HUNTER NEW ENGLAND HUMAN RESEARCH ETHICS COMMITTEE
CLINICAL TRIALS SUBCOMMITTEE
TERMS OF REFERENCE
Version: 11 November 2010

1 Purpose

To advise the Hunter New England Human Research Ethics Committee (HNEHREC) on scientific aspects of clinical trials and innovative therapy.

2 Responsibilities

2.1 To review the scientific and safety aspects of clinical trial protocols in accordance with the *National Statement on Ethical Conduct in Human Research (2007)*

2.2 To advise the HNEHREC on the following:

- Where the project has been reviewed by an independent refereed national granting body their review will be considered
- Scientific value, methodological validity sampling criteria and safety of clinical trials proposed to be undertaken in HNEAHS
- Appropriateness of qualifications and expertise of investigators proposing to undertake clinical trials
- Modifications to clinical trial protocols which would improve their safety and scientific value
- Appropriate mechanisms for and intervals on monitoring of approved clinical trials
- Scientific appropriateness and safety of proposed amendments to clinical trial protocols
- Significance of adverse event reports and other technical information pertaining to approved clinical trials
- Scientific aspects of matters dealt with by HNEHREC such as the Special Access Scheme and innovative therapy
- Such other issues as are referred to it by HNEHREC

3 Status of the Clinical Trials Subcommittee within the Organisation

The Clinical Trial Sub-Committee (CTSC) is a subcommittee of the HNEHREC and established in accordance with s. 4.5 of the Terms of Reference for the HNEHREC.

4 Composition of the Committee

4.1 The composition of the CTSC shall reflect the mix of research activities across HNEAHS, and shall include as far as practical the following:

- Clinical pharmacologist
- Pharmacist with appropriate experience
- A statistician experienced in the design of clinical trials
- Persons with research experience and/or expertise relevant to the areas of research reviewed by the Committee.
- A Clinical Research Nurse
- A Clinical Epidemiologist

5 Appointment of Members and Terms of Appointment

5.1 The Chairperson and Deputy Chairperson shall be selected from the membership and appointed by the HNEH Chief Executive following consultation with the HNEHREC and with other senior institutional officers, as deemed appropriate.

5.2 Members of the CTSC shall be appointed by the Chief Executive after consultation with the Chairs of the CTSC and HNEHREC, as appropriate.

5.3 The term of appointment for the Chairperson and Deputy Chairperson shall normally be three years.

5.4 The term of appointment for CTSC members shall normally be three years.

5.5 Appointments may be renewed. Recommendations for renewal of appointment shall be made to the HNEAHS Chief Executive, through the Director of Population Health, Planning and Performance and by the Chairperson of the CTSC.

5.6 Upon appointment, each member shall be required to sign a statement undertaking:

- That all matters of which he/she becomes aware during the course of his/her work on the CTSC will be kept confidential.

- That any conflicts of interest which exist or may arise during his/her tenure on the CTSC will be declared.

5.7 Members of the CTSC will also be standing members of the HNEHREC but they will not be required to attend the meetings of the HNEHREC.

6 Meetings

6.1 Meetings of the CTSC shall be held at monthly intervals from February to December, or more frequently as necessary.

6.2 Meeting dates shall usually be at least two weeks before scheduled meeting for the HNEHREC

6.3 Meeting dates and agenda closing dates shall be published appropriately.

6.4 It may be appropriate for members to provide written comments in lieu of attendance. For the purposes of reaching decisions regarding research protocols or amendments, a quorum shall exist when 50 percent of voting members are present or the Chairperson is satisfied that members have received all papers and have had an opportunity to contribute their views and that these have been considered and recorded.

7 Procedures

7.1 Clinical trial proposals shall be submitted to the CTSC on the approved application form, with supporting documents as specified in the *ICH Guideline for Good Clinical Practice (3.1.2)*, plus any other information required by the Committee to enable it to fulfill its responsibilities.

7.2 The CTSC shall publish and regularly update the list of documents required for its consideration of clinical trial proposals.

7.3 In order to be considered at a scheduled meeting, clinical trial proposals and other correspondence shall be received at least one week before the advertised meeting dates.

7.4 The CTSC may seek advice from experts not amongst the members of the committee and may invite them to attend meetings.

7.5 Clinical trial proposals shall normally be considered at a scheduled CTSC meeting.

7.6 A CTSC member involved in a clinical trial proposal under consideration shall absent him/herself from the meeting during the discussion and until a decision has been reached (see point 5.6 above).

7.7 The CTSC shall reach decisions by consensus after all members have been given the opportunity to express their views. In the event that a consensus cannot be reached, a decision may be taken by voting (show of hands). A

two-thirds majority shall normally be required for a decision to be made. Dissenting views shall be recorded in the minutes.

7.8 The CTSC shall make one of the following recommendation to the HNEHREC in relation to every protocol it reviews:

- Approval;
- Provisional approval, subject to satisfactory replies to questions raised by the Committee being provided within the timeframe stipulated in the correspondence;
- Deferral on the basis that significant changes or additional information are required; or
- Not approved.

7.9 Where approval has been recommended subject to provision by the investigator of satisfactory replies to the CTSC's concerns, such replies will be considered by the HNEHREC, but may be referred back to the CTSC for further advice.

7.10 Correspondence from the investigators concerning proposed studies which have been deferred or rejected will be considered by the CTSC, which may subsequently recommend approval or approval subject to further amendments/modifications.

7.11 The CTSC may invite the investigators to a meeting to clarify outstanding issues. Alternatively the investigator can request to discuss issues with the CTSC at their monthly meeting.

8 Responsibilities of the Secretariat

8.1 The Secretariat shall set and distribute the agenda for the Clinical Trials CTSC as soon as possible after the closing date for applications at least one week before the meeting

8.2 The Secretariat shall be responsible for the preparation of the minutes of meetings (which shall clearly identify the trial and the documents reviewed), and of correspondence arising from the minutes.

8.4 The Secretariat shall store minutes of CTSC meetings, copies of all documentation which it considers, and correspondence for a period of at least fifteen (15) years after the completion of each clinical trial.

8.5 The Secretariat shall undertake such other tasks as are requested by the Chairperson and/or the CTSC.

9 Reporting to the Ethics Committee

9.1 A written report (in the form of minutes) containing the advice on each protocol reviewed by the CTSC shall be provided on a monthly basis no more than four days after the meeting.

9.2 The minutes of the CTSC meeting will be tabled at the next meeting of the HNEHREC.