Conducting a clinical trial or research study in New Zealand

A rough guide through ethics (ethics approval), locality authorisation (site approval) and regulatory approval

The main requirements for commencement of a clinical trial are:

1. **Ethics approval** including approval of the study protocol and written participant information sheet & consent form (for studies involving participants).

2. **Locality authorisation** from your institution (e.g. hospital or university where the research will be conducted).

3. For trials involving a new medicine **regulatory approval** in NZ is required from MedSafe, The Ministry of Health.

The process for obtaining these approvals can be commenced in parallel, however it should be noted that locality authorisation is generally only granted once HDEC approval is in place.

Ethical review

What is ethics?

All health and disability research must comply with established ethical standards. The New Zealand guidelines for ethical standards are established by the National Ethics Advisory Committee (NEAC): 2012. *Ethical Guidelines for Intervention Studies: Revised edition*, and 2012. *Ethical Guidelines for Observational Studies: Observational research, audits and related activities*.

These standards apply to all health and disability research, regardless of whether Health and Disability Ethics Committees (**HDEC**) review is required for that research.

http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research.

Will my research require ethics review?

In general health and disability research involving human participants, human tissue or the use of health information requires HDEC review.

Some types of low risk research are exempt from the need to undertake HDEC review including studies involving: low risk (class I) medical devices, some types of audit or audit-like research, observational studies that do not involve more than minimal risk and the use of existing anonymised human tissue samples with consent. Regardless of whether HDEC approval is required, researchers in such studies will still be required by the Code of Health and Disability Services Consumers' Rights 1996 to comply with the established ethical standards that apply to them.

In order to determine whether or not your research requires HDEC review:

I. Refer to the section 3 of the Standard Operating Procedures for Health and Disability Ethics Committees, version 2.0 (August 2014). http://ethics.health.govt.nz/operating-procedures.

II. Work through the 'Does your study require HDEC review?' flowchart: http://ethics.health.govt.nz/applying-review

III. Work through the first 10 questions on the HDEC online form as these screen applications to see if HDEC review is necessary. However, please note this is only a guide. To be certain that your research does not require HDEC review, HDEC recommends submitting a full application.

IV. If you are still unsure whether your research requires HDEC review please contact HDEC for further advice.

Health and Disability Ethics Committees (HDEC) website: http://ethics.health.govt.nz/

Research outside the scope of HDEC review may still require ethical review and approval. Contact the research office or coordinator at your institution to determine if this will apply to your study. A list of institutional ethics committees can be found on the HDEC website: http://ethics.health.govt.nz/system/files/documents/pages/iec-contacts-30jul2013.doc

How do I apply for ethics approval from an HDEC?

All applications to HDECs are submitted through the Online Forms website: https://nz.ethicsform.org. This site allows you to answer questions in the HDEC application form, upload documents, request electronic signatures from other parties involved in your research, and track the progress of your application. This website is also used to submit any amendments or reports to the HDEC post-approval.

Further guidance can be found on the HDEC website:
http://ethics.health.govt.nz/applying-review/how-do-i-apply

The HDEC review process can approve studies that will be carried out at a single locality ("trial site") or at multiple localities across New Zealand. There is no need to submit a separate HDEC submission for each trial site individually; however, each site where the study will be conducted will require locality approval.

Where a study will involve multiple sites a Coordinating Investigator (CI) needs to be nominated. The CI will hold overall responsibility for the conduct of the study and must be professionally based either wholly or partly in New Zealand. An international study will need to have a local CI for the New Zealand part of the study.

Online forms website:
Each Online Forms user including the CI and site Principal Investigators must have an account to submit or authorise an application. https://nz.ethicsform.org/

Technical support for the application form is available from our IT help desk:
Tel: 0800 634 758 or +64 4 9747675 (available from 12pm to 6pm NZT Mon to Fri)
E-mail: helpdesk@infonetica.net

Locality Authorisation

What is locality authorisation?

Locality review is the process by which a locality assesses its suitability for the safe and effective conduct of a study. If a locality is satisfied that this is the case, it *authorises* the study. It is a standard condition of HDEC approval that locality authorisation, which focusses on these locality-specific research governance issues, be obtained before a study commences at that locality.

