue., S10. Consent for tissue , S13. Will you be storing, preserving or using human tissue without consent?

Please provide a justification for the use of tissue without consent.

For guidance on a waiver of consent for use of tissue please click the help button.

Tissue Storage

Depends on S9. Use of Human Tissue., Full Review, S9. Use of Human Tissue., Expedited Review

F5. Please describe how tissue will be labelled and the identifiability of samples at each stage during collection, analysis and storage.

Tissue Disposal

Depends on S9. Use of Human Tissue., Full Review, S9. Use of Human Tissue., Expedited Review

F6. Is it possible for samples to be returned to participants if they request it?

- Yes
- No

Dependents: 2 Depends on S9. Use of Human Tissue., S9. Use of Human Tissue., Full Review, Expedited Review

F7. Will a karakia be available at time of tissue destruction?

- Yes
- No

Depends on F7. Will a karakia be available at time of tissue destruction?, F7. Will a karakia be available at time of tissue destruction?

Please advise participants of this in the Information Sheet and Consent Form.

Withdrawal of Tissue

Depends on S9. Use of Human Tissue., Full Review, S9. Use of Human Tissue., Expedited Review

F8. Please describe whether / how a participant may withdraw their tissue from the main study and any associated optional consented uses.

Optional uses of tissue

Dependents: 2 Depends on S9. Use of Human Tissue., Full Review, S9. Use of Human Tissue., Expedited Review

F9. Will any tissue collected / accessed during this study be used for **additional optional research?** (Only if the participant provides additional optional consent).

- ○ Yes
- ○ No

Depends on F9. Optional use of tissue

F9.1 Please explain in plain English the optional uses of tissue collected / accessed in this study.

F9.2 Please upload any optional tissue research PISCFs.

Depends on F9. Optional use of tissue

F9.2 Please upload any optional tissue research PISCFs.

Upload Document

Add Another

Tissue Management Plan

Tissue Management Plan

Dependents: 4 Depends on S9. Use of Human Tissue., Full Review, S9. Use of Human Tissue., Expedited Review

F10. Is the study's tissue management plan combined with the data management plan into a single document?

- ○ YES, the study uses a COMBINED data and tissue management plan document.
- ○ NO, the study has SEPARATE documents for the data and tissue management plans.

Depends on F10. Combined DTMP

Please upload a copy of the study's tissue management plan.

Upload Document

Depends on F10. Combined DTMP

Please upload a copy of the study's data and tissue management plan.

Upload Document

G. Data management

Data storage and governance

Data storage and governance

Depends on Full Review, Expedited Review, Data only expedited

G1. Please describe what health information will be used or generated by the study.

- Will pre-existing identified health data be accessed before the study, for example to identify potential participants?
- Will identified health data be generated by the study?
- Who will have access to this data?

Dependents: 1 Depends on Full Review, Expedited Review, Data only expedited

G2. Will data be stored or analysed in an **identifiable** form?

- ○ Yes
- ○ No

Depends on G2. Will data be stored or analysed in an identifiable form?

G3. Please include a justification on why it is appropriate to store/analyse data in an identifiable form.

Waiver of consent

Depends on Data only expedited

G4. Describe the scientific, practical and/or ethical reasons for not seeking consent to access health information.

Depends on Data only expedited

G4.1 Please describe how the nature of possible benefits of the research outweigh the possible harms of not seeking consent.

Depends on Data only expedited

Any documents to support a waiver of consent may be uploaded here.

Upload Document

Data Management Plan

G5. A data management plan that complies with Chapter 12 of the NEAC Standards is required.

Please upload a copy of the data management plan (and any associated documents).

Depends on Full Review, Expedited Review, Data only expedited, S9. Use of Human Tissue., S9. Use of Human Tissue., S9. Use of Human Tissue., Full Review, S9. Use of Human Tissue., F10. Combined DTMP, Expedited Review, S9. Use of Human Tissue., F10. Combined DTMP

G5. A data management plan that complies with Chapter 12 of the NEAC Standards is required.

Please upload a copy of the data management plan (and any associated documents).

Upload Document

Add Another

Depends on Full Review, Expedited Review

G6 Please describe whether / how a participant may withdraw their data from the study and associated uses.

