ACT HEALTH HUMAN RESEARCH ETHICS COMMITTEE (HREC)

Clinical Trials Sub-Committee

Terms of Reference – June 2016

The role of the Clinical Trials Sub-Committee (CTSC) is to provide advice to the ACT Health Human Research Ethics Committee (HREC) on the research merit and integrity of research proposals referred to the sub-committee. This advice will be provided in such a way the HREC will not be required to duplicate the discussion with respect to the research merit and integrity criterion.

Terms of Reference

1. Objectives

The Subcommittee shall review and make recommendations, to the Ethics Committee, on the research merit and integrity of research proposals referred to it. CTSC shall consider proposed protocols in terms of:

- Scientific validity, study design and statistical aspects (eg, justification of sample size, power calculations)
- Safety of participants in relation to the proposed use of drug/device and other interventions
- Regulatory and procedural issues and ability to meet Australian and/or international Guidelines for Good Clinical Research Practice
- Technical issues including but not limited to manufacturing and toxicology
- Value of the trial with regard to contribution to clinical care and body of knowledge

The Sub-committee may provide other advice to the HREC on a proposal, including in relation to the other three National Statement criteria of beneficence, respect and justice, where the Sub-committee wishes to do so. The Subcommittee shall consider other matters relevant to its operation as requested by HREC.

The terms of reference shall be reviewed periodically to ensure their ongoing relevance.

Membership

CTSC shall consist of:

- At least five clinicians with relevant research experience and from a suitable mix of disciplines
- At least one epidemiologist or biostatistician

CTSC shall be provided with the appropriate level of administrative support.

At least one member of CTSC, preferably the Chair, shall also be a member of HREC

CTSC may, from time to time, consult with a person or persons with specialist knowledge relating to a matter under discussion.

Membership of CTSC is by appointment from the Chair of HREC who will consider the recommendations of the HREC and CTSC Chairs and give due consideration to the knowledge base of the membership and current research trends.

Appointments will be for a minimum of 12 months. Members, including the Chair, may serve successive terms at the discretion of the HREC Chair.

Members will complete conflict of interest declarations on an annual basis. A member who is not covered by a current COI declaration will not be permitted to attend meetings.

Quorum

A quorum shall consist of at least four members, including the Chair or Acting Chair and at least two clinicians.

No decision shall be taken where a quorum is not represented. Representation may include provision of written material.

Where the Secretary of the Committee believes that a forthcoming meeting may not achieve quorum representation due to foreseen absences, he or she should consider the following options:

- Declare the meeting conducted out of session
- Postpone/ re-schedule the meeting
- Cancel the meeting

Schedule of meetings and reporting

CTSC shall meet once per month for 11 months of the year (January to November) where there are proposals for the Sub-committee to review. Meeting dates will be scheduled to complement the HREC meeting schedule. Meeting dates and agenda closing dates shall be available on the website. CTSC recommendations will be reported to HREC in a standard format, and will be distributed to HREC members at least nine calendar days before the HREC meeting date.