Standard Operating Procedures - Human Research Ethics Committee Office Staff

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1. Introduction

1.1 Purpose

The procedures in this document describe the role of the Mater Misericordiae Ltd (MML) Human Research Ethics Committee (HREC) and the administrative processes involved in relation to the ethics review of human research.

1.2 Scope and context

Human research conducted at MML or for which MML is responsible must be reviewed in terms of scientific and ethical validity and monitored in accordance with documents set out in Section 1.3.

These procedures apply to the conduct of all human research that is carried out in collaboration with MML, Mater Research Ltd (MR) facilities, or involving people human tissue and data (medical and personal records or information).

1.3 Fundamental guidelines

Document ID	Document title
	NHMRC National Statement on Ethical Conduct in Human Research 2007 (updated 2018)
CT-RSH-300000	Mater Misericordiae Ltd Human Research Ethics Committee (MML HREC) (EC00332) Terms of Reference

2. Procedure requirements

In general, all proposals that do not qualify for exemption from the requirement of full HREC review, expedited review, or a review under exceptional circumstances (as described in section 3.1.4), must be submitted to MML HREC for approval.

This requirement does not preclude the institution accepting an ethical approval conducted by another certified HREC.

The following procedures are to be followed:

2.1 New Application for Ethical Review

2.1.1 Applications for ethical review

- All new applications for ethical review are to be submitted using the Ethical Review Manager (ERM) version of the Human Research Ethics Application (HREA).

- All studies with a risk level deemed by the HREC Liaison Officer and/or Chairperson as more than low risk *(NS 2.1.6-7),* satisfying criteria *National Statement* 5.1.6 (b), or requiring approval of a waiver of consent or an opt-out consent will be placed on the next agenda for full Committee review.
- Applications intended for review at the next HREC meeting must be submitted to the HREC Office via ERM by closing time on the closing day for applications. Late submissions will be held over until the following HREC meeting unless the CPI/PI has negotiated the late submission with the HREC Office.
- Only those confirmed as valid applications by the HREC Liaison Officer or delegate will be placed on the agenda.
- Upon receipt of an application, the HREC Office must check that validation requirements have been satisfied as per Work Instruction- New Applications (WI-RSH-3.004.01). This includes, but is not limited to:
  - All required signatures are in the application – CPI or PI plus supervisor/s if the PI is a student or undertaking the research for the purpose of a higher degree
  - All appropriate supporting documentation has been submitted.

2.1.2 Low and negligible risk (LNR) research [*National Statement* 2.1.6,5.1.18-5.1.21]

- Low risk studies that seek participant consent and where the only foreseeable risk is one of discomfort, or negligible risk research in which there is no foreseeable risk of harm or discomfort may be reviewed by two HREC members (one of which may be the Chairperson).
- Low risk studies requiring a waiver of consent (National Statement sections 2.3.9-11 and Section 95, 95A and 95AA of the Privacy Act) or an opt-out consent process (National Statement sections 2.3.6-8) will be reviewed by the full Committee.
- Even where the risk is considered low if described in National Statement 5.1.6 (b) it requires review by the full Committee. This includes:
  - Chapter 4.1: Women who are pregnant and the human fetus
  - Chapter 4.4: People highly dependent on medical care who may be unable to give consent
  - Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness
  - Chapter 4.7: Aboriginal and Torres Strait Islander Peoples, and some categories of research
  - Some categories of research falling under Chapter 4.6: People who may be involved in illegal activities.
- Low risk applications must be submitted using the ERM version of the HREA
- Additional information may be required before approval
- An electronic copy of the approval letter is provided to the researcher via ERM

- Approval of the research project may be granted between meetings and noted by MML HREC at the next meeting
- The decision to grant the waiver of consent, or opt-out consent, and the reasons for the decision, and as appropriate the ethical and legal justification, must be recorded in the HREC approval letter.

2.1.3 Exemption from the requirement of HREC approval by MML HREC

- The NHRMC National Approach recognises the need for Single Ethical Review for Multi-Centre research.
- In recognition of this, Mater Misericordiae Limited (MML) maintains a Memorandum of Understanding with Queensland Health and QIMR Berghofer for matters related to HREC approval.
- Therefore, if an application has been approved by another certified lead HREC that conforms with this MoU and lists Mater Misericordiae Ltd as a site on the HREC approval, further review by MML HREC is not required. The application may proceed to the Research Governance Office for site authorisation requirements.
- Research considered exempt from HREC review must satisfy *National Statement* 5.1.22 (a) and (b) and 5.1.23.

