Locality Authorisation Guide for ADHB

Please read this section carefully as there have been important changes to this process since 2012.

The term "Locality Authorisation" that is used here refers specifically to the process used by the NZ Health and Disability Ethics Committees (HDECs) for ascertaining that all local governance issues have been addressed at sites participating in a research project. If ADHB is a site for your research project (i.e. one or more of the procedures described in the study protocol will be conducted at ADHB) and your project requires approval from an HDEC, then you will need to request a Locality Authorisation from ADHB via the HDEC online application system Online Forms. For a complete guide to this process use the link to access the User Manual. However, briefly, when you have created a "new project" in the system there will be an associated set of tabs. One of these is "Authorisations". Click on this to view a table of categories of authorisers. Select "Locality" by clicking on "Request". You'll then be asked for an email address. You should use researchoffice@adhb.govt.nz and no other.

Locality Authorisation is distinct from the ADHB research approval process, which is required for all ADHB research regardless of whether there is an HDEC application. However, when the research does require a Locality Authorisation from ADHB this will be the final step in the ADHB process and will only be executed once the research is otherwise fully approved at ADHB. Full approval requires evidence of ethical approval, so don't expect ADHB to action the Locality Authorisation request until the HDEC has fully approved your study. It is your responsibility to ensure the Research Office is informed that this has happened by providing an HDEC approval letter. Normally the Locality Authorisation request will be approved on the same day you receive your ADHB research approval letter. This will be done automatically by the ADHB Research Office staff.

Below is the extract from the "Standard Operating Procedures for Health and Disability Ethics Committees" Section 10, page 37 which describes the HDEC Locality Authorisation purpose and rules. An important change to note from the previous (pre-2012) Operating Procedures is that it is now the responsibility of localities to ensure that appropriate consultation with Māori has been undertaken, whereas previously this was the responsibility of the HDECs. For a complete guide to the current, full HDEC process use the below link: http://ethics.health.govt.nz/system/files/documents/pages/SOPs%20for%20HDECs%20%28v1.0%29.docx

10. Locality authorisation

Introduction

The Government's response to the Health Committee's clinical trials report requires updated SOPs for HDECs to clarify that localities (such as district health boards (DHBs)), rather than HDECs, are responsible for checking local governance issues that may arise from the conduct of a study at a given locality. This section addresses that requirement. It replaces the current 'locality assessment' process described at section 7 of the *Operational Standard for Ethics Committees*.

Key changes and clarifications include:

- defining ‘locality’ more narrowly, to include only a subset of the organisations involved in the conduct of studies
- making the DHB the natural unit for locality review within the public health system
- allowing one locality review to cover multiple sites (for example hospitals or departments) within a single locality
- clarifying and expanding the issues relevant to locality review; for example, to include issues relevant to a locality’s ability to meet its potential liabilities in intervention studies for which compensation is not available under the ACC Act.

Key changes to this section following consultation include:

- expanding the definition of ‘locality’ to include organisations involved in the conduct of observational studies (while recognising that not all such studies will involve localities)
- clarifying that the study team as a whole (rather than the study sponsor) is responsible for ensuring that locality review is conducted by the appropriate individuals at a locality
- more clearly requiring that a locality’s chief executive officer authorise the person completing a locality review
- requiring locality review to be conducted afresh as soon as possible, rather than immediately following a change of the lead/principal investigator at a particular locality.

HDEC approval and locality authorisation are separate processes

1. HDEC review is the process by which an HDEC checks that a study meets or exceeds established ethical standards. If an HDEC is satisfied that this is the case, it *approves* the study.
2. 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.

What is a locality?

3. For the purposes of these SOPs, 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.
4. Almost all intervention studies and many observational studies will involve at least one locality.
5. Localities for studies within the New Zealand public health system will usually be DHBs. Examples of localities outside the public health system may include:

5.1. academic institutions (such as universities)

5.2. private companies (such as clinical trial units)

5.3. private hospitals or clinical practices

5.4. other health and disability research centres.

6. The following are not localities:

6.1. clinicians, clinical units or other organisations making referrals to a research team

6.2. clinicians, clinical units or other organisations involved only in identifying potential participants or facilitating recruitment by the research team, and not responsible for informed consent or any other procedures set out in the study protocol

6.3. research units undertaking support functions such as project management, site monitoring, data analysis or report writing.

