The Melbourne Clinic
by Healthscope

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

The Melbourne Clinic Human Research Ethics Committee

Terms of Reference and Standard Operating Procedures (Version 2, July 2026)

This document sets out how The Melbourne Clinic Human Research Ethics Committee (TMC REC) is constituted and how it operates. Part A, the Terms of Reference, describes the Committee's purpose, scope, membership and governance. Part B, the Standard Operating Procedures, describes how the Committee carries out its ethical review, monitoring and governance functions in practice.

Both parts should be read together with the National Statement on Ethical Conduct in Human Research (2025), issued jointly by the National Health and Medical Research Council (NHMRC), the Australian Research Council and Universities Australia. This document is intended for researchers preparing an application to TMC REC, Committee members, and members of the public seeking to understand how the Committee operates.

Contents

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

SOP 13 – Suspension or Withdrawal of Ethical Approval
SOP 14 – Fees
SOP 15 – Member Governance: Appointment, Induction and Training
SOP 16 – Additional Safeguards for Research Involving People Experiencing Mental Ill-Health
SOP 17 – Additional Safeguards for Research Involving Children and Young People
SOP 18 – Additional Safeguards for Research Involving Aboriginal and/or Torres Strait Islander People and Communities

Definitions

HREC: Human Research Ethics Committee — a committee constituted under the National Statement to review the ethical and scientific acceptability of research involving humans.

National Statement: The National Statement on Ethical Conduct in Human Research (2025), issued jointly by the National Health and Medical Research Council (NHMRC), the Australian Research Council and Universities Australia.

Principal investigator: The researcher who takes overall responsibility for a research project and is TMC REC's primary contact for that project.

Sponsor: An individual, company, institution or organisation that takes responsibility for the initiation, management or financing of a research project.

Serious adverse event (SAE): An untoward occurrence that results in death, is life-threatening, requires or prolongs hospitalisation, results in persistent or significant disability, or is a congenital anomaly.

SUSAR: Suspected Unexpected Serious Adverse Reaction — a serious adverse reaction to an investigational product that is inconsistent with the known safety information for that product.

Quorum: The minimum representation of membership categories required for TMC REC to decide at a meeting.

Secretariat: The administrative staff supporting TMC REC's operations, correspondence and record keeping.

Expedited review: Review of a low-risk application by the Chair, Deputy Chair or a delegated sub-committee outside a full Committee meeting, ratified at the next meeting.

Exemption: A determination that a negligible-risk research activity does not require HREC review, under National Statement paragraph 5.1.17.

Assent: A child or young person's agreement to participate in research, sought in addition to, not instead of, consent from a parent, guardian or other authorised person where the child or young person cannot themselves give valid consent.

The Melbourne Clinic
by Healthscope

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

Part A – Terms of Reference

Name

The name of the committee is The Melbourne Clinic Human Research Ethics Committee (TMC REC).

Aim and Purpose

The aim of TMC REC is to facilitate discussion of ethical issues related to patient health care (including such areas as research, education, health promotion, community education and participation), recognising that neither the hospital nor its patients exist in isolation, but as part of a wider community.

The purpose of TMC REC is to: provide independent, competent and timely review and monitoring of research projects; ensure that all research projects are reviewed in accordance with the National Statement on Ethical Conduct in Human Research (2025), issued jointly by the National Health and Medical Research Council (NHMRC), the Australian Research Council and Universities Australia, incorporating all subsequent updates (the National Statement); protect the welfare, dignity, rights, safety and wellbeing of all participants in research projects it reviews; and facilitate research that has been, or will be, of benefit to the wider community.

Scope of Responsibility

TMC REC is part of an independent, private organisation established to conduct scientific and ethical reviews of research proposals to be undertaken at or under the auspices of The Melbourne Clinic and/or another Healthscope facility, and/or by affiliated research partners.

TMC REC may review treatment trials submitted as part of applications to the Therapeutic Goods Administration (TGA) for access to unapproved therapeutic goods via the Authorised Prescriber and Special Access Schemes.

TMC REC decides on a case-by-case basis, having regard to its current expertise, whether it will review studies, including studies submitted by researchers who are not affiliated with The Melbourne Clinic or Healthscope.

