

Policies and Procedures for the Submission of Research Proposals in clinical psychiatry to The Melbourne Clinic Research Ethics Committee

Please read this document fully

The Melbourne Clinic Research Ethics Committee accepts applications for research projects involving clinical work at this hospital and other Healthscope hospitals.

Research proposals are required to undergo an evaluation process to ensure that standards of patient care are not compromised in any way and that the proposed research complies with acceptable ethical standards for medical research. As a guideline, the NH&MRC Statement on National Statement on Ethical Conduct in Human Research (2007) and the Royal Australian and New Zealand College of Psychiatrists' Code of Ethics will be used as references. In the event that the research is emanating from and/or is based in another 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. 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. All Clinical trials should be registered prospectively on a publically accessible Clinical Trials website, such as the Australian New Zealand Clinical Trials Registry (ACTR) as per the guidelines of the National Statement on Ethical Conduct in Human Research (2007).

Because Healthscope hospitals' are private hospitals, in addition to the usual appropriate informed consent of patients being obtained, it is required that individual Consultant Psychiatrists give permission for the involvement in research of individual patients under their care.

PROCEDURE:

1. An application for approval of a research proposal should be lodged on the appropriate form obtainable from Deidre Smith (Research Manager, Professorial Unit) who can be reached via email djsmit@unimelb.edu.au or by phoning Deidre on 9420 9353. If necessary or appropriate, the proposal can be discussed with one of the following – Deidre Smith, the Chairman of the Research Ethics Committee or the Professor of Psychiatry to ensure that the research design complies with the requirements.
2. Twelve (12) copies of the completed application form, written proposal and all appendix & attachments should be forwarded to the Research Ethics Committee to 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 which exceed the dimensions of a sheet of A4 paper.

To assist the Committee in its consideration of the project, researchers are requested to highlight on the Consent Form any variations from The Melbourne Clinic standard consent form.

3. The principal investigator should be the individual involved in the research with final responsibility for the conduct of the research. In the case of student research the student's supervisor is the person who is regarded as the principal investigator.

If this is the first application from a principal investigator then a brief curriculum vitae for the principal investigator should be attached to the application giving details of research

experience and expertise, including grants and publications and especially covering areas of relevance to the application.

4. The principal researcher of the research group is 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. The Committee meets between 2 and 3 pm in the Boardroom at The Melbourne Clinic, 130 Church Street, Richmond. The Research Manager will advise you of the time when your study will be considered. Other investigators may also attend and when it is a student research project the Committee invites the student to attend **in addition to** the supervisor.
5. Following the approval by the Research Ethics Committee, the result will be notified to the applicant. Written undertaking will then be sought from the researcher/s that compliance with the stated requirements will be met. Any modifications to the protocol will require further approval.
6. Informed consent for participation in the research is to be established by the following steps:
 - a) Written permission must be obtained from the relevant consultant psychiatrist for the involvement of each patient, together with confirmation that the patient is capable of providing informed consent.
 - b) Formal written consent must then be obtained from each patient in a manner conforming to the guidelines.
 - d) Copies of both the patient and psychiatrist's consent are to be made and kept on the patient's medical record.
7. Progress reports on the research are required to be submitted to the Research Ethics Committee annually, usually by the last meeting date in December. You will be sent a form for completion in advance.
8. Completed research projects are expected to be submitted for publication, and the participation of The Melbourne Clinic will be required to be appropriately acknowledged. A copy of the material published should be provided to The Clinic for its file.