

PETER MACCALLUM CANCER CENTRE CLINICAL RESEARCH COMMITTEE

TERMS OF REFERENCE

CONTEXT

The Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC) is constituted in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research 2023* (and as amended) (*National Statement*).

The HREC is supported by sub-committees and review panels. The sub-committees and review panels each have their own terms of reference and operate within those terms.

STATEMENT OF PURPOSE

The Clinical Research Committee (CRC) is a sub-committee of the HREC. The CRC has been established to assist the HREC to review human research projects in accordance with the *National Statement* values of research merit and integrity, justice, beneficence, and respect for human beings.

FUNCTIONS

Per delegation from the HREC:

- a) Evaluate the scholarly and scientific standards of clinical research submitted for review by the HREC and advise the HREC on the scholarly and scientific merit of the research.
- b) Ensure that clinical research submitted for review by the HREC complies with relevant research policies, guidelines and legislation.
- c) Review and approve amendments to approved projects.
- d) Monitor trial specific safety events for projects which have been ethically approved by the HREC.
- e) Monitor trial specific safety events for research project participants at the Peter MacCallum Cancer Centre.

MEMBERSHIP

The members of the Committee will comprise of:

- a) Chair (Senior Medical Clinician)
- b) Clinician Researcher Representatives: at minimum from Medical Oncology, Haematology, and Radiation Oncology
- c) Clinical Trial Pharmacy Representative
- d) Parkville Cancer Clinical Trials Unit Representative
- e) Cancer Research Division Representative
- f) Radiation Therapy Representative
- g) Medical Radiation Safety Representative
- h) Biostatistician
- i) Department of Health Services Research Representative
- j) One or more research active staff from any discipline

The CRC Chair is appointed by the HREC Chair.

A CRC Deputy Chair is nominated as required from the CRC membership group, by the membership group.

For membership categories b) to i), a pool of members may be appointed to draw on as needed.

Member appointments are reviewed at least every three years.

Members are not remunerated for their services to the committee.

Secretariat services and minuting is provided by the Human Research Ethics & Governance office.

ATTENDEES

Researchers and research project teams can request to attend a meeting to discuss project related matters.

Observers can request to attend a meeting to observe proceedings.

CRC may request attendance of a person with expertise needed to support its decision making.

CONVENOR

Chair of Committee

MEETING FREQUENCY

Meetings are held monthly, excluding January. Additional meetings may be held, as necessary.

QUORUM

A quorum shall consist of six of the members, two of whom are senior research clinicians.

Where a member is unable to attend a CRC meeting, their input is sought ahead of the meeting and review comments presented during the CRC meeting for the Committee's consideration.

CONFLICTS OF INTEREST

Members are required to declare any actual or potential conflict of interest they might have in relation to items under review. If the Chair is conflicted, a Deputy Chair is appointed.

FEES

Fees are charged for review per fee schedule published on the Peter MacCallum Cancer Centre website.

REVIEW

The Terms of Reference are reviewed by the CRC bi-annually.

The operation of the CRC is reviewed annually by the Manager, Human Research Ethics & Governance.

REPORTS TO

Peter MacCallum Cancer Centre Human Research Ethics Committee

CRC Chair or delegate attend the Peter MacCallum Cancer Centre Human Research Ethics Committee meetings.