Where a lower-risk ethics review process or sub-committee is established by the institution, TMC REC's relationship to that process, and the circumstances in which matters are referred to it, is set out in Part B of this document.

Functions

TMC REC is constituted and operates in accordance with the National Statement and, in respect of clinical trials, the ICH Guideline for Good Clinical Practice (ICH-GCP). The role of the Committee is to fulfil the following objectives:

- Review submitted psychiatric and related mental health research proposals to be undertaken at The Melbourne Clinic and other Victorian Healthscope psychiatric hospitals (either alone or in conjunction with other establishments).
- Consider both the scientific merit and the ethical acceptability of research proposals and determine whether they are acceptable, require modification, or should be rejected.
- Monitor the progress of approved research, in a manner commensurate with its risk, size and complexity, until completion and publication, to ensure ongoing compliance with the approved proposal and the National Statement.

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

- Review and approve TGA-notified treatment trials in terms of scientific validity, safety and ethical acceptability, and monitor trial conduct.
- Identify, disclose and manage actual and potential conflicts of interest affecting the Committee's review of research, in accordance with the National Statement.
- Receive, handle and seek to resolve complaints about research it has reviewed or about the conduct of the Committee.
- Maintain the Committee's registration with the NHMRC and establish and maintain communication with NHMRC's Australian Health Ethics Committee (AHEC), providing access on request to information in the Committee's records.
- Establish further policies as required to satisfactorily accomplish these goals.
- Advise the General Manager on policy governing research at The Melbourne Clinic.
- Support the organisation's pursuit of excellence in all areas of service provision by discussing ethical issues related to patient care, clinical practices, programs and services provided at the hospitals, and advise the General Manager of recommendations.

Membership

In accordance with the National Statement, TMC REC will maintain a minimum membership of eight members, including:

- a chairperson with suitable experience, including previous HREC membership, whose other responsibilities will not impair the Committee's capacity to carry out its obligations under the National Statement,
- two members who bring a broad community or consumer perspective and who have no paid affiliation with the institution,
- a member with knowledge of, and current experience in, the professional care or treatment of people (for example, a nurse, counsellor or allied health professional),
- a member who performs a pastoral care role in a community, including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader,
- a qualified lawyer, who may or may not be currently practising and, where possible, is not engaged to advise the institution on research-related or any other matters,
- two members with current research experience relevant to the proposals considered at the meetings they attend.

No individual may represent more than one of the above categories at a given meeting, although they may represent a different category at a separate meeting, provided that all minimum membership categories continue to be represented at each meeting. As far as practicable, TMC REC will maintain diversity, including gender diversity, among its membership, and will seek to ensure that at least one-third of those participating at each meeting are from outside The Melbourne Clinic and Healthscope. Where research concerns Aboriginal and/or Torres Strait Islander people or communities, the Committee will ensure a member with relevant knowledge or cultural expertise is appointed or invited to the meeting, if not already represented above.

In addition, TMC REC has chosen to appoint a Deputy Chair from among the above members to act as Chair during periods of absence; when acting as Chair, the Deputy Chair's own membership category (if any) will be filled by another Committee member. A Secretary, normally a staff

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

member of the institution, supports the Committee.
Invitees of the Chair may include researchers,
external experts or other individuals whose knowledge may assist TMC REC's decision-making. All such invitees may be asked to leave the meeting during TMC REC's deliberations and decision-making and have no voting rights.

Appointments

All members of TMC REC are appointed, using an open and transparent process, by the Chair (or Deputy) for a minimum term of three years and may be eligible for reappointment for subsequent term(s). Appointments are reviewed at least every three years. Members are appointed as individuals, on the basis of their knowledge, qualities and experience, and not as representatives of any organisation, department or group.

Members are advised in writing of their appointment and its conditions, including the membership category or categories they represent, their responsibilities (including participation, induction, continuing education, confidentiality and disclosure of interests), their term of appointment, and details of any remuneration or other benefits. No remuneration is provided, as membership is voluntary. Members are also provided with documentation relating to this document, relevant NHMRC guidelines, a list of Committee members, and other information relevant to TMC REC's processes and procedures, together with confirmation of the legal protection described below.