The term locality authorisation/approval is equivalent to the Australian governance approval process.

A locality is an organisation responsible for a hospital, health centre, surgery or other establishment or facility in New Zealand at or from which the procedures outlined in the protocol of a study are to be conducted. Examples of a locality include a District Health Board/hospital, an academic institution (such as a university), private hospitals or private clinical trial units.

Locality authorisation must be obtained from each locality and can be done after HDEC submission, but must be done before commencement of the study at that locality.

Confirmation of locality authorisation is completed electronically in the Online Forms system. The study may commence immediately at a locality once HDEC approval and locality authorisation have been granted, there is no need for the outcome of each locality review to be further reviewed or approved by the HDEC.

How do I apply for locality authorisation?

Each institution/organisation has its own process for the submission and review of locality authorisation. This review will usually encompass review of the resource implications, funding and indemnity arrangements, legal arrangements such as establishment of a contract with the trial organiser, if applicable.

A list of District Health Board research office contacts is located on the HDEC website:
http://ethics.health.govt.nz/system/files/documents/pages/dhb_research_contacts_list.doc

If the location you intend to conduct the study at is not a District Health Board contact your research office to determine the requirements for obtaining locality authorisation.

Regulatory Approval

Does my study require regulatory approval?

Approval is required before a clinical trial using a **new medicine** may commence in New Zealand. The approval process for clinical trials is administered by Medsafe, applications are reviewed by the Standing Committee on Therapeutic Trials (SCOTT) or the Gene Technology Advisory Committee (GTAC).

The term '**new medicine**' applies to medicines for which Ministerial consent for distribution in New Zealand has not been granted (unapproved medicines). These 'unapproved medicines' include new chemical or biological entities and new dosage forms and strengths of approved medicines.

Approval is not required for a clinical trial that uses only approved medicines even if the trial is investigating a new indication. However, the medicine used in the trial must be the actual medicine for which consent for distribution in New Zealand has been granted.

The term new medicine excludes the following:

- placebos
- repackaged approved medicines for use in a clinical trial
- medical devices; trials of medical devices do not require regulatory approval under New Zealand legislation

Guideline on the Regulation of Therapeutic Products in New Zealand. Part 11: regulatory approval and good clinical practice requirements
http://www.medsafe.govt.nz/medicines/clinical-trials.asp

How do I apply for regulatory approval?

An application may be made by completing an online application or a paper-based application.

An online application is made using the Online Forms available at https://www.ethicsform.org/nz/SignIn.aspx
The applicant must complete the form, attach the supporting documentation and covering letter, and submit the application electronically. No paper copies should be sent to Medsafe.

To make a paper-based application, the applicant must complete and sign an Application for approval of a clinical trial under Section 30 of the Medicines Act 1981 form http://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/ScheduleAForm11.1.doc and submit this to MedSafe and either SCOTT or GTA, if applicable, as detailed in the Guideline on the Regulation of Therapeutic Products in New Zealand - Part 11.

Ongoing obligations

The following is an outline of some of the main obligations of the coordinating and principal investigator throughout the duration of a clinical trial.

Ethics

After HDEC approval is granted it is the responsibility of the coordinating investigator to submit updates and amendments to the HDEC. This may include:

- progress reports, at least annually;
- amendments to the approved study documentation, such as the participant information sheet or protocol;
- study termination.

Safety reporting: NZ HDECs do not require the submission of individual serious adverse event reports. Intervention studies involving a new medicine (as defined by Section 30 of the Medicines Act 1981) are required to submit an annual summary of safety information.

Locality

The requirements for ongoing reporting and submission of amendments to the **locality** by the site principal investigator differ. Refer to your research office for guidance.

Regulatory Approval

After regulatory approval is granted it is the responsibility of the sponsor to submit the following to MedSafe:

- progress reports six monthly;
- withdrawal from development/the market of the investigational drug in any country;
- termination of an overseas study using the investigational drug;
- safety information: all fatal or life-threatening suspected unexpected serious adverse reactions (SUSARs) occurring in New Zealand trial participants where the treatment is known;
- study termination.