

Minimum Requirements for Human Research Ethics and Governance Proposals

There are two human ethics review processes available, depending on the level of risk participants may be exposed to as a result of their participation in the research. Regular Human Research Ethics Committee (HREC) meetings deal with higher risk research. Research involving no more than low risk may be reviewed under other processes as described in the National Statement paragraphs 5.1.18 to 5.1.21. Institutions may also determine that some human research is exempt from ethical review see National Statement paragraphs 5.1.22 and 5.1.23. All human research applications also require a submission to the Research Governance Office.

Submissions to HREC meetings

To the Research Ethics Office

1. Covering letter outlining request for ethical review and all supporting documentation listed
2. Completed application forms
 - a. Go to www.neaf.gov.au to access the National Ethics Application Form (the Mater Ethics Application Form has been archived and is no longer accepted).
 - b. For multicentre projects, if you have already received HREC approval from another hospital/institution please provide the ethics approval letters received. Mater HREC adopts a review process that eliminates unnecessary duplication of ethical review (National Statement, paragraph 5.3.1).
3. Research Protocol (or successful peer-reviewed internationally or nationally recognized grant application, e.g. NHMRC, ARC).
4. Patient Information Sheet & Consent Form (See Consent Guidelines on Useful Links section of website)
5. Child/Young Person Information Sheet & Assent Form (these documents should be designed to be understood at various developmental or other stages of cognitive capacity, and where additional consent from a parent/guardian is warranted you may need to consider developing more than one information sheet).
6. Staff Information Sheet (on Useful Links section of website)

Five hard copies (one original and four photocopies) of all documentation are to be submitted to the Mater Research Ethics Secretariat office. In addition, an electronic copy (*.doc, *.docx, *.pdf) of all documentation is to be emailed to research.ethics@mmri.mater.org.au.

The closing time for submissions is 4pm. Please note: there are no exceptions to the closing time without prior agreement by the HREC Administrator (ext. 2392).

The Scientific Advisory Committee (SAC) and HREC meet monthly (except January). Please refer to the Calendar for closing dates and meeting dates.

To download application form, consent & patient information sheet guidelines, or access the calendar please go to the Human Research Ethics and Governance website.

To the Research Governance Office

1. Site Specific Assessment form (located on website).
2. Pathology Agreement (if applicable – e.g. are you collecting, storing, and transporting any pathological samples/tissues? An agreement is required to clearly outline who is covering these costs).
3. Pharmacy Agreement (if applicable – e.g. will the pharmacy be storing or dispensing the study medication?).
4. Radiology Agreement (if applicable – e.g. will your participants require more MRIs, CT scans, chest x-rays than they would normally receive under standard care? These costs must be covered by research funds).
5. Radiation Safety Report (if applicable – e.g. If your research includes radiation therapy).
6. Clinical Trial Agreement, CTN, Insurance and Indemnity – liaise with Mr. Justin Sharp, Rogencamp & Co (Lawyers@mater.org.au) if advice is required or documents to be checked.
7. Resource Implications – (Please liaise with your Management Accountant, they can provide advice on how to prepare your budget):
 - a. Have you completed your Budget?
 - b. Has it been endorsed by your Management Accountant?
8. Endorsement from the Executive Director of the participating hospital/hospitals. The Executive Director/s will sign the application after financial sign off.
9. Do you require a Mater sponsor? **If the Principal Investigator is not a Mater staff member, the project must include a Mater sponsor.** Please ensure that the Mater sponsor understands their responsibilities in regards to the conduct of the study at Mater.
10. Please ensure you give sufficient time to your Accountant, Mater sponsor and Executive Director to sign your application. Applications that have not been signed will not be accepted.
11. Collaborative Research Agreement (CRA) – All projects conducted between MHS/MMRI and other Institutions require a research agreement between all parties involved before work can commence. Please contact the Research Governance Officer for advice on preparing a CRA.

Amendments

All amendments (including administrative changes) to previously approved documentation require approval before being implemented in ongoing research.

To the Research Ethics Office

1. Covering letter outlining amendment request and all amended documentation listed (including amended Version no. and Date).
2. One 'tracked changes' copy (highlighting differences) and clean (tracked changes accepted) copy of any previously approved documentation altered by the amendment.

Three hard copies (one original and two photocopies) of all documentation (both tracked and clean copies) are to be submitted to the Mater Research Ethics Secretariat office. In addition, an electronic copy (*.doc, *.docx, *.pdf) of all documentation is to be emailed to research.ethics@mmri.mater.org.au.

To the Research Governance Office

1. One 'tracked changes' copy (highlighting differences) and clean (tracked changes accepted) copy of the SSA and any previously approved documentation altered by the amendment.

Progress Reports

Under Section 3.3.22 of the National Statement on Ethical Conduct in Human Research, the granting and continuation of ethical approval of clinical research must be on the condition that, for any trial site under the HREC's responsibility, the researcher provides reports of the progress of the trial to the HREC, at a frequency directed by the HREC (but at least annually), and related to the degree of risk to participants.

To the Research Ethics and Governance Office

1. Mater Progress Report Form (located on website).

Submissions for Low and Negligible Risk projects & exempt from ethical review process

To the Research Ethics and Governance Office

1. Mater Low and Negligible Risk Application Form (located on website).
2. Research Protocol (or successful peer-reviewed internationally or nationally recognised grant application, e.g. NHMRC, ARC).
3. Resource Implications – (Please liaise with your Management Accountant, they can provide advice on how to prepare your budget):
 - a. Have you completed your Budget?
 - b. Has it been endorsed by your Management Accountant?
4. Endorsement from the Executive Director of the participating hospital/hospitals. The Executive Director/s will sign the application after financial sign off.
5. Do you require a Mater sponsor? **If the Principal Investigator is not a Mater staff member, the project must include a Mater sponsor.** Please ensure that the Mater sponsor understands their responsibilities in regards to the conduct of the study at Mater.
6. Please ensure you give sufficient time to your Accountant, Mater sponsor and Executive Director to sign your application. Applications that have not been signed will not be accepted by the Research Ethics Secretariat.

Applications for Low and Negligible Risk, or Exempt from ethical review may be submitted at any time (i.e. not subject to closing dates and meeting dates)

Three hard copies (one original and two photocopies) of all documentation are to be submitted to the Mater Research Ethics Secretariat office. In addition, an electronic copy (*.doc, *.docx, *.pdf) of all documentation is to be emailed to research.ethics@mmri.mater.org.au.

Note

ALL INCOMPLETE APPLICATIONS ARE DEEMED INVALID AND WILL NOT BE ACCEPTED.

ALL DOCUMENTS MUST BE COLLATED AND CLIPPED TOGETHER, AND CONTAIN VERSION NUMBERS, VERSION DATES AND PAGE NUMBERS. DOUBLE-SIDED PHOTOCOPYING IS RECOMMENDED.

Contact

Research Ethics & Governance Office

Ph: (07) 3163 2392

Fax: (07) 3163 1571

Email: research.ethics@mmri.mater.org.au for ethics or

research.governance@mmri.mater.org.au for governance enquiries

Website: www.mater.org.au/Home/Research/Human-Research-Ethics-Committee.aspx