Liability Coverage

Healthscope will provide legal protection for all decisions and advice given by TMC REC members (whether Healthscope employees or not) and will provide legal protection in respect of any liabilities that may arise during the bona fide conduct of their duties as Committee members.

Meetings

TMC REC will meet six (6) times per year, on dates and times determined by the Committee and circulated at the beginning of each 12-month period. As far as practicable, meetings will be arranged to enable attendance, either in person or using available technology such as videoconference, of members from all minimum membership categories. Meeting papers will be provided to members sufficiently in advance of each meeting to enable them to be fully informed. All matters relating to the protocols and Committee proceedings are confidential. Project files are kept in the Research Unit. After use, all papers will be disposed of through confidential recycling.

Quorum

Quorum is reached when representatives of at least 50% of the minimum membership categories described in the National Statement are present. Where there is less than full attendance of the minimum membership categories at a meeting, the Chair must be satisfied, before a decision is reached, that the views of those absent members belonging to the minimum membership categories have been received and considered, in accordance with the National Statement.

Decision Making

The TMC REC Secretary will attend all Committee meetings and will record the discussion and resolutions of the Committee in the minutes. Decisions at meetings must be made following an exchange of opinions from each of the members who constitute the minimum membership, whether at a face-to-face meeting, by teleconference or videoconference, or, where one of those

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

members is absent, by the receipt and consideration of that member's views. The Committee will try to reach decisions by general agreement or consensus; voting is neither required nor prohibited. Any dissent, and the reasons for it where requested by the dissenting member, will be recorded in the minutes. The TMC REC Secretary will record decisions about the approval, modification or rejection of proposals, with reasons for those decisions linked, where possible, to the relevant sections, chapters or paragraphs of the National Statement.

TMC REC may delegate some of its responsibilities to the Chair, a member, a sub-committee or its administrative officers (for example, for expedited review of proposals or approval of minor amendments). Actions taken under such delegation are not equivalent to decisions of the full Committee, and TMC REC will determine which actions require its ratification.

Maintenance of Records

Minutes will be distributed to all members within one week of the meeting. A master copy of the minutes will be filed by the Secretary and held by the Chairperson. The agenda for the next meeting will be distributed at least one week prior to that meeting.

Procedures

TMC REC shall establish, implement and document its working procedures concerning:

- frequency of meetings,
- attendance at meetings,
- conduct and structure of meetings and deliberations,
- preparation of agendas and minutes,
- timely distribution of papers prior to meetings,
- presentation, timely consideration and review of applications for ethical review, including applications from researchers who are not affiliated with the institution,
- disclosure of interests and management of conflicts of interest,
- communicating with researchers, including face to face, by telephone and in writing (including email),
- reporting on its activities to the Institution,
- methods of decision making,
- prompt notification of decisions,
- record keeping,
- monitoring of approved research,
- reporting and handling of adverse events,
- receiving and handling of complaints, including referral to an independent assessor where a complaint cannot be resolved directly with the Committee,
- advising institution(s) or organisation(s) of decisions to suspend or withdraw ethical approval of a research project,
- attendance, as observers, of people other than members or researchers,
- fees, if any, to be charged (a current fee schedule is available on request from the TMC REC Secretariat); and
- confidentiality of the content of protocols and of Committee proceedings.

These working procedures are set out in Part B of this document.

The Melbourne Clinic
by Healthscope

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

Expedited Review

The Chair may seek advice from other TMC REC members or other relevant representatives of The Melbourne Clinic (e.g. legal), as appropriate, before reaching a decision on an application considered outside a full Committee meeting. Any approval granted in this way will be reported to TMC REC for ratification at its next meeting.

Reporting

TMC REC is registered with the NHMRC and reports annually, or on request, to the NHMRC through the Australian Health Ethics Committee (AHEC). The report format is determined by the NHMRC and may include statistics on TMC REC's activity and its compliance with the National Statement.

In addition, an activity report may be provided to:

- The Melbourne Clinic General Manager
- The Melbourne Clinic Executive Team

TMC REC, through the Chair and/or a delegate, may at any time bring to the attention of the General Manager or Executive Team any issues of significant concern that may merit prompt consideration and attention.

