

NEWSLETTER

Hunter New England Health Human Research Ethics

Issued: 16 December 2005

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1. New Structure for Human Research Ethics Review for Hunter New England Health

As of 1 January 2006 the Hunter New England Human Research Ethics Committee will become operational replacing the Hunter and New England Area Research Ethics Committees. The new Committee will be the sole Human Research Ethics Committee for Hunter New England Health and has been established to review research:

- where patients/clients or employees of Hunter New England Health are participants;
- conducted by staff of Hunter New England Health;
- involving personal health data or tissue samples in the custody of Hunter New England Health; or
- using resources of Hunter New England Health.

The Committee will approve such research when it is in accordance with the *National Statement in Ethical Conduct in Research Involving Humans 1999*.

The HNEHREC will be advised by two subcommittees:

- Clinical Trials Subcommittee
- Rural Research Methods Support Group

The **Clinical Trials Subcommittee** advises the Hunter New England Human Research Ethics Committee on methodological and pharmacological aspects of applications to conduct clinical trials and innovative therapy.

The establishment of the Clinical Trials Subcommittee does not negate submission to the NSW Health Shared Scientific Assessment Committee. See www.health.nsw.gov.au/healthethics/ssas.html for details.

The **Rural Research Methods Support Group** advises the Hunter New England Human Research Ethics Committee on methodological and additional concerns about applications to conduct rural research in the Hunter New England Health area.

The Rural Research Methods Support Group will also act as a resource for those embarking on research.

The Professional Officer (Research Ethics) will determine whether an application needs to be reviewed by the Rural Research Methods Support Group prior to being considered by the Hunter New England Human Research Ethics Committee.

2. Meeting dates for 2006

All submissions are due the last working of the month before the application will be considered.

The **Clinical Trials Subcommittee** will usually meet the 2nd Wednesday of each month except January. The submission and meeting dates for 2006 are:

Submission	Meeting
31 January	8 February
28 February	8 March
31 March	12 April
28 April	10 May
31 May	14 June
30 June	12 July
31 July	9 August
31 August	13 September
29 September	11 October
31 October	8 November
30 November	6 December

The **Rural Research Methods Support Group** will usually meet the 2nd Thursday of each month except January.

The submission and meeting dates for 2006 are:

Submission	Meeting
31 January	9 February
28 February	9 March
31 March	13 April
28 April	11 May
31 May	15 June
30 June	13 July
31 July	10 August
31 August	14 September
29 September	12 October
31 October	9 November
30 November	7 December

The Hunter New England Human Research Ethics Committee will usually meet the 4th Wednesday of the month except January. Submission and meeting dates for 2006 are:

Submission	Meeting
31 January	22 February
28 February	22 March
31 March	26 April
28 April	24 May
31 May	28 June
30 June	26 July
31 July	23 August
31 August	27 September
29 September	25 October
31 October	22 November
30 November	13 December

3. New Research Ethics website for Hunter New England Human Research Ethics Process

There is a new website for the Human Research Ethics Review Process and information about the Committee and its subcommittees at <http://intranet.hne.health.nsw.gov.au/ethics/researchethics.htm> - intranet http://www.hne.health.nsw.gov.au/research_ethics_process.htm - internet

4. New Application forms and Guidelines

There are new forms for initial applications, variations to approved protocols and renewal applications for the Hunter New England Human Research Ethics Committee – these are available on the website.

The guidelines for the initial application form have also been updated and should be consulted when completing that form as there are important changes.

The same forms are used for the Human Research Ethics Committee and its subcommittees.

5. New Fee Schedule

The Fee Schedule is derived from the NSW Health Policy Directive – Human Research Ethics Committees (HRECs) Fee Policy for Review of Clinical Trials within NSW Health. PD2005_628, 25 October 2005 www.health.nsw.gov.au/policies/pd/2005/PD2005_628.html

Type of application	Fee (inc. GST)
Clinical trials with full industry sponsorship	\$3300.00
Clinical trials sponsored By collaborative groups	\$150.00
Amendments to trials with full industry sponsorship*	\$550.00
Addition of sub-studies to full industry sponsored trials	\$1665.00
Investigator Initiated CTN clinical trials without industry sponsorship	\$150.00
Clinical Trials sponsored by for profit organisation not the Pharmaceutical Industry.	\$550.00(CTN) \$100.00(non CTN)

6. Arrangements with the University of Newcastle

An agreement has been reached between Hunter New England Health and the University of Newcastle (the University) to accept the decisions of the other institution's Human Research

Ethics Committee for research which previously would have required submission to and approval from both the Hunter Area Research Ethics Committee and the University of Newcastle Human Research Ethics Committee.

