Terms of Reference

1. These terms of reference shall be agreed by the membership of the Clinical Trials Coordinator Network (CTCN) and endorsed by the Clinical Trials Management Group (CTMG)
2. These terms of reference shall be reviewed not less than annually

Role

3. The CTCN has been established to facilitate the implementation and integration of a research governance framework (the framework) for ACT Health Directorate (HD) and Canberra Health Services (CHS)
4. To embody the interconnected and collaborative environment in which clinical trials*, registries and biobanks (collectively referred to as research) are conducted across HD and CHS
5. Through its reporting relationship to the CTMG, create closer connections between coordinators and researchers
6. Play a leadership role in the continuing development and conduct of the Clinical Trials Coordinator Network (CTCN)
    6.1 Members will be active participants in the development of clinical trials research at CHS and should be proactive in bringing forward issues and solutions
7. To establish, on an as needs basis, topic or project based working groups to address specific plans, projects, or topics
    7.1 Any working group established through the CTCN shall operate in accordance with its own Terms of Reference and any existing policy or procedure governing clinical trials and working groups

*A clinical trial is defined as clinical research where a therapeutic intervention in human subjects is being evaluated. This definition may be expanded in the future.

Reporting Mechanisms

8. Reporting from the CTCN:
    8.1 The CTCN will report to the CTMG by provision of its meeting minutes and activity reports to the next available meeting of the CTMG
        8.1.1 Any working groups formed by the CTCN will provide minutes of meetings and reports of activities to the CTMG

Functions

1. Represent the interests of the CTCN to the CTMG
2. In connection with the CTMG, Research Ethics and Governance Office (REGO), Clinical Trials Administration (CTA) team, support the development, maintenance and evaluation of standard operating procedures for the conduct and management of clinical trials, registries and biobanks
3. Develop and support opportunities for networking and mentoring within the trial coordinator and research support workforce
4. Participate in capacity building activities to foster a culture of research and the embedding of research into core business for HD and CHS

5. Facilitate the implementation of strategic direction set by the CTGSC in relation to the conduct of research across HD and CHS
6. Facilitate the implementation of research governance frameworks developed and/or endorsed by the CTGSC
7. Provide leadership and support to the clinical trial coordinator workforce

Membership

8. All persons employed in clinical trial coordinator roles with CHS, whether they be registered nurses, research officers or other classifications

   8.2 One clinical trial coordinator will represent the CTCN as a member of the Clinical Trials Management Group^

      8.2.1 This member shall act as Network Chair

9. Representative of CHS Pharmacy Department (with clinical trials knowledge)
10. Representative of ACT Pathology (with clinical trials knowledge)
11. Representative of CHS Medical Imaging Department (with clinical trials knowledge)
12. Ex-Officio members, in supporting roles:

    12.1 Head of Research Ethics and Governance

    12.2 Manager, Clinical Trials (Central Administration Team)

    12.3 Finance and Project Officer (Central Administration Team)

13. Meetings may be attended by invited non-members at the discretion of the CTCN. Invited non-members will sign a confidentiality agreement before receiving any paperwork associated with the meeting

    13.1 Where there is no associated paperwork invited non-members will sign a confidentiality agreement before attending any meeting of the CTCN

^On agreement with clinical services this member shall be allocated 0.1 FTE to participate in the CTMG meetings and other associated activities

Quorum

14. A quorum shall be considered 10 members one of whom must be the Chair or nominated acting Chair
15. In the case of absence members are asked to inform the secretariat with as must notice as possible before the meeting
16. Where the secretariat believes an upcoming meeting may be inquorate the following options should be considered:

    16.1 The meeting may be conducted out of session via email

    16.2 The meeting may be postponed

    16.3 The meeting may be cancelled

Conflicts of Interest

17. Members are to declare conflicts of interest, whether actual or perceived, in relation to any matters before the Group

18. As the CTCN is not a decision making body members having made a declaration of interest shall not be excluded from the discussion but rather will continue to participate as an informed advocate
19. Where the Chair calls for a vote, members having made a declaration of interest shall not participate in any vote on the matter

Secretariat

20. Secretariat functions will be provided by the Clinical Trials Hub Administration team
21. In consultation with members the secretariat will set a schedule of meeting dates for the year in advance

    21.1 Meetings will be held on a monthly basis and will be scheduled for 60 minutes duration

    21.2 Members will receive agenda papers five calendar days prior to the meeting date
22. Minutes of meetings will circulated within three working days of the meeting and be included in the next available set of agenda papers for endorsement