2.1.4 Research that may be exempted from HREC review

- Researchers should write to the HREC Chairperson and justify that their project is exempt in accordance with the National Statement guidance. If the HREC Chairperson agrees the researcher will be provided with a letter advising their project is exempt from the requirement of full ethical review in accordance with section 5.1.22 (a) and (b) and section 5.1.23. These projects are not exempt from the requirement of research governance review and authorisation.

2.1.5 Procedure for seeking exemption from HREC review for projects that are not research

- An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a quality assurance (QA) activity (e.g. an audit of practice against current standards). Terms such as "peer review", "quality assurance", "quality improvement", "quality activities", "quality studies" and "audit" are often used interchangeably and are considered part of a QA program, as is a project undertaken to understand the service provided (service evaluation).
- Undertaking a QA project does not require HREC approval and formal exemption from the requirement of full ethical review may be granted by the HREC Chairperson. This may occur when the project is recognised as not being research in accordance with the definition of research on page 6 of the *National Statement*.
- The project should be submitted via ERM under the Exempt pathway.
- The HREC Chairperson will review the submitted documentation and do one of the following:

- Consider the project, and provide a letter of exemption from the requirement of further ethical review stating that it does not meet the definition of research; or
- After review of the project recommend review by the HREC or sub-Committee because it is research and cannot be exempt from the requirement of ethical review. The researcher will then be required to prepare a HREA and submit under those requirements.

- Exemption from the requirement of full HREC review may be granted for presentations at conferences.
- Exemption from the requirement of full HREC review may be granted for case studies to be published. Many case studies are not research; and form part of clinical care and clinical training and they generally do not require any research ethics oversight. Where multiple case studies are presented they may constitute a case series, a form of research.
- Any presentation or publication outside of MML or MR of resulting information from a QA project requires oversight by MML Privacy Office.
- Research Governance authorisation is not required unless the project is considered research or has a research component however approval from MML Privacy Office is required for all projects.
- Applicants should always follow hospital policy in regard to clinical governance requirements for National Safety and Quality Health Service Standards and an associated Australian Health Service and Quality Accreditation (AHSSQA) Scheme.

2.1.6 Exceptional circumstances

- Applications that may qualify for a review under exceptional circumstances can be made through MML HREC Liaison Officer to the Chairperson. These include:
  - studies requiring an urgent review on the basis of maintaining, improving, sustaining or ensuring patient wellbeing and safety
  - studies requiring an urgent review to identify, reduce, expose or eliminate a real or potential risk or burden to participant safety or wellbeing
  - the necessity to eliminate an immediate hazard to the research participants
  - the urgent need for research data where there is an imminent threat to public health and / or
  - the chance to capitalise on a unique opportunity for significant research where there is only a limited time to consider participation.
- The application is first reviewed and assessed for its validity and suitability by the HREC Office and MML HREC Chairperson. If the Chairperson is satisfied that the application qualifies for review under exceptional circumstances, the Chairperson may:
  - Decide that expedited approval may be granted
  - Refer the application to any other member of MML HREC or expert reviewers for comment to assist in deciding whether approval should be given
  - Require amendment of the application, or
  - Refuse to grant expedited approval.

Exceptional circumstances review may be conducted on single site or multi-centre applications.

All levels of review and approval undertaken outside the monthly meeting will be noted or ratified by the full HREC at its next available monthly meeting.

2.1.7 The National Approach – single ethical review for multi-centre research

- MML HREC, MML and MR will operate in accordance with certification and; as outlined in the NHMRC National Approach to Single Ethical Review of Multi-centre Research and; as outlined in the MoU with Queensland Health and QIMR Berghofer.

2.1.8 Memorandums of Understanding (MoU)

- MML and MML HREC have formal mutual acceptance/recognition agreements with Queensland Health and QIMR Berghofer. The ethics approval procedure is set out in the agreement.
- The following advised procedures will be followed in the case of studies also involving QH or QIMR Berghofer sites.

SOP for QH HREC Administrators (External documents, reference 13)

Queensland Health advises:

- Only one HREC review is required for multi-centre research studies being undertaken in Queensland Health and MML.
- The HREC review from MML HREC is accepted throughout Queensland Health for all types of research, and is not restricted to clinical trials.
- MML HREC is not a signatory to the Interstate MoU (also known as the National Mutual Acceptance Scheme, abbreviated to NMA) therefore the review of MML HREC will not be accepted in public institutions outside of Queensland.
- MML is unable to participate in NMA.
- All participating sites for which the HREC review is valid must be listed on the HREC Approval letter.

