Screening form guide for first-time applicants

The HDEC uses a screening form as the introduction to the application form in Ethics RM. By using this, answering these questions accurately provides automatic feedback on whether a study requires HDEC review or not. This guide gives further context to the HDEC screening form with explanations for what the questions are asking to aid new researchers in the HDEC process. This guide only covers the screening portion, and not the rest of the form if a study is within scope for HDEC, nor is a complete substitute for other materials available.

S1. Is your study health or disability research?

HDECs only review health and disability research. This is defined in the HDEC Standard Operating Procedure as "research that aims to generate knowledge for the purpose of improving health and independence outcomes".

The first question is for researchers to self-declare whether their study is health or disability research.

The HDEC Secretariat acknowledges it can sometimes be difficult to apply the above definition to studies involving wellbeing, exercise, nutrition and other crossovers with health research. Further guidance on what constitutes health research can be found in the National Ethical Standards. Researchers unsure whether their study would be considered health or disability research are advised to email HDECS@health.govt.nz for guidance.

Answering 'no' to S1 will end the form with an out-of-scope option.

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

The above definition of health and disability research does not include research that creates or uses a human gamete, human embryo or hybrid embryo. The Human Assisted Reproductive Technology Act 2004 requires that such 'human reproductive research' be approved by the Ethics Committee on Assisted Reproductive Technology.

Answering 'yes' to S2 will end the form with an out-of-scope option.

S3. Which category best describes your study?

This question is to determine whether the study is an intervention study, an observational study or an audit or quality improvement activity.

The National Ethical Standards define an intervention study as a study in which an investigator controls and studies an intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of that intervention(s). The term 'intervention study' is often used

interchangeably with 'experimental study'. Many intervention studies are clinical trials. **Intervention studies are always in scope (with one exception noted in Exclusion later in the form).**

Observational studies are in scope if they are **above minimal risk** (i.e., the participant is exposed to more risk than they would reasonably encounter as part of their participation of the study than if they were not a participant)**.** This is research in which (in contrast to intervention or experimental studies) no intervention other than the recording, classifying, counting and analysing of data takes place. In observational studies the investigator has no control over study variables and merely observes outcomes.

Audits/quality improvements are undertaken primarily for the purpose of evaluating current or slightly new practices, and the primary aim is to inform current care in a localised scope, rather than generate generalisable information. Some Observational research may be misattributed to being an audit/quality improvement activity. Audits and quality improvement activities are in scope if they involve the use of **tissue samples without consent. Otherwise, Audits and quality improvement activities are always out of scope.**

Researchers unsure whether their study involving existing data would be considered a retrospective observational study or an audit/quality improvement activity are advised to email HDECS@health.govt.nz.

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)?

This question determines whether the audit / quality improvement activity selected in S3 involves the use of human tissue without consent.

Answering 'yes' will bring your audit / quality improvement activity in scope for HDEC review.

Answering 'no' will end the form with an out-of-scope option.

S4. Does your study involve the active participation of any human participants?

This question determines whether the study involves human participants or pre-existing data only.

- Consumers of health or disability support services
- Relatives or caregivers of consumers of health or disability support services
- Volunteers in clinical trials
- No active human participants

The three categories of participants are from the HDEC Standard Operating Procedure. The specific participant category selected does not matter and return the same option. Researchers intending to recruit participants who are not technically consumers of health services are advised to select volunteers in clinical trials.

Selecting one of the first three categories will unlock the standard HDEC application form if the study is in scope.

Selecting 'no active human participants' will unlock the abbreviated HDEC form for applying for a waiver of consent for secondary re-use of data. This is the correct option for if your study involves a retrospective review of data and/or tissue only.

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

This question determines vulnerability of participants and contributes to whether the study is allocated to the full or expedited review pathway.

- One or more human participants who will not have given informed consent to participate
- One or more human participants who have a restricted ability to make independent decisions about their participation (e.g. children)
- None of the above

Selecting one of the first two options will allocate the study for the **full review pathway.**

Selecting 'none of the above' will allocate the study to the **expedited pathway**, if the study is in scope and does not contain any other high-risk features in question S15.

Please note that if you selected 'no active human participants', the question will not generate as it's not relevant. If a study involves no active human participants and that was not selected in S4, this question will generate. It is a common error among new applicants to select "One ore more human participants who will not have given informed consent to participate" thinking it relates to use of data without consent to seek a waiver. This question relates to active participants so that option should only be selected if participants truly are not consenting, such as unconscious patients in an ICU.