H. Administrative section

Study registration

Registration of intervention studies

Dependents: 1 Depends on S3. Study category, Full Review, S3. Study category, Expedited Review

H1. *Intervention studies must be registered prior to commencement*

Has your intervention study already been registered in a clinical trials registry approved by the World Health Organisation?

- Yes
- No

Depends on H1. Has your intervention study already been registered?

H2. Name of Registry:

Registry identifier (e.g. ANZCTR number):

Applicant and sponsor details

Co-ordinating Investigator

H3. Please enter the CI's details.

Note as per Section 38 of the HDEC Standard Operating Procedure the **CI must be professionally based, in whole or in part, in New Zealand.**

For international studies a local investigator must be nominated as the CI for the New Zealand arm of the study.

Depends on Full Review, Expedited Review, Data only expedited

Title

Depends on Full Review, Expedited Review, Data only expedited

First Name

Depends on Full Review, Expedited Review, Data only expedited

Surname

Depends on Full Review, Expedited Review, Data only expedited

Organisation

Depends on Full Review, Expedited Review, Data only expedited

Department

Depends on Full Review, Expedited Review, Data only expedited

Faculty

Depends on Full Review, Expedited Review, Data only expedited

Address

Depends on Full Review, Expedited Review, Data only expedited

City

Depends on Full Review, Expedited Review, Data only expedited

Postcode

Depends on Full Review, Expedited Review, Data only expedited

Telephone

Depends on Full Review, Expedited Review, Data only expedited

Email

Depends on Full Review, Expedited Review, Data only expedited

Country

Please Select...

Depends on Full Review, Expedited Review, Data only expedited

Please upload a copy of the CI's CV

N.B. The CI must be professionally based, in whole or in part, in New Zealand.

Upload Document

Primary Contact Person

Dependents: 9 Depends on Full Review, Expedited Review, Data only expedited

H4. Is the CI the primary contact person for the study?

- Yes
- No

B.6.3.2. Please enter the details for the Primary Contact Person

Depends on H4. Is the CI the primary contact person for the study?

Title

Depends on H4. Is the CI the primary contact person for the study?

First Name

Depends on H4. Is the CI the primary contact person for the study?

Surname

Depends on H4. Is the CI the primary contact person for the study?

Organisation

Depends on H4. Is the CI the primary contact person for the study?

Address

Depends on H4. Is the CI the primary contact person for the study?

City

Depends on H4. Is the CI the primary contact person for the study?

Telephone

Depends on H4. Is the CI the primary contact person for the study?

Email

Depends on H4. Is the CI the primary contact person for the study?

Country

Please Select...

Local Sponsor

Dependents: 8 Depends on Full Review, Expedited Review, Data only expedited

H5. Does the study have a New Zealand based Sponsor? (e.g. a DHB, University, pharmaceutical company, device manufacturer, private clinical trial company etc.)

- Yes
- No

Details on the local (New Zealand based) sponsor

Depends on H5. New Zealand Sponsor

Please enter details on the New Zealand based Sponsor (or representative).

Depends on H5. New Zealand Sponsor

Title

Depends on H5. New Zealand Sponsor

First Name

Depends on H5. New Zealand Sponsor

Surname

Depends on H5. New Zealand Sponsor

Organisation

Depends on H5. New Zealand Sponsor

Address

Depends on H5. New Zealand Sponsor

Email

Global Sponsor

Dependents: 11 Depends on Full Review, Expedited Review, Data only expedited

H6. Does the study have a global sponsor?

- Yes
- No

Global Sponsor

Depends on H6. Global Sponsor

Please enter details on the global sponsor

Depends on H6. Global Sponsor

Title

Depends on H6. Global Sponsor

First Name

Depends on H6. Global Sponsor

Surname

Depends on H6. Global Sponsor

Organisation

Depends on H6. Global Sponsor

Address

Depends on H6. Global Sponsor

City

Depends on H6. Global Sponsor

Telephone

Depends on H6. Global Sponsor

Email

Depends on H6. Global Sponsor

Country

Please Select...

Add Another

Supporting Documents

Supporting Documents

Dependents: 15 Depends on Full Review, Expedited Review, Data only expedited

H7. Please tick the box for any *additional* supporting documents to upload.

***Do not** duplicate documents already uploaded to questions on the main form.*

If you are responding to a Provisional Approval please ensure both clean and tracked changes copies of documents are provided.

