Terms of Reference

1. These terms of reference shall be agreed by the membership of the Clinical Trials Management Group (CTMG) and endorsed by the CEO, Canberra Health Services
2. These terms of reference shall be reviewed every three years

Role

3. To support the implementation and integration of a national clinical trials governance framework (the framework) for the Australian clinical trials sector including the Health Directorate (HD) and Canberra Health Services (CHS)
4. To ensure the processes that support the framework are developed so as to foster an interconnected and collaborative environment for the conduct of clinical trials*, clinical research**, registries and biobanks(collectively referred to as research) across the sector
5. Create closer connections between researchers and executives
6. Establishment and ongoing monitoring of research related key performance indicators (KPIs) for researchers and research performance and activities across CHS
7. Play a leadership role in the establishment and ongoing monitoring of centralised administrative support functions for research
8. To provide leadership and create closer connections between researchers, those who conduct research and research support activities on a day-to-day basis
9. Create a triangulation of research review, governance and oversight processes by linking with the Research Ethics and Governance Officer (including the Human Research Ethics Committee) and clinical governance processes:
    - 9.1 Accept referral of items or matters for review from the HREC and research governance office to ensure appropriate clinical and administrative oversight
    - 9.2 Referred items or matters may include, but are not limited to:
        - 9.2.1 Protocol deviation reports
        - 9.2.2 Serious breach reports
        - 9.2.3 Suspected or actual breaches of good clinical practice (GCP)
        - 9.2.4 Matters of research conduct, including resource matters
10. Conduct feasibility assessments of new research proposals:
    - 10.1 In line with established criteria and using assessment tools developed and/or endorsed by its members and relevant executives, the CTMG will consider the feasibility of research proposals as follows:
        - 10.1.1 Value to HD and CHS including funding, strategic fit, available resources, ability to successfully recruit subjects and benefit to patient care and the community
        - 10.1.2 Assessment may include advice drawn from existing processes and support areas including, but not limited to:
            - 10.1.2.1 The Research Ethics and Governance Office (REGO
            - 10.1.2.2 The Clinical Trials Support Unit (CTSU) team

10.1.2.3 The Clinical Trials Coordinator Network (CTCN) and any of its 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.

**Clinical research is defined as any research project that involves a process, procedure or treatment that is additional to standard of care including but not limited to blood draws, biological samples, imaging, tests or randomisation.

Reporting Mechanisms

11. Reporting from the CTMG:
    - 11.1 The CTMG will provide quarterly reports to the CHS CEO, as per clause 39.2.1.4
    - 11.2 The CTMG will provide annual reports to the CHS Office of Research and Education
12. Reporting to the CTMG:
    - 12.1 The CTMG will:
        - 12.1.1 receive regular reports from the CTCN by way of its meeting minutes and other reports provided by the CTCN
        - 12.1.2 receive information or submissions from stakeholders, as relevant to research and/or the clinical trials governance framework
13. Complaints:
    - 13.1 The CTMG will receive complaints regarding its processes or decisions
    - 13.2 Complaints will be received in the first instance by the Secretariat and will be forwarded to the Chair for initiation review
    - 13.3 The Chair may raise such complaints for discussion by the Group
    - 13.4 Complainants should receive a response from the Chair within 21 days of lodging a complaint
    - 13.5 Where a complaint is not able to be resolved to the satisfaction of all parties the Chair will refer the matter to the CEO
    - 13.6 Complaints referred to the CEO will be managed in line with established complaints process
    - 13.7 Where the Group has recommended a research project not proceed the applicant may request a meeting with the Chair or with the full Group
14. Appeals
    - 14.1 Where a research project is not endorsed by the Clinical Director (CD) the PI should request a review by the Executive Director (ED)
    - 14.2 Where a project is not endorsed by the ED the PI should request a review from the CTMG
    - 14.3 The CTMG will provide advice to the CEO as part of any review or appeal process
    - 14.4 Any request for the CTMG to review a decision of the CD or ED must include evidence of consultation and review with both the CD and ED and the reasons for which those positions did not endorse the project

14.5 Review by the CTMG should be conducted and concluded within 21 calendar days of receipt of the request

14.6 The outcome of the review should be communicated to the requestor no more than seven calendars after the review has concluded

14.7 An appeal of any decision or recommendation of the CTMG may be lodged with the CEO to be managed in line with established process

Functions

14. Act as advocates for research
15. Develop and support opportunities for networking within and between HD, CHS and external partners, locally, nationally and internationally
16. Develop and support methods of communication within and between the groups mentioned in clause 15 so as to foster a culture of interconnectedness and collaboration for research and researchers
17. Support and participate in capacity building activities to foster a culture of research and embed research into core business for HD and CHS
18. Support and facilitate the implementation of strategic direction set by HD and CHS
19. Support and facilitate the implementation of research governance frameworks developed and/or endorsed by HD and CHS
20. Provide leadership and support to the CTSU team
21. Contribute to research governance through triangulation of processes with the REGO/HREC and clinical services

