



The Melbourne Clinic Research Ethics Committee

Conditions and Guidelines

Please read this document fully

1. Mission

The Melbourne Clinic Research Ethics Committee (TMC REC) has a commitment to excellence in clinical research leading to improved outcomes.

2. Roles and Responsibilities of the TMC REC and Researchers

The role of the TMC REC is to develop policy and monitor and review all matters pertaining to human research ethics for Healthscope Psychiatric and Mental Health facilities in Victoria.

The TMC REC is responsible for liaison with external organisations, the co-ordination of information and will also act as a committee of appeal against decisions and will hear complaints on projects within its purview.

The research proposal evaluation process ensures that standards of patient care are not compromised and that investigators and the institution are protected.

The Principal Investigator (PI) is the individual who is responsible for the conduct of the research. In the case of a student researcher the student's supervisor is the person who is regarded as the PI.

3. Guidelines and Policy

The TMC REC uses as a reference, the NHMRC *National Statement on Ethics Conduct in Human Research (2007)* and as a basic standard it is expected that all researchers will comply with the *Australian Code for the Responsible Conduct of Research (2007)* and the *ICH Guidelines for Good Clinical Practice (GCP)*. These guidelines apply to all persons conducting research within a Healthscope facility.

In addition, it is expected that all researchers are familiar with, and will conform to, the Healthscope Corporate Policy and Procedures in conjunction with State and Commonwealth laws and principals concerning, privacy, health records, guardianship and administration.

A further requirement is that the nature of the research is such that it can be integrated with ongoing patient care in a way that complements existing clinical programs.

Because Healthscope hospitals are private hospitals, in addition to the usual Patient Informed Consent, it is required that the treating Consultant Psychiatrists give permission for the involvement of individual patients under his or her care.

4. Which projects are reviewed by TMC REC?

The TMC REC accepts applications for research projects involving clinical work at TMC and other Healthscope hospitals in Victoria, which are primarily concerned with psychiatry, mental health and the behavioural sciences. TMC REC reviews clinical trials of psychiatric and psychological treatment, which may include medications, physical, psychosocial treatments and program evaluation.

TMC REC does not review research projects for Healthscope facilities in a state other than Victoria, nor does it review research projects with a primary Surgical or Medical focus. In these circumstances, it is suggested that you approach the nearest Human Research Ethics Committee registered with the National Health & Medical Research Council in your area. Such Committees are likely to be found at your nearest teaching hospital or University. Please note that if you do fall under these latter categories once you have received Ethics Approval it is the PIs' responsibility to make the General Manager and the Medical Advisory Committee of the Healthscope facility in which you intend to carry out your project aware of the fact.

5. Quality Assurance Projects & Program Evaluation

Whether collecting data directly or indirectly from a patient it is sometimes difficult to decide whether a project that falls under the banner of Quality Assurance, Program Evaluation or Research. Quality Assurance, Peer Review, and Audit are all terms sometimes used interchangeably and fall on a continuum with research. What matters is, that those staff who undertake any of these activities are compliant with the relevant ethical institutional, State and Commonwealth laws and principals as outlined above in point 3. *Guidelines and Policy*. If your project is likely to impinge on any of these areas then the wisest solution is to seek Ethics Approval.

When deciding whether or not a quality assurance project requires ethics review the following link to the NHMRC document "*When does quality assurance in health care require independent ethics review*" (2003) can provide assistance, particularly the questions on pages 6 & 7.

<http://www.nhmrc.gov.au/publications/synopses/e46syn.htm>

Additionally, be aware that if you intend to publish your Audit or Quality Assurance project that some journal editors insist that a Research Ethics Committee has reviewed the project.

6. Procedure and required documents for submission of a new research proposal to The Melbourne Clinic Research Ethics Committee

- An application for approval of a research proposal should be lodged on the **TMC REC Application** form obtainable from this web site (as are a number of other forms mentioned in this section) or can be obtained by contacting:

Deidre Smith
The Melbourne Clinic Research & Ethics Committee Secretariat,
Professorial Unit
The Melbourne Clinic
130 Church St
Richmond Vic 3121
Ph: 9420 9353
Email: djsmit@unimelb.edu.au

- A formal **Letter to the Chair** of the TMC REC requesting a review of the application should accompany the TMC Application Form.
- A **Research Proposal** containing a literature review, the aims of the study and a research plan i.e. the methodology and planned data analysis should also accompany the application.
- The **Patient Information and Consent Form** is an integral part of the application.
- The **Consultant Psychiatrist Consent Form**.

- If the proposed study is an industry sponsored clinical trial of medication or a physical device then indemnity, insurance and the CTN documents should be attached as part of the proposal.
- Twelve (12) copies of the completed application form, written proposal and all appendix & attachments should be forwarded to the Secretariat of the TMC Research Ethics Committee (at the address above). They should be received at least three weeks prior to the date of the meeting at which it will be considered. The copies should be double sided on A4 paper. Please do not use folders or inserts that exceed the dimensions of a sheet of A4 paper.
- If this the application is a first ever application from a Principal Investigator; then a brief **Curriculum Vitae for the PI** should be attached to the application giving details of research experience and expertise, including grants and publications.
- In the event that the research is to be based in a hospital or institution other than a Healthscope hospital, evidence will be required that the proposal has been accepted by the ethics committee of that hospital or institution. The evidence is usually in the form of a copy of the **Letter of Approval**.
- Please ensure that all applications contain all **contact details** for the Principal investigator including postal address, email and mobile ph number.
- If further information regarding your application is required, then contact Ms Deidre Smith.

7. Research and Ethics Processes

The principal researcher of the research group will be requested to attend the meeting of The Melbourne Clinic Research Ethics Committee to present a brief outline of the study and answer any questions the Committee may have. Other investigators may also attend. If the project is a student research project the Committee invites the student to attend **in addition to** the supervisor.

The Committee meets between 2 and 3 pm in the Boardroom at The Melbourne Clinic, 130 Church Street Richmond (see Melways ref 2H A4). The TMC Secretariat will advise you of your appointment time.

Following approval by the Research Ethics Committee, the applicant will be notified in writing. A written undertaking will then be sought from the researcher/s that compliance with the stated requirements will be met.

8. Fees

Please note that the submission of industry-sponsored projects will incur a fee.

9. Ongoing Management of Approved Projects

Amendments

- All changes to the conduct of an approved project are to put in writing using the TMC REC Application Form with a covering letter to the Chair briefly outlining the proposed change.

Safety & Adverse Events Reporting

- The TMC REC requires written notification of all serious and non-serious adverse events at the next committee meeting date following the event.

Change of PI Contact Details

- Any changes to the PI contact details must be forwarded to the Secretariat as soon as possible.

Annual Reports

- Progress reports on the research are required annually, usually by the last meeting date in December. You will be sent a form for completion in advance of the December meeting.

Complaints Procedure

- Complaints should be forwarded in writing to the Chair.

It is expected that completed research projects will be submitted for publication, and the participation of The Melbourne Clinic Research Ethics Committee should be appropriately acknowledged. A copy of published papers should be provided to the Secretariat for the Research Ethics file.

TMC Research Ethics Committee dates & deadlines for 2009

Submission Dates

January 28th
March 25th
May 27th
July 29th
September 30th
November 25th

Meeting Dates

February 11th
April 8th
June 10th
August 12th
October 14th
December 9th

TMC Research Ethics Committee Dates & Deadlines for 2010

Submission Dates

January 27th
March 24th
May 26th
July 28th
September 29th
November 24th

Meeting Dates

February 10th
April 7th
June 9th
August 11th
October 13th
December 8th