- ☐ Advertisements
- ☐ AI Impact and Risk Assessment
- ☐ Assent form
- ☐ Best interest form / statement
- ☐ Covering letter
- ☐ Evidence of Consultation
- ☐ Evidence of Sponsor Insurance
- ☐ Investigator Brochure
- ☐ Non-Review Document (e.g. site-specific ID cards, translated documents)
- ☐ Other
- ☐ PIS/CF
- ☐ Protocol
- ☐ Scientific Peer Review
- ☐ Survey/questionnaire

If you do not have additional documents please proceed to the next page.

Upload additional advertisements

Depends on H7. Supporting documents to be uploaded

Upload additional advertisements

Upload Document

Add Another

Upload additional AI Impact and Risk Assessment documents

Depends on H7. Supporting documents to be uploaded

Upload additional AI Impact and Risk Assessment documents

Upload Document

Add Another

Upload additional Assent Forms

Depends on H7. Supporting documents to be uploaded

Upload additional Assent Forms

Upload Document

Add Another

Upload additional 'best interest' form or relevant documents

Depends on H7. Supporting documents to be uploaded

Upload additional 'best interest' form or relevant documents

Upload Document

Add Another

Upload a cover letter

A cover letter that only details the list of supporting documents does not need to be uploaded.

Depends on H7. Supporting documents to be uploaded

Upload a cover letter

A cover letter that only details the list of supporting documents does not need to be uploaded.

Upload Document

Add Another

Upload additional evidence of relevant consultation documents

Depends on H7. Supporting documents to be uploaded

Upload additional evidence of relevant consultation documents

Upload Document

Add Another

Upload additional documents related to Sponsor insurance

Depends on H7. Supporting documents to be uploaded

Upload additional documents related to Sponsor insurance

Upload Document

Add Another

Upload evidence of GMP

Depends on H7. Supporting documents to be uploaded

Upload evidence of GMP

Upload Document

Add Another

Upload Investigator's Brochure

Depends on H7. Supporting documents to be uploaded

Upload Investigator's Brochure

Upload Document

Add Another

Upload other documents out of scope for HDEC review (e.g. locality / site specific study documents).

Note these will not be reviewed but will be included in the list of supporting documents.

Depends on H7. Supporting documents to be uploaded

Upload other documents out of scope for HDEC review (e.g. locality / site specific study documents).

Note these will **not** be reviewed but will be included in the list of supporting documents.

Upload Document

Add Another

Upload any other relevant documents that do not fall into a standard category

Depends on H7. Supporting documents to be uploaded

Upload any other relevant documents that do not fall into a standard category

Upload Document

Add Another

Upload additional Participant Information Sheets and Consent Forms

Note localised PISCFs with site-specific details do not need to be submitted; only the main template requires review.

Depends on H7. Supporting documents to be uploaded

Upload additional Participant Information Sheets and Consent Forms

Note localised PISCFs with site-specific details do not need to be submitted; only the main template requires review.

Upload Document

Add Another

Upload additional documents related to the protocol

Depends on H7. Supporting documents to be uploaded

Upload additional documents related to the protocol

Upload Document

Add Another

Upload additional documents related to Scientific Peer Review

Depends on H7. Supporting documents to be uploaded

Upload additional documents related to Scientific Peer Review

Upload Document

Add Another

Upload additional surveys / questionnaires

Depends on H7. Supporting documents to be uploaded

Upload additional surveys / questionnaires

Upload Document

Add Another

I. Declarations

Declarations and Authorisation

CI Declaration

Depends on Full Review, Expedited Review, Data only expedited

Coordinating Investigator

Request Sign

Sponsor's declaration

Authorising Sponsor Representative

Depends on H5. New Zealand Sponsor, H6. Global Sponsor

Authorising Sponsor Representative

Request

Add Another

Locality declaration

Authorising Locality

Depends on B14.3. Study localities

Authorising Locality

Request

Add Another

Primary Contact Person declaration

Depends on Full Review, Expedited Review, Data only expedited

Declaration from person completing form:

I agree that:

- All version numbers and dates of supporting documents are correct. I understand that HDEC cannot amend approval letters to replace incorrect versions/dates.
- The Coordinating Investigator has reviewed and signed off the protocol.
- The information on the application and all associated documents is correct
- I have read and accepted the EthicsRM Terms and Conditions.

Request Sign