HUNTER NEW ENGLAND HUMAN RESEARCH ETHICS COMMITTEE
CLINICAL TRIALS SUB-COMMITTEE
TERMS OF REFERENCE
Version: September 2020

1 Purpose

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

2 Responsibilities

2.1 To review the scientific and safety aspects of all submission for submissions involving clinical research and innovative therapy submitted to the HNEHREC for review in accordance with the requirements of the *National Statement on Ethical Conduct in Human Research 2007* (Updated 2018).

2.2 To advise the HNEHREC on the following:

- Scientific value, methodological validity, sampling criteria, analysis plan and safety of all submissions referred to the Clinical Trials Subcommittee for review;
- Appropriateness of qualifications and expertise of investigators proposing to undertake the research;
- Modifications to the protocols which would improve their safety and scientific value;
- Appropriate mechanisms for and intervals on monitoring of approved the research; and
- Such other issues as are referred to it by HNEHREC.

3 Status of the Clinical Trials Sub-Committee within the Organisation

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

4 Composition of the Sub-Committee

4.1 The composition of the CTSC shall reflect the range of clinical research and innovative therapy submissions to the HNEHREC, 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

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 HNELHD Chief Executive or delegate 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 or delegate 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 HNELHD Chief Executive, through the Director of Research 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 and may, but are not 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 one week before scheduled meeting for the HNEHREC.

6.3 Meeting dates and agenda closing dates shall be publicly available and published on the HNELHD Research Office Website from October the previous year.

7 Procedures

7.1 Clinical trial proposals shall be submitted through the NSW Health, Research Ethics and Governance Information System (REGIS) 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 fulfil 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 submitted through REGIS 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.

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:

- Recommend the HNEHREC approve the application;
- Recommend the HNEHREC approve the application contingent on a satisfactory response to the CTSC questions or concerns; or
- Recommend the HNEHREC not approve the application, and provide reasons for the recommendation.

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

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

8 Responsibilities of the Executive Officer

8.1 The Executive Officer of the HNEHREC will provide executive support to the CTSC.

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8.2. The Executive Officer will determine which of the submissions of the HNEHREC require prior review by the CTSC.

8.3 The Executive Officer or their delegate shall set and distribute the agenda for CTSC via REGIS at least one week before the meeting.

8.4 The Executive Officer shall be responsible for the preparation of the minutes of meetings (which shall clearly identify the trial and the CTSC recommendation to the HNEHREC), and of correspondence arising from the minutes.

8.5 The Executive Officer shall consult with the Chair or CTSC member concerning responses to the CTSC concerns and questions regarding a submission.

8.6 The Minutes of CTSC meetings, copies of all documentation which it considers, and correspondence shall be stored electronically for a period of at least fifteen (15) years after the completion of each clinical trial.

8.7 The Executive Officer shall undertake such other tasks as are requested by the Chairperson and/or the CTSC.

9 Reporting to the HNEHREC

9.1 The Draft minutes of the CTSC minutes containing the advice and a recommendation on each protocol reviewed by the CTSC shall be provided to the HNEHREC members via email at least three days before the HNEHREC meeting.

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

9.3 The CTSC advice and/or recommendation for each protocol it reviews, shall be incorporated into the HNEHREC minutes.

9.4 The CTSC will receive the HNEHRE minutes for noting.