Membership

22. The Director of Clinical Trials (DCT)
    22.1 Occupant of the DCT position shall serve as Chair of the Group
23. At least three members^ at senior clinical researcher levels (clinical director or senior principal investigator) of the clinical areas conducting clinical trials or clinical research
24. One member from the Clinical Trials Coordinator Network, preferably the Chair of that group
    24.1 The CTCN representative may delegate attendance on an as needs basis
25. With the exception of the Chair, membership shall be for fixed terms of three years
    25.1 In ordinary circumstances members would not serve more than two consecutive terms
26. Members may be sought through open advertisement or through direct approach from the Chair on behalf of the membership
27. Members will be appointed based on skills and experience in the conduct of clinical trials/clinical research
27. Meetings may be attended by invited non-members at the discretion of the Chair. Invited non-members will sign a confidentiality agreement before receiving any paperwork associated with the meeting

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

28. Ex-Officio non-voting members

28.1 Senior Director, Research Ethics and Governance

28.2 Manager, Clinical Trials (Clinical Trials Support Unit)

^On agreement with clinical services voting members shall be allocated 0.1 FTE to participate in the Group, meetings and other associated activities

Quorum

30. A quorum shall be considered three voting members one of whom must be the Chair or nominated acting Chair

31. In the case of absence members are asked to inform the secretariat with as much notice as possible before the meeting

32. Where the secretariat believes an upcoming meeting may be inquorate the following options should be considered:

32.1 The meeting may be conducted out of session via email

32.2 The meeting may be postponed

32.3 The meeting may be cancelled

Confidentiality and Conflicts of Interest

33. Members will sign confidentiality agreements and conflict of interest statements on an annual basis

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

35. The Group will consider the declaration and determine actions to be taken subject to the following provisions:

35.1 Where a member is involved a research project as an investigator, a team member, or supervisor of the principal investigator, the member may not participate in any discussion or vote on the matter. The Group may request the member leave the room for the duration of discussions

35.2 Where a member is not involved as per clause 22.1 but has been involved in formal or informal discussion about a research project prior to its submission to CTMG, the member may provide information to the Group as requested but may not participate in any vote on the matter

35.3 Where the member has endorsed a project as a Head of Department, and has had no other involvement in the project, the member may participate in discussion on the matter but may not participate in any vote

36. Where the matter is not related to a research project, the member will disclose the conflict, or perceived conflict, with actions taken subject to the following:

36.1 Where the member holds a financial, personal or professional interest in the outcome of the matter, the member will be excluded from the discussion and any decision making on the matter

37. Declarations of interest and actions taken must be recorded in the minutes of the meeting
38. Where a member was requested to leave the room for the duration of discussions this fact should be included in the minutes and in any advice or correspondence resulting from the matter

Project Review and Authorisation Process

39. Review and authorisation will be a two-stage process

39.1 Stage one – feasibility review:

39.1.1 Following submission of required documentation to REGO and subsequent provision to the CTMG, the CTMG will undertake an initial review in line with the established feasibility assessment process

39.1.2 The CTMG will provide advice to the researcher:

39.1.2.1 Requesting further information; or

39.1.2.2 advising that contract and budget negotiations may commence along with preparations for full ethics and governance submission

39.1.3 At the conclusion of contract and budget negotiations the researcher will make a submission to REGO for ethics and/or site governance review

39.2 Stage two – final authorisation

39.2.1 On receipt of a full ethics and/or site governance submission, including the recommendation of the CTMG, REGO will coordinate the final authorisation

39.2.1.1 The CEO (or delegate) will decide on the endorsement of research contracts, forms of indemnity and the site governance clearance sheet which indicates available resources, including finances and facilities

39.2.1.2 In ordinary circumstances the Chair of the CTMG will act as delegate for the CEO with authority to endorse site governance clearance sheets, research contracts, forms of indemnity and other documents required to begin a clinical trial or research project

39.2.1.3 In the case of conflict of interest on the part of the delegate, delegation will revert to the CEO

39.2.1.4 The Chair, CTMG will provide quarterly updates to the CEO on approvals issued

39.2.1.5 Following endorsement by the CEO (or delegate), REGO will provide a site governance approval notification to the researcher

39.2.2 Final authorisation will be at the discretion of the CEO (or delegate)

39.2.3 All authorisations will be reported to the next available meeting of the CTMG

Secretariat

40. Secretariat functions will be provided by Research Ethics and Governance Office
41. In consultation with members the secretariat will set a schedule of meeting dates for the year in advance

41.1 Meetings will be held on a fortnightly basis and will be scheduled for 60 minutes duration

41.2 Members will receive agenda papers three calendar days prior to the meeting date

41.3 The secretariat will make public a schedule of meeting and submission dates

42. The secretariat will communicate decisions of the meeting to applicants in writing within three calendar days of the meeting date

43. Minutes of meetings will be included in the next available set of agenda papers

The secretariat will ensure compliance with established policies, processes and procedures including the provision of supporting documentation to enable effective and efficient work of the CTMG