The Melbourne Clinic
by Healthscope

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

Part B – Standard Operating Procedures

SOP 1 – Application Pathway: Submission and Levels of Review

All research conducted at The Melbourne Clinic must comply with the National Statement, the Australian Code for the Responsible Conduct of Research, the ICH Guideline for Good Clinical Practice, Healthscope's Code of Conduct and corporate policies and procedures, and applicable State and Commonwealth law, including privacy, health records and guardianship legislation. TMC REC reviews research conducted within TMC's own inpatient and outpatient/community programs, as well as research submitted by other institutions, research organisations or sponsors to be conducted at or in connection with The Melbourne Clinic or another Healthscope facility.

1. Researchers submit a cover letter addressed to the Chair, the TMC REC application form, the protocol or project description, participant information and consent form(s) (or a consent waiver request), investigator CV(s) for first-time applicants, and any TGA or clinical trial registration documentation to the Secretariat.
2. Applications for full Committee review must be received at least three weeks before the scheduled meeting date.
3. Before submitting a research application, staff should first confirm the activity is research and not quality assurance or clinical audit (data used only to compare local practice against an existing standard, with no intention to publish generalisable findings). Quality assurance activity does not require HREC review but should be notified to the Secretariat if there is any doubt.
4. The Secretariat checks each application for completeness and returns incomplete applications with a list of outstanding items.
5. The Chair (or delegate) assesses the risk level of the research against Chapter 2.1 of the National Statement (minimal, low, greater than low, or high risk) and sets the review pathway: greater-than-low risk, deception, a consent waiver or an opt-out approach proceeds to a full Committee meeting; no more than low risk may be considered by the Chair, Deputy Chair or an expedited sub-committee under delegated authority, for ratification at the next meeting; research that may be eligible for exemption under National Statement paragraph 5.1.17 is assessed by the Chair, with the decision and reasons recorded in an exemption register.
6. Before approaching an individual patient about a project, the researcher must obtain the treating consultant psychiatrist's or doctor's written permission on the Consultant Permission Form. This safeguard applies in addition to, and does not replace, the patient's own informed consent (see SOP 16).
7. Clinical trials of investigational medicines, devices or psychosocial interventions are prospectively registered on a publicly accessible clinical trials registry (e.g. ANZCTR) before commencement; the registration number is provided to the Secretariat.

SOP 2 – Meeting Procedures: Frequency, Attendance, Conduct

- TMC REC meets six times per year, on dates set and circulated at the start of each 12-month period.

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

- Members attend in person or by videoconference or teleconference. The Secretariat records which membership category each attending member represents; no individual represents more than one category at a given meeting. Quorum — representation of at least 50% of the minimum membership categories — is confirmed before business commences. Where a category is unrepresented, the Chair decides whether to proceed after obtaining that member's views in advance, or to defer the item.
- The Chair conducts the meeting in the following order: declarations of interest; confirmation of the previous minutes; new applications, with the principal investigator invited to present and answer questions; amendments; progress and annual reports; incident and adverse event reports; and general business.
- The Chair may invite external experts or observers to attend; a student researcher's supervisor may attend with the student. All such attendees leave the meeting before deliberation and decision-making, have no vote, and are bound by confidentiality.

SOP 3 – Agendas, Papers and Minutes

- The Secretariat prepares the agenda and compiles application papers, distributing the agenda at least one week before the meeting and application papers sufficiently in advance for members to be fully informed.
- The Secretariat drafts minutes covering attendance and apologies, conflict-of-interest declarations, confirmation of the previous minutes, new applications and decisions, amendments, progress and annual reports, incident and adverse event reports, complaints, and the next meeting date.
- Draft minutes are approved by the Chair and ratified as a true record at the next meeting.

SOP 4 – Deliberation and Decision-Making

- Each member forms an independent view, having read the papers in advance, on the scientific merit and ethical acceptability of the proposal. The Chair facilitates an exchange of opinions among members present and, where a minimum-membership-category member is absent, ensures that member's pre-submitted views are considered before a decision is made.
- Where the Committee lacks the specific expertise to assess an application — for example, a novel device, technology or intervention — the Chair may seek written advice from a suitably qualified person outside the Committee's membership. Any such expert declares in writing that they have no conflict of interest in relation to the application and agrees to maintain confidentiality; their advice is considered by the Committee, which retains sole responsibility for the decision.
- TMC REC seeks to reach decisions by consensus; voting is neither required nor prohibited. Possible outcomes are: approve; approve subject to conditions; require modification and resubmission; reject; or defer.
- Any dissent is recorded in the minutes, with reasons if the dissenting member requests this. Reasons for rejecting or withdrawing approval of a proposal, or for requiring modification, are linked, where possible, to the relevant National Statement paragraph. If genuine

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

consensus cannot be reached, the Chair calls for a vote by a show of hands; the outcome with the greatest number of votes is recorded as the Committee's decision.