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

This question determines the identifiability of information about participants that will be accessed, collected or used during the study. Identifiable health data includes name, date of birth, NHI number and other identifiers that can identify an individual.

If at any stage of the study a participant's name, NHI, date of birth of other identifiers will be known to the researchers please select **'yes'**. This will likely bring the study **in scope** for HDEC review.

If study participants are fully anonymised (e.g. completing an anonymous online survey) or you are receiving a dataset with no identifiers please answer **'no'**. This will contribute to an **out-of-scope** option.

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

This question asks whether consent for the use of pre-existing information has already been obtained (e.g. consent to write a case study). Consent under hospital admission forms do not count as informed consent for the purposes of answering 'yes' to this question.

If consent to access this information has **already been obtained** answering **'yes'** will contribute to an **out-of-scope** option.

If consent has not been **already obtained** and consent will be sought for the purpose of this study or a waiver of consent will be requested, please answer '**no'.**

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

This question determines the risk of data disclosure for studies involving data only. If your study involves active human participants please select '**no'** as active participation at minimum will involve collection or knowledge of full names of participants.

Answering 'yes, all information will be received by researchers previously deidentified' will contribute to an **out-of-scope** option.

Answering 'no, identifiers will be attached and the data will be deidentified by the research team' will bring an application **in scope.**

It is worth noting that researchers who already have access to identifiable information (i.e., working at a hospital with access to clinical records) that are collecting it themselves and then de-identifying it should answer 'no'.

S9. Will your study use human tissue?

Human tissue is defined as material collected from a living individual or body under the Human Tissue Act. You should refer to this if you are unsure, however tissue broadly can be things like swab samples, sputum, blood, etc.

Answering '**yes'** will unlock further questions regarding tissue use and access and may bring a study **in scope** depending on other answers in the form.

Answering **'no'** may bring a study in or out of scope depending on other answers in the form.

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

This question asks whether consent for the use of pre-existing tissue has already been obtained (e.g. previous donation to a tissue bank where donators were informed that their tissue would be used for future research.

Answering **'yes'** may bring your study **out of scope** depending on other answers in the form.

Answering **'no'** will unlock further questions regarding identifiability of tissue.

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

Any identifiers attached to the sample will mean the tissue is identifiable. This can be just a date of birth, or surname. Direct and Indirect identifiers are explained in the National Ethical Standards and further up in the screening form under Health Information.

Answering **'yes'** may bring your study out of scope depending on other answers in the form.

Answering **'no'** will unlock further questions regarding exemptions around use.

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):*

The exemptions for ethical review are outlined in 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. There are limited circumstances in which this exemption applies. If you are unsure whether your project meets the definition of this exemption, email HDECS@health.govt.nz for guidance

Answering '**yes'** may bring your study out of scope depending on other answers in the form.

Answering **'no'** will unlock further questions regarding use.

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

Answering **'yes'** will bring the study into scope.

Answering **'no'** will unlock further questions regarding future use.

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

Future unspecified research (FUR) on tissue is considered a high-risk feature of a study. These are also important to answer correctly as they generate options in the wider application that need to be answered.

Answering **'yes'** will bring your study in scope for the Full review pathway.

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

- 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

These are all High-Risk features of research. Selecting anything other than None of the above will pull a study into scope for the Full Review pathway.

It is important to clarify that 'change to standard treatment/care' can sometimes be clicked for incorrect reasons. This only relates to when a patient's standard of care is being withheld or changed to what the study is wishing to explore and is experimental. If this is something the participant is not usually receiving at all but is an addition being introduced, there is no change to standard of care.

Exemptions
These questions relate to exemptions to the HDEC scope as outlined in their Standard Operating Procedures. These are exceptions to our scope and will bring something in scope to be out of scope for HDEC review.

S16. Does your study primarily involve evaluating a device the TGA would classify as Class I?

Answering **'yes'** will bring this study out of scope, unless there are other risk factors selected.

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

Observational research conducted at a Masters level or below (including Honours projects) are out of scope for HDEC and can be reviewed by the student's institutional ethics committee.

Answering **'yes'** will bring the study out of scope provided it is an Observational study.

Inclusions
These questions relate to inclusion criteria that create exceptions to studies that would otherwise be out of scope and will bring your study in scope for HDEC review.

S18. 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)?

This applies only when your study is both HRC funded and you are unable to access an HRC approved ethics committee. It is worth checking the list here before answering.

Answering **'yes'** will bring the study into scope regardless of any answers that may have determined your study as out of scope.

S19. 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')?

Answering **'yes'** will bring the study into scope regardless of any answers that may have determined your study as out of scope.