

# General HDECs FAQ

This FAQ is not a substitute for information provided in the [Standard Operating Procedures for Health and Disability Ethics Committees](#) or the [National Ethical Standards](#), but can be helpful for expanding on or clarifying points.

## I am unsure if my study needs HDEC review. How can I check?

- If you have looked at Chapter 3 of our [Standard Operating Procedures for Health and Disability Ethics Committees](#) and are still unsure, you can create an application in [ETHICS RM](#) and answer the screening questions for immediate feedback.
- Alternatively, you can email the following information to the HDECs Secretariat ([hdec@health.govt.nz](mailto:hdec@health.govt.nz)):
  - Description of how participants are recruited, or if there are no active participants, in what form will data be made available to researchers (identifiable, de-identified, etc.)
  - Whether it is an Intervention or Observational study.
  - Anything else you are uncertain of from the Standard Operating Procedures.

## What makes a project an audit/quality improvement, and are they always out of scope?

- 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.
- As per paragraph 30 of the Standard Operating Procedures, audits/quality improvement related activities are out of scope, except for cases of audits that involve use, collection, or storage of 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).
- The [National Ethical Standards](#) describes this in more detail.

## Is my study health and disability research?

- The definition is broad, but studies that aim to generate knowledge for the purpose of improving health and health/disability independence outcomes are always considered health and disability research.
- As per the [National Ethical Standards](#), health and disability research should broadly:
  - 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.
- The standards further outline what should not be considered health and disability research. If you are still unsure, you can contact the HDECs Secretariat for advice ([hdecs@health.govt.nz](mailto:hdecs@health.govt.nz))

## I am doing a study that does not involve participants, just their information. Do I still need HDEC review?

- Your study may require HDEC review if it involves the use of identifiable information without consent for the purpose of research, or has other factors that increase risks (i.e. privacy). Our scope is outlined in Chapter 3 of our [Standard Operating Procedures for Health and Disability Ethics Committees](#).

## I am out of scope of HDEC review, where can I get an alternative ethics review?

- If you are part of an institution like a University or District Health Board, you should seek ethics review from an internal committee at your institution.
- Alternatively, there are committees not administered by the Health Research Council (HRC) that offer ethical approval, but you may wish to seek out clarification with your intended publication whether they are acceptable.

## My Institutional Ethics Committee requires proof that HDEC review is not required for my project. How can I get this?

- Finishing the screening questions in the application form in [ETHICS RM](#) will return an automated email outlining that your project is out of scope for HDEC review if questions are answered correctly.

## When conducting research in New Zealand, should researchers from abroad be required to obtain ethics approval in New Zealand?

- Any research conducted in New Zealand (i.e., at least one site located in New Zealand) requires ethics approval from a New Zealand committee.
- If your study is in scope for HDEC review, a locally based Co-ordinating Investigator (CI) must be nominated and listed in the HDEC application.

## Can there be more than one Co-ordinating Investigator (CI) (for example, Co-CIs) on a single trial for a New Zealand site?

- While there can be, the HDECs require only one to be listed and the application form can only accept one.
- If your study has more than one CI, it is the responsibility of the study team to select who is the CI for the purpose of the HDEC application and has the oversight required to maintain ethics approval.

## What is required as part of Independent Scientific Peer Review?

- Please see the [guidance on our website](#) for what constitutes Independent Scientific Peer Review.

- Independent Scientific Peer Review is required for any study reviewed by HDECs.

## When is evidence of professional indemnity held by the Co-ordinating Investigator required?

- Evidence of professional indemnity is only required in studies that are commercially sponsored. Please see the [Standard Operating Procedures for Health and Disability Ethics Committees, paragraph 39.4.7.](#)

## Can I request to be reviewed by a specific HDEC?

- There are various reasons why you can request a specific HDEC. These reasons commonly include (but are not limited to):
  - Your submission was previously Declined by an HDEC and they are familiar with your study.
  - You have had similar studies approved by an HDEC and they are familiar with your studies.
  - There is a known conflict of interest between you and a member in a particular HDEC, so you may request a different one to avoid this.
- There is an option in the application form to do this and provide justification. It is important to note that if the HDECs Secretariat are unable to accommodate your request to be reviewed by a specific HDEC, they will contact you with details of this either via email or the 'Correspondence' tab on ETHICS RM.

## I am only available during a certain time to attend my application's review. How can I request a specific time? Can I change my application time?

- If ahead of your application submission you know what times that you are available for, please provide detail of this in a cover letter for your application, or email the HDECs Secretariat ([hdec@health.govt.nz](mailto:hdec@health.govt.nz)). Please note that if multiple applicants request the same/similar time slots, it may not be possible to honour all requests.
- You may request a different time after you have received your validation letter outlining your time slot, but it may not be possible to arrange an alternative time for you.
- Please check the [start time](#) of meetings before you request a timeslot to ensure your request is workable. The first 30 minutes of any meeting is reserved for HDEC business.

## When is my submission being reviewed?

- If your submission is a Full application, this will be reviewed at the next available full HDEC meeting. A schedule of when these take place can be found on [our website](#). The clock for Full applications is 35 days and are validated on the agenda closing date it was submitted by.
- If you have a full application and selected a specific HDEC, it will be reviewed at the next available meeting for that Committee.
- If your submission is an Expedited application or a post-approval form (Amendment, Progress Report, etc.) then unless otherwise told, your application is reviewed online by a Subcommittee and not at a full meeting. The clock for these submissions is 15 days.