- TMC REC may delegate responsibilities — for example, expedited review or approval of minor amendments — to the Chair, a member, a sub-committee or the Secretariat. Delegated decisions are not equivalent to Committee decisions and are ratified at the next meeting.

SOP 5 – Applications from Unaffiliated Researchers and Multi-Site Research

- A researcher who is not a Healthscope staff member must have a Healthscope staff member act as supervisor or collaborator, providing clinical cover for the project. The Secretariat can help identify a suitable staff member if needed.
- TMC REC reviews research in the specialty of psychiatry, mental health and the behavioural sciences, conducted at The Melbourne Clinic and other Victorian Healthscope hospitals. It does not review research with a primary surgical or medical (non-psychiatric) focus, or research at Healthscope facilities outside Victoria; researchers with such proposals are directed to their nearest NHMRC-registered HREC.
- Where a project is also conducted at another institution, the researcher provides evidence of that institution's ethics approval before TMC REC's approval takes effect for the TMC site.

SOP 6 – Disclosure of Interests and Management of Conflicts of Interest

- At the start of each meeting, and again for each agenda item, the Chair asks members to disclose any actual, potential or perceived conflict of interest, financial or non-financial.
- Being named as an investigator on an application is treated as a substantial conflict: that member takes no part in deliberation or decision-making on the item and leaves the meeting for it. Where the Chair holds the conflict, the Deputy Chair assumes the Chair's role for that item.
- Other, non-substantial conflicts (for example, a professional or collegial connection to the researcher, without personal involvement in the study) are discussed with the Chair. In these cases the member may, at their discretion, remain for the discussion or choose to leave the meeting for that item.
- All disclosures, and how they were managed, are recorded in the minutes.
- Conflicts of interest disclosed by researchers in an application are assessed by the Committee, which may require disclosure to participants, a changed research role, independent oversight arrangements, or other measures consistent with National Statement Chapter 5.6.
- Where a conflict of interest arises at an institutional level — for example, a financial relationship between Healthscope and a study sponsor — the Committee identifies and manages it in the same way as an individual conflict, including by seeking independent oversight or advice where appropriate.

SOP 7 – Confidentiality

- Applications, supporting documents, correspondence, agendas and minutes are treated as confidential. Meetings are held in private.

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

- All members, invited experts and observers are bound by confidentiality; external experts sign a confidentiality undertaking.
- Committee correspondence is addressed to the principal investigator or nominated contact and is not released to a sponsor or other party except through the researcher.
- Papers are disposed of through confidential recycling after use.

SOP 8 – Notification and Communication with Researchers

- The Secretariat notifies researchers of the Committee's decision in writing, within 10 business days of the meeting.
- Approvals, rejections and withdrawals state explicitly whether the proposal meets the requirements of the National Statement, with reasons where relevant.
- Where modification is requested, the notification, or recorded informal communication, specifies the required changes and who the response should be directed to.
- Each approved project is allocated a project number, to be used in all future correspondence with the Committee.

SOP 9 – Record Keeping

The Secretariat maintains a complete record for every proposal received, including: the institution(s) covered by the approval; project ID and title; principal researcher(s); correspondence about the review; advice of approval, rejection or amendment; conditions and duration of approval; expected completion date; any other review body consulted; approved monitoring mechanisms; and any privacy-related assessments; and the review pathway used (full Committee, expedited, or exemption).

- Applications, amendments and supporting documents are submitted to the Secretariat electronically, together with any hard copies specified in the current application instructions.
- Approved project documentation and related correspondence are retained for a minimum of seven years after completion of the research, consistent with Victorian health records retention requirements, or a minimum of fifteen years for clinical trial research, whichever is longer, or such longer period as required by the sponsor agreement, TGA requirements or Healthscope policy. Identifiable health research data relating to a participant who was a minor at the time of the research may need to be retained until that participant turns 25.
- All members, invited experts and observers are bound by confidentiality in respect of these records.

