

STANDARD OPERATING PROCEDURE

HUMAN RESEARCH ETHICS & GOVERNANCE OFFICE (HREG)

SOP001 ETHICAL REVIEW – HUMAN RESEARCH

TARGET AUDIENCE

The target audience is Sponsors, Contract Research Organisations, Investigators, participating Institutions and their delegates, of research projects that will be reviewed or were approved by the Peter MacCallum Cancer Centre Human Research Ethics Committee.

RELATED PETER MAC POLICIES, PROCEDURES OR GUIDELINES

POLICY Responsible Conduct of Research

PURPOSE

The purpose of this document is to describe the human research ethics committee system implemented by the Peter MacCallum Cancer Centre (Peter Mac) to protect the interests of human participants in research and to facilitate the conduct of that research.

This SOP outlines the role and function of the Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC), its sub-committees and panels, and of the Human Research Ethics & Governance office (HREG). The HREC is registered with and certified by with the National Health and Medical Research Council (NHMRC) to review human research in oncology under code EC00235. The HREC is a 'reviewing HREC' under the National Mutual Acceptance scheme and this SOP applies equally to single centre and multi centre ethical review.

PROCEDURE

1.1 COMMITTEE SYSTEM

The HREC is constituted and operates in accordance with the *National Statement on Ethical Conduct in Human Research (2023 and as amended)* (National Statement) and relevant state and national legislation, regulations and guidelines and is certified by the National Health and Medical Research Council and is accredited by the Victorian Consultative Council for Clinical Trial Research as a reviewing HREC.

The HREC operates in accordance with National Statement *Chapter 5.2 Responsibilities of HRECs and other ethics review bodies*.

It is the responsibility of the HREC to ensure that all human research at Peter Mac is conducted according to the National Statement.

The HREC also delegates this responsibility to the following subcommittees and panels:

- Clinical Research Committee (CRC),
- Tissue Research Committee (TRC),

- Lower Risk Research Committee (LRRC),
- Out of Session (OOS) Review Panel,
- Divisional Review Panels.

The function and membership of the committees and panels are detailed in their Terms of Reference. Meetings may be conducted in real time, in person or online, or may be conducted via circulation of member review comments.

Method of deliberation and decision-making is to reach decisions through discussion and consensus agreement.

Members are advised that all proceedings are strictly confidential.

All members are required to declare any actual or potential conflict of interest they might have in relation to items under review. Any member declaring a conflict for a meeting item does not participate in decision making for that meeting item. At the discretion of the chair, they may be asked to address committee queries regarding the meeting item. Any declaration is recorded in the meeting minutes.

Member attendance is recorded in the meeting minutes.

Scheduled meetings, submission due dates and submission instructions are posted on the HREG website:

www.petermac.org/research/research-support-services/ethics-and-governance

The HREC meets each month, except for January.

The CRC meets in the week prior to the HREC meeting.

The TRC meets in the week prior to the HREC meeting.

The LRRC meets in the week prior to the HREC meeting.

The OOS review panel meets between full meetings of the CRC/TRC.

The Divisional Review Panels meet as necessary and are managed within the clinical divisions or by the HREG.

Submissions are allocated by the HREG for proportionate review based on level of risk, in accordance with the guidance on risk in the National Statement Chapter 2.1, and on reviewer expertise.

Documentation required for review and approval in accordance with National Statement 5.2.15 to 5.2.18.

Researcher responsibilities are outlined in National Statement *Chapter 5.3 Responsibilities of researchers*.

Committee, subcommittee and panel members are provided up to six calendar days to review meeting agenda and submissions.

Target timelines for notification of decisions to researchers:

Committee or subcommittee review of new projects, resubmissions, reply to queries, or substantial amendments: within 4 business days after meeting date.

All other items: within 10 business days after meeting date.

A. Human Research Ethics Committee (HREC)

The primary role of the HREC is to consider ethical aspects of human research in accordance with the requirements of the National Statement and relevant state and national legislation, regulations and guidelines. One part of this is the review and, as appropriate, approval or rejection of new research projects and amendments submitted by researchers. New research projects are first reviewed by an appropriate sub-committee. Review and approval of lower risk research projects may be delegated to a sub-committee or panel. Review and approval of substantial amendments and safety reporting items may be delegated to a sub-committee or panel. Review and approval of progress reports and administrative matters may be delegated to the HREG.

B. Clinical Research Committee (CRC)

The role of the CRC is to ensure that clinical research submitted for review at Peter Mac complies with relevant clinical research policies, guidelines and legislation. This involves evaluating that applications for

clinical research are designed and conducted to meet relevant scholarly and scientific standards.

For selected matters, the CRC is permitted to provide approval via delegation.

The following are examples of such matters:

- amendments to approved clinical research projects;
- responses from researchers to feedback from the committees
- safety reporting items

C. Tissue Research Committee (TRC)

Research principally involving the use of human biospecimens or genetic material or genetic information is considered by the TRC.