Under this agreement, researchers who are staff or students of, or whose research funding is being administered through, the University, and who wish to conduct research involving:

- Staff/clients/patients of Hunter New England Health as participants
- Access to records of Hunter New England Health; or
- Access to human tissue held by Hunter New England Health

will only have to submit applications to the Hunter New England Human Research Ethics Committee in the first instance. Once that application is approved then a copy of the full application, correspondence with the Hunter New England Health Human Research Ethics Committee and the approval letter are to be forwarded to the University's Human Research Ethics Officer for reporting to the University's Human Research Ethics Committee. **This is the responsibility of the Chief Investigator or Project Supervisor.** Monitoring, that is reviewing and where appropriate approving variations, reviewing serious adverse events and annual reports of approved protocols in this category will be undertaken by the Hunter New England Human Research Ethics Committee.

For those researchers who are staff or students of the University of Newcastle who wish to conduct

the research utilising Hunter New England Health equipment or facilities, for example imaging or pathology, but the participants in such research are other than staff or clients/patients of Hunter New England Health then an application for ethics approval should be submitted to the University of Newcastle Human Research Ethics Committee. Confirmation should be provided by the relevant Hunter New England Health facility that the research may proceed.

Hunter New England Health staff who wish to conduct research involving:

- Staff or students of the University as participants; or
- Access to records held by the University

and the research does not involve Hunter New England Health staff, clients or patients as participants or access to Hunter New England Health records or stored tissue samples, will only have to submit applications to the University of Newcastle Human Research Ethics Committee.

Once research reviewed by the University of Newcastle Human Research Ethics Committee is approved, a copy of the application, correspondence with the Committee, and the approval certificate for that research should be forwarded to the Professional Officer (Research Ethics).

If you are uncertain as to which Human Research Ethics Committee should review your research please contact Dr Nicole Gerrand on 4921 4950 or nicole.gerrand@hnehealth.nsw.gov.au or Ms Susan O'Connor, Human Research Ethics Officer

at the University of Newcastle on 4921 6333 or human-ethics@newcastle.edu.au

7. Recruitment documentation for ongoing research

For ongoing research approved by the Hunter Area Research Ethics Committee, the following amendments should be made to the information statement

The first sentence under the complaints statements should be changed to: "This research has been approved by the Hunter Area Research Ethics Committee (whose functions will now be preformed by the Hunter New England Human Research Ethics Committee from 1 January 2006) Reference No : XX/XX/XX/X.XX".

The contact details for the Professional Officer should be amended as follows:

Dr Nicole Gerrand
Professional Officer (Research Ethics)
Hunter New England Human Research Ethics Committee
Phone: (02) 4921 4950
Fax: (02) 4921 4818
Email: nicole.gerrand@hnehealth.nsw.gov.au

For ongoing research approved by the New England Research Ethics Committee the following amendments should be made to the information statement:

The first sentence in the complaints statements should be: "This research has been approved by the Hunter Area Research Ethics Committee (whose functions will now be preformed by the Hunter New

England Human Research Ethics Committee from 1 January 2006) Reference No: DB XXX"

And the contact details for the Professional Officer (Research Ethics) given above should be added.

8. Research Ethics Unit for Hunter New England Health

The Hunter New England Health Research Ethics Unit is located on the Ground floor of the Administration Building, Lookout Rd New Lambton (on the John Hunter Hospital)

The Staff in the Unit are:

Dr Nicole Gerrand
Professional Officer (Research Ethics)
Phone: 4921 4950
Email: nicole.gerrand@hnehealth.nsw.gov.au

Please contact Dr Gerrand for all ethical and methodological enquiries and for issues of complaint.

Ms Michelle Lane
Senior Administration Officer
Phone: 4921 4943
Email: michelle.lane@hnehealth.nsw.gov.au

Please contact Ms Lane for complex administrative enquiries.

Ms Emma McCall
Administrative Officer
Phone 4985 5929
Email: emma.mccall@hnehealth.nsw.gov.au

Please contact Ms McCall for routine administrative enquiries.