SOP 10 – Monitoring of Approved Research, Amendments and Progress Reports

- Approval is granted for three years. Researchers apply for an extension before the approval end date; if no extension is sought, approval for the project terminates.
- Researchers submit a progress report at least annually and at completion of the project, covering progress or outcome to date, the security of project data, and compliance with the approved proposal and its conditions. TMC REC sends the progress report form ahead of the final meeting of the year.

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

- All changes to an approved project are submitted in writing with a covering letter to the Chair, other than a change made to immediately eliminate a risk to participants, which is reported as soon as possible afterwards. Amended documents are provided in tracked-changes and clean versions, with an updated version number, date and pagination.
- The study team keeps insurance, indemnity and Clinical Trial Notification documentation current and forwards updates to the Committee before expiry.
- A copy of any resulting publication is provided to the Secretariat with the annual report, and TMC REC's role should be acknowledged in the publication.
- The Secretariat maintains a monitoring register and follows up overdue reports. Continuation of approval is conditional on timely compliance with these requirements.
- For clinical trials of investigational medicines or devices, an Annual Safety Report is submitted for each year the trial continues, in line with the NHMRC guidance on safety monitoring and reporting in clinical trials involving therapeutic goods. This is separate from, and in addition to, individual adverse event reports (SOP 11) and the annual progress report above.

SOP 11 – Adverse Events, Incidents and Safety Reporting

Reportable events include:

- serious and non-serious adverse events in investigator-initiated studies;
- suspected unexpected serious adverse reactions and unanticipated serious adverse device effects in clinical trials;
- protocol deviations or breaches;
- data or privacy breaches;
- unexpected participant harm or distress not foreshadowed in the application; and
- complaints made directly to a researcher about the conduct of the research, which are handled as an incident (see SOP 12).
- Investigator-initiated studies: written notification of all serious and non-serious adverse events is provided at the next Committee meeting following the event. An event is reportable if it falls outside the expected outcomes for enrolled participants, or is a serious adverse event — one that results in death, is life-threatening, requires or prolongs hospitalisation, results in persistent or significant disability, or is a congenital anomaly. A participant death is reported within 24 hours.
- Industry-sponsored studies: six-monthly line listings of suspected unexpected serious adverse reactions are acceptable, in addition to any individual expedited reports required by the sponsor.
- The Secretariat triages incoming reports. Where there is a serious or ongoing risk to participants, the report is escalated immediately to the Chair for consideration of interim action (see SOP 13); otherwise it is placed on the agenda for the next meeting.
- When reviewing a report, the Committee considers whether it explains what happened and why, whether the researcher's remedial action is adequate, whether there is unmanaged ongoing risk, and whether it may indicate a breach of the Australian Code for the Responsible

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

Conduct of Research, in which case it is referred to Healthscope's research governance function.

- Data or privacy breaches that may constitute a notifiable data breach under the Privacy Act 1988 (Cth) are escalated immediately to the Chair and to Healthscope's Privacy Officer, who determine whether notification to the Office of the Australian Information Commissioner and affected individuals is required.

SOP 12 – Complaints

Complaints about a research project or researcher

- Made in writing to the Chair, care of the TMC REC Secretariat (phone +61 3 9420 9353, email tmc.research@healthscope.com.au). Contact details are also included in every project's Patient/Subject Information Form. The Secretariat logs and acknowledges the complaint and handles it as an incident report under SOP 11. Complaints raising a possible breach of the Australian Code for the Responsible Conduct of Research are referred to Healthscope's research governance function.

Reconsideration of a decision

- Where an application is rejected, or approved subject to conditions the researcher disputes, the researcher may either resubmit an amended application addressing the Committee's concerns, or lodge a written request for reconsideration with the Chair, setting out the grounds.
- A request for reconsideration is considered by the Committee at its next meeting, or under delegation where the original decision was made under delegation. The researcher is notified of the outcome in writing, with reasons.

