

EDITORIAL

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Chair of National Ethics Advisory Committee



The National Ethics Advisory Committee (NEAC) is an independent statutory advisor to the Minister of Health on ethical issues of national significance in health and disability. NEAC's 2003 review recommended the changes to ethics committee review that are now being implemented. Key aspects of the new arrangements were outlined in the first two issues of *Ethics Review*. This issue provides further information, especially on locality assessment.

Through NEAC's 2003 review, and in other ways, many and diverse New Zealanders have demonstrated their commitment to high ethical standards in research. The insights and goodwill of these ethics committee members, researchers, public bodies and other community members are informing and assisting the current change process. The 'field testing' experience of all those involved will contribute to further refinements over time.

In its 2003 review, NEAC recommended there be 'one study, one review'. Ethics committee review

checks that each study would meet established ethical standards if conducted at the right localities. NEAC also recommended there be strengthened local input, to confirm that each proposed study locality is indeed appropriate, with the required local arrangements made. The 'locality organisations' where studies are to be carried out are responsible for making this 'locality assessment' check, as a requirement for ethics committee approval of study conduct at each locality. This approach, and NEAC's recent follow-up recommendations on points of detail, are now being implemented.

The work of NEAC has so far focused on research ethics. Its current projects concern Māori framework and governance framework ('Who is responsible for what?') for research ethics. In addition, NEAC has a new project on the ethics of intervention studies and innovative practice.

The Committee is also inviting comment from stakeholders by 17 December 2004 on its current draft guidance 'Ethics of Observational Studies: Observational Studies, Audit, and Related Activities'. We welcome your input. If you haven't received a copy already, please download this document from www.newhealth.govt.nz/neac.htm.

Finally, NEAC offers its best wishes to the new bodies as they establish themselves in the important role of ethics committee review.

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Locality Assessment

In the new system of ethical review, locality assessment will replace the General Manager signature on the current Part V signature page of the application form, EA0502.

The locality assessment form will soon be available from committee administrators. From January 2005, researchers should include this form with all new applications. It will be incorporated into a revised version of the application form and guidelines later in the new year.

What is locality assessment?

Ethics committees assess whether the study would meet established ethical standards, if conducted at an appropriate study locality or set of localities. Locality assessment ensures that each study locality is suitable and that the researcher has made appropriate local arrangements.

Locality assessment will check that the researcher has adequately addressed:

- the suitability of any local arrangements
- the suitability of any local research environment
- any specific issues relating to the local community.

Locality assessment must be carried out for each locality where a study is to be conducted. Some single-region and most multi-region studies will require multiple locality assessments to be carried out. However, some single-region studies will have only one locality, and therefore require one locality assessment. A national study that is to be carried out using data from a national database would also require only one locality assessment.

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Ethics Committee Members

We are pleased to announce that the following people have been appointed to the seven new ethics committees.

Multi-region Ethics Committee

Name	Member category	Term (years)
Martin Tolich (Chair)	Ethicist	3
Sheila Williams	Biostatistician	3
Barry Smith	Community representative; Māori	3
Janine Ahie	Community representative; Māori	2
Maliaga Erick	Consumer representative	3
Carolyn Weston	Consumer representative	2
Christopher Wynne	Health practitioner	3
Graham Mellsop	Health practitioner	2
Fiona McCrimmon	Lawyer	2
Cynthia Darlington	Pharmacologist / pharmacist	3
Jane Koziol-McLean	Researcher	2
Lois Surgenor	Researcher	3

Northern X Regional Ethics Committee

Name	Member category	Term (years)
Tim Dare (Chair)	Ethicist	1
Teena West	Biostatistician; Māori	3
Patricia Hanlen	Community representative	2
Louisa Wall	Community representative; Māori	3
Robyn Northey	Consumer representative	3
Emma Ngawhare	Consumer representative; Māori	2
Scott Macfarlane	Health practitioner	2
Lester Reed	Health practitioner	3
Adina Halpern	Lawyer	3
Jeffrey Harrison	Pharmacologist / pharmacist	2
John France	Researcher	2
Stephanie Palmer	Researcher; Māori	3

Northern Y Regional Ethics Committee

Name	Member category	Term (years)
Paul Flanagan (Chair)	Community representative	3
Robert Crawford	Biostatistician	3
Peter Coughlan	Community representative	2
Michael Vale	Consumer representative	2
Heather Thomson	Consumer representative; Māori	3
Christina Bryant	Ethicist	2
Elizabeth Spellacy	Health practitioner	2
John Moodie	Health practitioner	3
Huhana Hickey	Lawyer; Māori	2
Claire Stott	Pharmacologist / pharmacist	3
Felicity Dumble	Researcher	2
Trecia Wouldes	Researcher	3

Who carries out locality assessment?

In most cases, the 'locality organisation' at each place of active study recruitment or conduct will carry out locality assessment. Locality organisations will most often be district health boards, but may be primary health organisations, iwi service providers, or disability service providers.