The role of the TRC is to review research projects using human biospecimens or genetic material or genetic information for scientific validity and scientific merit.

For selected matters, the TRC is permitted to provide approval via delegation.

The following are examples of such matters:

- amendments to approved research projects;
- responses from researchers to feedback from the committees.

D. Lower Risk Research Ethics Committee (LRREC)

The LRREC reviews lower risk research, as defined in National Statement Chapter 2.1, in which the only foreseeable risk to participants or others is no greater than discomfort. The risk can be associated with the conduct of research or the proposed outcomes of the research.

Typical lower risk research may include:

- surveys/focus groups/interviews with patients, carers or health professionals;
- medical record review; and
- some quality assurance projects – particularly those involving minor privacy concerns.

Research using human biospecimens or genetic material or genetic information or research accessing, determining or asking for sensitive information will not be reviewed by the LRREC.

The LRREC can provide approval via delegation for new projects and amendments within its review scope.

E. Divisional Review Panels

The Divisional Review Panels are responsible for reviewing research projects for Peter Mac staff examining Peter Mac data.

Examples of this type of research include:

- retrospective research studies which are a chart/database review of Peter Mac patient data by Peter Mac staff, with reference to a research hypothesis; and
- retrospective research studies, as above, that also collect prospectively anything that qualifies as clinical follow-up data. This could include survival/status at last contact, date of last contact, date and cause of death or other information related to the management of patients' disease.

Research providing data to other organisations or obtaining data from other organisations will not be reviewed by the Divisional Research Panels.

The Divisional Review Panels can provide approval via delegation for new projects and amendments within its review scope.

F. Out of Session Review Panel

The Out of Session review process allows for review of selected matters outside of formal meeting times. For selected matters, the Out of Session Review Panel is can provide approval via delegation.

The following are examples of such matters:

- amendments to approved research projects
- responses from researchers to feedback from the committees

G. External Experts

If an expert opinion is required for an early phase clinical trial, which cannot be found within the existing internal committee structure, the opinion of an external scientific expert reviewer can be sought per the Victoria State Government *Early Phase Clinical Trials Guidance on the Scientific Expert Review Toolkit, 2019*.

External experts for the review other research may be sought if required per guidance of National Statement 5.2.6.

1.2 COMMUNICATION

The HREC and its sub-committees and panels are supported by the Human Research Ethics & Governance office (HREG). The HREC, sub-committees and panels delegate all communication and correspondence to the HREG. The HREG prepares and distributes meeting agenda and minutes, review outcomes and approvals, and other required correspondence.

All communication between sponsors, researchers and their delegates and the HREC or sub-committees and panels is via the HREG office.

Sponsors, researchers and their delegates may be invited to or request to attend an HREC or sub-committee meeting.

- A. If a sponsor, researcher or their delegate requests to attend a meeting, the following must occur:
 - the sponsor, researcher or their delegate must notify the HREG office;
 - a date and time of attendance is agreed; and the relevant project is put on the meeting agenda;
 - a record of their attendance will be captured in the meeting minutes and the outcome of the visit will be recorded.
- B. If a committee requests to have a sponsor, researcher or their delegate attend a meeting, the following must occur:
 - the committee Chair/Member must inform the HREG office of the request;
 - the HREG office contact the sponsor, researcher or their delegate and inform them of the request;
 - if they accept, a date and time of attendance is agreed;
 - a record of their attendance will be captured in the meeting minutes and the outcome of the visit will be recorded.
- C. If an observer is invited or requests to attend a meeting, the following must occur:
 - the HREG office informs the Observer of the invitation or acceptance of the attendance request;
 - a date and time of attendance is agreed;
 - the HREG office informs the Observer as to the confidential nature of the discussions and if they are external to Peter Mac they will be requested to sign a Confidentiality Agreement. Peter Mac Staff will already have signed a confidentiality agreement as part of their employment conditions;
 - the observer will only receive a copy of agenda, the observer will not receive the items for review;
 - a record of the Observer's attendance will be captured in the meeting minutes.

D. Records

The HREG maintains records of all submissions, reviews, communication and approvals in accordance with National Statement 5.2.19 to 5.2.20.

1.3 FEES

Fees shall be charged for ethical review of new research projects and other items submitted to the HREC or for site specific assessment by Peter Mac. Peter Mac will charge either an ethical review fee or a site specific assessment fee, but not both. The fees to be charged will be set by Peter Mac and may change from time to time. The current fee schedule is available on the HREG webpage: www.petermac.org/research/research-support-services/ethics-and-governance

LEGISLATION/REFERENCES/SUPPORTING DOCUMENTS

National Statement on Ethical Conduct in Human Research (2023 and as amended)

AUTHORISED BY

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