Complaints about TMC REC's own conduct

- The Chair first seeks to resolve the complaint directly with the complainant.
- If unresolved, the matter is referred to an independent assessor, appointed by the General Manager, who is not a member of TMC REC and not otherwise involved in the matter, for a procedural fairness review. The outcome is communicated to the complainant and the Committee in writing. A procedural fairness finding may result in an application being returned to TMC REC for a fresh review; the Committee's substantive ethical judgement is not overridden by the institution.
- All complaints and their outcomes are logged in a complaints register, which informs TMC REC's annual report.

SOP 13 – Suspension or Withdrawal of Ethical Approval

- Where TMC REC has reason to believe that continuing a project will compromise participant welfare, or that approval conditions are not being met, the Chair convenes the Committee, or acts under delegation subject to ratification, to decide whether approval should be suspended or withdrawn.
- Only the authorising institution can instruct a researcher to suspend or cease a project; TMC REC determines and advises the ethics position.

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

- Any suspension or withdrawal decision, with reasons, is communicated in writing to the researcher and the institution, and reported to the General Manager and Executive Team. Where possible, participants are informed and continuity of care or support is arranged.
- Resumption after suspension requires either an approved modification addressing the concern, or the researcher satisfying the Committee that continuation will not compromise participant welfare. Resumption after withdrawal requires a new application.

SOP 14 – Ethics Fees

TMC REC charges a fee for the review of most projects, and for all industry-sponsored projects, as set out below. Fees are payable before submission and are invoiced by the Secretariat.

Category	Fee (AUD, excl. GST)
Commercially sponsored – initial application	$6000
Commercially sponsored – ongoing annual administration fee	$1500
Commercially sponsored – protocol amendment (per version)	$800
Industry sponsored sub-study or extension	$3000
Investigator initiated (sponsor funded)	$3000
Non sponsored, Collaborative Group, Government or Philanthropic Grant	$600
Administrative amendments (not The Melbourne Clinic)	$100
Healthscope staff (not The Melbourne Clinic)	$0
Student (external to The Melbourne Clinic)	$100
Annual service fee (external to The Melbourne Clinic)	$100

Research by Healthscope or TMC staff for internal quality, education or professional development purposes with no external funding is not charged a fee.

The Chair may waive or reduce a fee where it would otherwise discourage worthwhile research, consistent with National Statement Chapter 5.1. Changes to the fee schedule are approved by the Chair in consultation with the General Manager.

SOP 15 – Member Governance: Appointment, Induction and Training

Appointment terms, review cycles and remuneration are set out in Part A of this document (Appointments). This SOP covers induction and ongoing training.

- New members receive induction covering the Terms of Reference, these SOPs, the National Statement, and their confidentiality and conflict-of-interest obligations, with mentoring by an experienced member where available.
- Members undertake continuing education or training in research ethics at least every three years, or more frequently if offered.
- Members confirm in writing, on appointment and periodically thereafter, that they understand and will comply with their confidentiality and disclosure-of-interest obligations.
- The Secretariat maintains a record of each member's induction and training. Current TMC REC membership is published on the TMC REC webpage.

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

SOP 16 – Additional Safeguards for Research Involving People Experiencing Mental Ill-Health

TMC REC's participant population will typically include people experiencing mental ill-health, some of whom may be inpatients receiving acute treatment. These safeguards apply in addition to SOPs 1–15.

- Presumption of capacity: every adult is assumed able to make their own decision about participation, unless an individual assessment indicates otherwise. A diagnosis or group label must never, by itself, be treated as evidence of incapacity. A patient's legal status, including where a patient is receiving treatment on a compulsory basis under applicable Victorian mental health legislation, does not by itself mean they lack the capacity to make a decision about research participation; capacity is assessed individually and is specific to the decision at hand.
- Assessing capacity: applications must specify how capacity to consent will be assessed, by whom, on what criteria, and how it will be reviewed if capacity may fluctuate during the research. Where capacity is absent or fluctuating, applications describe arrangements for seeking consent from a person authorised to make the decision (for example, a guardian or medical treatment decision maker), while still explaining the research to the participant to the extent possible and seeking their agreement to participate, and describe how the participant's own wishes will be identified and followed.
- Independence from the treating relationship: the Consultant Permission Form (SOP 1) applies in addition to the patient's own consent. Where the researcher is also the participant's treating clinician, the Committee will consider whether an independent person should make the initial approach and/or seek consent.
- Managing distress: reluctance, discomfort or distress during a research activity is not automatically treated as a wish to withdraw. Applications describe a protocol for pausing the activity, exploring the reasons with the participant, and what happens if a participant becomes acutely unwell or at risk of self-harm during participation, including how the treating team is informed. A sustained and unequivocal refusal to continue is always respected.
- Review pathway: research involving people who are acutely unwell, or otherwise unable to provide consent at the time of recruitment, usually requires full Committee review; an alternative pathway must be specifically justified. Lower-risk research involving participants with full capacity, such as anonymous outpatient surveys, may use the expedited pathway described in SOP 1.