## What can I expect following submission of my full application?

- Applications submitted by 12pm of the agenda closing date will be validated (if valid) and assigned to the next available meeting. You will receive a valid letter confirming the date and time of your review within a few working days of this.
- During your allocated timeslot, the Committee will ask questions and raise ethical issues. Some matters may be resolved during the meeting, and some may require document amendments that will need to be sent back to the Committee. You will be advised of your decision via a letter on ETHICS RM.

## Do I need to prepare/bring anything to the (full review) HDEC meeting?

- No prior preparation is required; however, it can be helpful for researchers to have their study documents and application form on hand (electronically or printed) as the Committee may refer to pages directly with their questions.

## No one in the research team was present for the review of our application. How will I hear about the discussion?

- It is preferable for researchers to attend so that issues raised could be resolved within the meeting. Regardless of attendance, researchers are provided with a decision letter following the review of their full application.

## When can I expect to receive my letter from the full meeting?

- The minutes following the meeting can take up to 2 weeks or more for the HDECs Secretariat to complete. Letters are sent following the completion of the minutes by the HDECs Secretariat.
- If a letter is taking longer than usual/more than 2 weeks after the meeting, please contact the HDECs Secretariat ([hdecs@health.govt.nz](mailto:hdecs@health.govt.nz)) to check if there are any expected delays or for expected timeframes. We will endeavour to provide updates in advance.

## When can I start my study?

- You can start your study once you have received an Approval letter for your application and you have completed all Standard and any Non-standard conditions (if any) listed in the letter.

## What can be submitted with annual reports?

- Some studies are only required to fill in the annual progress report form and submit.
- You can submit any non-substantial updated documents for filing for your progress report.
- If your study involves a new medicine, you will need to submit a safety report.
- For more information see the [Standard Operating Procedures for Health and Disability Ethics Committees, paragraphs 198 – 205](#). Please note that the annual reports should not be used to submit substantial amendments and will require separate submission.

## Will I get a reminder when my progress report is due?

- At this stage we are unable to do this in Ethics RM but will hopefully have this feature in the future.
- Please ensure you are aware of your reporting period, which is outlined in your application approval letter and any subsequent progress report submissions. Your annual report date is determined by the date of your application approval letter.

## I have submitted my application/post-approval form but a document is missing, can you add it to my project for me?

- Unless the Committee has asked for something to be added or this addition has been discussed with the HDECs Secretariat, we cannot add anything new once the application has been validated. This includes sending documents via the 'Correspondence' tab in ETHICS RM.

## How do I respond to Provisional Approval?

- If your submission was submitted prior to 01 September 2021 in Online Forms, you will need to email the HDECs Secretariat ([hdecs@health.govt.nz](mailto:hdecs@health.govt.nz)) with all tracked changes and clean documents requested in your Provisional Approval letter.
- If your submission was submitted after 01 September 2021, as per your Provisional Approval letter, the form is now unlocked and documents (tracked and clean versions) can be uploaded, along with any changes to the application form (if any were requested). The original documents **must not** be removed from the form, and the new documents should be uploaded under '**H7**' of the form at the end.

## I will not make the 90-day deadline for responding to Provisional Approval. Can I have an extension?

- Please email the HDECs Secretariat ([hdecs@health.govt.nz](mailto:hdecs@health.govt.nz)) as soon as you are aware that you are unable to meet the deadline.

## I was referred to an HDEC template in the list of changes I need to make. Is it mandatory to use HDEC templates?

- [HDEC templates](#) are not mandatory; however, they were created in consultation with the HDEC members to ensure that they cover all items required under the National Ethical Standards.
- Templates are often recommended to researchers as guidance to meet all National Ethical Standards and can be used as guides or adapted for each study's needs.

## I went to submit something on Online Forms, but it says that this is no longer in use.

- The HDECs replaced Online Forms with [ETHICS RM](#) on 01 September 2021.
- If this is your first time logging in on ETHICS RM, your login details from Online Forms remain unchanged for ETHICS RM.

I have read the Standard Operating Procedures and am still unsure if my updated documents require submission as an amendment.

- If you have read the [Standard Operating Procedures for Health and Disability Ethics Committees, paragraphs 185 – 189](#) and are still unsure, you can email the HDECs Secretariat ([hdec@health.govt.nz](mailto:hdec@health.govt.nz)).
- A general rule is that anything that affects participants or potential participants to some degree is considered substantial, such as recruitment material, changes to the information sheet that are not administrative, changes to the study design or study procedures, etc.

Can I use documents I have submitted as an amendment while waiting for HDEC approval?

- Until you have received an Approval letter, anything submitted as an amendment (i.e., recruitment material) cannot be used until then.

What is a locality? What can I expect from locality review?

- Chapter 10 of the [Standard Operating Procedures for Health and Disability Ethics Committees](#) outlines this in detail.
- District Health boards, academic institutions (such as universities), private companies (such as clinical trial units), private hospitals or clinical practices, or other health and disability research centres are all considered a locality. What a locality checks is outlined under paragraph 173 of the Standard Operating Procedures.

My study was created prior to the release of the National Ethical Standards (2019). Do I need to ensure that my study complies with the new Standards?

- Yes, all studies that maintain ongoing HDEC approval must be in line with the current [National Ethical Standards](#).
- Some studies may be asked, when they submit post-approval items, to ensure that their study is updated to incorporate the current National Ethical Standards.

Where can I follow the progress of a submission that I have made to HDECs?

- You can follow the progress of your submission by looking at the 'History' tab in ETHICS RM.