Locality organisations may be different from the organisations where researchers are based or employed. Many researchers are employed by universities, but recruit or conduct their studies through health or disability organisations. Other studies may not have a locality organisation, such as where study participants are recruited from the electoral roll.

Where there is no locality organisation, or the researcher has substantial influence over the locality organisation (eg, as a director or senior manager within the organisation), the relevant ethics committee will carry out locality assessment.

Which comes first – locality assessment or ethical review?

Ethics committee review and locality assessment may happen in tandem. If the researcher does not provide the completed locality assessment with the ethics committee application, ethical approval will be subject to the administrator receiving favourable locality assessment.

If all localities are required for the study to be valid, favourable locality assessments from all localities must be received by the administrator before ethical approval can be confirmed. If only some of the proposed localities are

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Central Regional Ethics Committee

Name	Member category	Term (years)
Helen Colebrook (Chair)	Lawyer	2
Matire Harwood	Biostatistician; Māori	3
Trevor James	Community representative	3
Anne Tuffin	Community representative	2
Dianne Wepa	Consumer representative	3
Andrea Needham	Consumer representative	2
John Kleinsman	Ethicist	3
David Sinclair	Health practitioner	2
Jacqueline Virtue	Health practitioner	3
Joe Asghar	Pharmacologist / pharmacist	2
Maureen Holdaway	Researcher	2
Guy Taylor	Researcher	3

Upper South A Regional Ethics Committee

Name	Member category	Term (years)
Carolyn Mason (Chair)	Ethicist	3
John Horwood	Biostatistician	3
Lee-Ann Ryan-Verry	Community representative	2
Edie Moke	Community representative; Māori	3
Derek Cone	Consumer representative	2
Andrea Duncan	Consumer representative	3
Alison Luckey	Health practitioner	3
Russell Scott	Health practitioner	2
Carolynn Bull	Lawyer; Māori	2
Christopher Budgen	Pharmacologist / pharmacist	2
Thomas Marshall	Researcher	3
Dianne Harker	Researcher	2

Upper South B Regional Ethics Committee

Name	Member category	Term (years)
Gray Crawford (Chair)	Consumer representative	3
Patrick Graham	Biostatistician	3
Michael Gough	Community representative; Māori	2
Kathrine Townshend	Community representative	2
Brenda Moran	Consumer representative	2
Simon Clarke	Ethicist	3
David McGregor	Health practitioner	2
Mark Smith	Health practitioner	3
Rosemary Carruthers	Lawyer	2
Sharon Gardiner	Pharmacologist / pharmacist	3
Robin Fraser	Researcher	2
Annette Finlay	Researcher; Māori	3

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Ethics Committee Members

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Lower South Regional Ethics Committee

Name	Member category	Term (years)
Jennifer Beck (Chair)	Lawyer	2
M Clare Robertson	Biostatistician	3
Kenneth Copland	Community representative	3
Khyla Russell	Community representative; Māori	2
Fay McDonald	Consumer representative	2
Gwen Neave	Consumer representative; Māori	3
Sandra Elkin	Ethicist	2
Nikki Kerruish	Health practitioner	2
Philip White	Health practitioner	3
Nerida Smith	Pharmacologist / pharmacist	3
Gail Tripp	Researcher	2
Alan Payne	Researcher	3

Locality Assessment *continues from page 3*

required for study validity – for example, where New Zealand localities are part of a worldwide study – then ethical approval can be given for each locality as each favourable locality assessment is received.

If a researcher wishes to request a study amendment that is likely to raise considerable locality issues, then a new locality assessment may be required. Researchers may seek ethics committee advice in this case.

Can locality organisations withdraw a favourable locality assessment?

Yes. A locality organisation may withdraw a favourable locality assessment, which would effectively withdraw ethics committee approval for study conduct at that locality. For this reason, the locality organisation should inform the researcher and the relevant ethics committee in advance of any withdrawal.

When researchers, ethics committees, and locality organisations have gained some experience through ‘field testing’ the new locality assessment process, a meeting of all parties will be held to advise on refining practice.

Can more localities be added after a study has been ethically approved?

Yes. In this case, researchers should proceed as for a request for a study amendment, and should

forward their request to the committee that gave the original approval.

If the original approval was from a Regional Ethics Committee, and if at least one of the requested new study localities is in a different ethics committee region, the administrator of the Regional Ethics Committee will then forward the file and the request for an amendment to the Multi-region Ethics Committee. The Multi-region Ethics Committee will review the amendment while referring to the original application, and advise the researcher and Regional Ethics Committee of its decision. If the amendment is approved, the file will transfer to the Multi-region Ethics Committee and all further correspondence will be between the researcher and the Multi-region Ethics Committee. If the amendment is not approved, the file will be returned to the Regional Ethics Committee and the researcher advised.

The following information should be forwarded with the amendment where applicable:

- reason for the amendment to the application
- names and contact details of any additional investigators
- new information sheet/consent form (if applicable)
- new Form A or B (if applicable)
- locality assessment.