SOP 17 – Additional Safeguards for Research Involving Children and Young People

TMC REC may receive applications for research involving people under 18 — a 'child' under the National Statement, with 'young person' often used for older children — including outpatient or community-based research submitted by external researchers, institutions, research organisations or sponsors. These safeguards apply in addition to SOPs 1–16, drawing on National Statement Chapter 4.3.

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

- Consent and assent: applications specify whether the young person's own consent will be sought, or their assent together with parental or guardian consent, and describe how the young person's capacity to consent or assent will be assessed — on an individual basis, having regard to their maturity and the nature of the research, not by age alone.
- Where a young person of developing maturity cannot provide valid consent and no parent, guardian or other authorised person is available to consent on their behalf, TMC REC may only approve their participation in the very limited circumstances set out in National Statement paragraph 4.3.8 — including that the young person can give informed assent, and that seeking parental or guardian consent is genuinely not practicable or would be contrary to the young person's interests.
- A child or young person's refusal to participate, or decision to withdraw, is respected. Applications describe the limited circumstances, if any, in which a parent or guardian's decision might override this, consistent with National Statement paragraph 4.3.9.
- Where researchers will have direct or indirect contact with children or young people, applications describe the supervision arrangements, contact methods, and relevant credentials or clearances held by researchers and project staff (for example, a Working with Children Check), and confirm the research is consistent with the National Principles for Child Safe Organisations.
- TMC REC ensures a member or invited reviewer with relevant knowledge of child or adolescent development, or paediatric/youth mental health, is involved in reviewing applications in this category, in addition to standing membership categories.
- This SOP applies equally to research proposed by TMC or Healthscope researchers and to research submitted by external institutions, research organisations or sponsors for outpatient or community-based settings.

SOP 18 – Additional Safeguards for Research Involving Aboriginal and/or Torres Strait Islander People and Communities

TMC REC may receive applications for research with, or involving a significant proportion of, Aboriginal and/or Torres Strait Islander people and communities, whether proposed by TMC or Healthscope researchers or submitted by external institutions, research organisations or sponsors. These safeguards apply in addition to SOPs 1–17, drawing on National Statement Chapter 4.7.

- Applications and the Committee's review are guided by NHMRC's Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders (2018) and its companion Keeping Research on Track II, and by the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020).
- Applications demonstrate respectful and meaningful engagement with the relevant Aboriginal and/or Torres Strait Islander people, organisations or communities, from the design stage of the research — for example, a research agreement, or written confirmation of agreement to participate from the relevant community or organisation.
- Applications describe how the research will benefit Aboriginal and/or Torres Strait Islander people and communities, how those benefits were discussed and agreed with participants or

130 Church Street,
Richmond VIC 3121
P (03) 9429 4688
F (03) 9427 7558
themelbourneclinic.com.au

communities, and how the researchers are culturally capable and competent to conduct the research, with supporting evidence.

- Where TMC REC does not have a member with relevant Aboriginal and/or Torres Strait Islander cultural knowledge and experience available for a particular application, the Chair seeks advice from a person who is culturally capable and competent, or from another HREC with specialist expertise in this area, consistent with National Statement paragraph 4.7.15.
- This SOP applies equally to research proposed by TMC or Healthscope researchers and to research submitted by external institutions, research organisations or sponsors.

Review of this document

This document is reviewed at least every three years, or earlier if there are significant changes to the National Statement or other applicable regulatory requirements.

Contact

TMC REC Secretariat — Phone: +61 3 9420 9353 — Email: tmc.research@healthscope.com.au