7. Where a study will be conducted at more than one site within the same locality (for example, at multiple hospitals within the same DHB), locality review should be carried out just once to cover all sites within that locality.

8. Where a third party under contract to a locality is to undertake any procedures outlined in the protocol of a study, issues specific to the third party should be considered as part of the locality review.

Who should complete locality review?

9. Locality review must be completed by either:

9.1. the locality's chief executive officer, or

9.2. an individual to whom the chief executive officer has delegated responsibility for conducting locality review.

10. It is not the role of the HDEC to ensure that the person who carries out locality review has been appropriately authorised to do so. This is the responsibility of the study team of the study in question.

Issues relevant to locality review

11. The central issue relevant to locality review is its suitability for the safe and effective conduct of the study in question. This involves checking that:

11.1. the lead/principal investigator(s) at the locality is/are suitably qualified, experienced, registered and indemnified to take professional responsibility (under the direction of the CI) for the conduct of the study at the locality

11.2. the locality's physical facilities are adequate for the conduct of the study

11.3. conducting the study at the locality would have no adverse effect on the provision of publicly funded health care at that locality

11.4. applicants have taken reasonable steps (particularly consultation with Māori, where appropriate) to ensure that they have identified and adequately addressed local cultural issues that may arise from the study

11.5. appropriate arrangements are in place for notifying other relevant local health or social care staff about the study, and for making available any extra support that might be required by participants

11.6. appropriate arrangements are in place for providing information to potential participants in the study who may not adequately understand information in English

11.7. applicants have included relevant locality-specific information and contact details in the local version of the participant information sheet and consent form

11.8. where participants injured as a result of treatment received as part of the study will not have access to ACC (see section 8):

11.8.1. members of the local research team hold appropriate professional indemnities, and

11.8.2. the locality itself understands the potential liabilities that may arise for it as a result of taking part in the study (for example, through the use of formal contracts and indemnity and compensation agreements, such as those developed by the New Zealand Association of Clinical Research), and has the ability to meet these liabilities

11.9. where the study involves the administration of a new medicine to participants who are in residence at sites within the locality, these sites are registered with Medsafe's Clinical Trial Site Self-Certification scheme.

12. The checks above are not intended to be exhaustive, or to limit the ability of localities to implement more detailed research governance processes that require additional information and assurances from sponsors and CIs.

Locality authorisation is a standard condition of HDEC approval

13. Locality authorisation is a standard condition of HDEC approval for the conduct of a study at a given locality. Once applicants have obtained HDEC approval for a study, and locality authorisation for the locality in which that study is to be conducted, the study may commence immediately. There is no need for the outcome of each locality review to be notified to the HDEC, or for the HDEC to confirm its approval for each locality.

14. Applicants must record locality authorisations in the electronic application system for HDEC review, allowing HDECs access to this information if they require.

15. Locality review and authorisation may occur at any stage of the HDEC review process. However, it is generally desirable that it occur at the same time as or as close as possible to HDEC review.

Cancellation of locality authorisation

16. Any locality may cancel locality authorisation for any study at any time at its sole discretion. If this occurs, the study may continue at all other localities for which applicants have obtained locality authorisation.

17. Where a locality cancels authorisation for reasons that may give the HDEC grounds to reconsider the approval in place for the study as a whole (in accordance with section 12), the locality should notify the HDEC of this as soon as possible.

18. There is no requirement for applicants to notify the HDEC of the routine closure of localities (or any sites within localities) used in a study. However, they must notify the HDEC of the conclusion or early termination of the study as a whole in New Zealand, in accordance with section 12.

Appointment of a new lead/principal investigator at a locality, or addition of new localities

19. The suitability of the lead/principal investigator(s) at a locality is a matter that is relevant to locality review. Localities should therefore conduct locality review again when a new lead/principal investigator is appointed, as soon as practical in the circumstances. There will usually be no need in such cases to notify the HDEC, since the appointment of a new lead/principal investigator does not in itself constitute a substantial amendment (see section 11).

20. Similarly, the addition to a study of a locality not listed in the original application for HDEC approval does not in itself constitute a substantial amendment, except where it is related to other amendments that are substantial. However, whether or not the addition of a new locality in a study comprises a substantial amendment, applicants must obtain locality authorisation before the study commences at each locality.