Outside the context of a formal MoU, MML HREC and individual institutions may still undertake single ethical review of a multi-centre research study in keeping with the National Statement Chapter 5.3, and MML HREC ToR Section 1.5.

2.1.9 Approving multi-centre research to be conducted at a Mater site when a lead National Mutual Acceptance (NMA) HREC is unable to add Mater as a site

Because MML is not a signatory to the NMA (see 2.1.8) research projects may require MML HREC to also review and approve the study in order to participate in the research when the lead certified HREC is unable to add Mater as a site. As MML will take full responsibility for the research to be conducted at a Mater site, full HREC review is required.

This type of review is often required to approve Catholic wording in a Participant Information Sheet and Consent Form (PICF).

A new HREA may not be required; this can be negotiated with the HREC Liaison Officer or Chairperson. A letter outlining the reasons for the submission in the light of approval by another Committee and the management of relevant ethical and other issues should be provided. Researchers may submit a copy of the approved application and all supporting documents including site specific Participant Information Sheet and Consent Form (PICF) to a MML HREC monthly meeting.

2.1.10 Multi-centre Studies

- All multi-centre studies must have a Coordinating Principal Investigator (CPI).
- The HREC may communicate with the CPI or nominated Study Coordinator or contact person.
- Multi-centre research applications of all risk levels will be reviewed by MML HREC in accordance with its certification and the Memorandum of Understanding between MML, QH and QIMR Berghofer.

2.1.11 Student Research

- Student research includes undergraduate and postgraduate student work, including PhD research for the purpose of a higher degree.
- All students undertaking research at MML or MR require a supervisor.
- If the student's primary supervisor is not an MML or MR employee, this supervisor must nominate a Mater contact.

2.1.12 Reviewing research for other private institutions

- Participating sites that will be monitored by MML HREC must be listed in the HREA. If these sites are private institutions, the following points must be satisfied:
  - Will the private institution accept the review of MML HREC?
  - If commercially sponsored research, has the private institution been listed on the Form of Indemnity – HREC Review Only? (see also 2.3.4), and
  - If investigator initiated research, has the private institution offered indemnity to MML HREC?
- Researchers will be referred to the Research Agreements Officer, Mater Research, to establish the adequacy of agreement / indemnity requirements.

2.1.13 Submission of new applications in ERM

- New applications are submitted using the HREA available in ERM.
- Applicants can access ERM User Guides via the Mater Research Ethics website or via the ERM forms website under Help\Templates.
- Every application should contain a protocol. The application form is not the protocol.
- No hard copies are required.

- New submissions should be checked for validation as they arrive.

2.1.14 Validation of applications

Valid application

A valid application will include all relevant material relating to that research project (including a completed HREA, protocol and all documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms [National Statement Section 5.2.25]).

Upon receipt of an application, the HREC Liaison Officer will check that the application meets the criteria for validity:

- The HREC Liaison Officer should refer to the validation checklist in Work Instruction- New Applications (WI-RSH-3.004.01) to ensure the validation of newly submitted applications.
- All studies should be validated as they are received to allow time for researchers to respond to requests for more information in the validation check.
- If further information is required prior to the application being considered valid for review, the HREC Liaison Officer will send an email request via ERM to the CPI/PI and Contact Person listed in the application.
- The researcher must respond to the request within whatever timeframe is given, or negotiate a new timeframe, to be included for review at the next meeting.

Invalid application

Applications are invalid when:

- The HREA is incomplete.
- The required relevant supporting documentation, such as protocol, information sheet and consent form, questionnaires and other tools, are not submitted with the HREA.
- A formal request for a waiver of consent is not included and properly justified, when necessary.
- The documentation is not signed by the CPI/PI.

The decision whether or not an application is valid may be made by MML HREC Liaison Officer, although if in doubt the HREC Chairperson would be consulted.

For invalid applications the CPI/PI will then be notified by MML HREC Liaison Officer that:

- The application will not be accepted for the next meeting and that the application will require further documentation prior to HREC review, or
- The CPI/PI must supply further information in relation to an application by a specific date for the application to be reviewed at the next meeting.

2.1.15 Allocation of applications for full ethics review

- The HREC Liaison Officer in consultation with the HREC Chairperson will allocate each valid application to a minimum of two HREC members to lead the review.
- Additional expert review may be sought from a panel of expert reviewers.

- All applications will be made available to reviewers electronically on ERM.

2.1.16 Revision of applications following submission

- Once a valid application has been made, no revisions may be made prior to HREC review except with the approval of the HREC Chairperson.
- If the applicant considers it necessary to revise the application form or the supporting documentation prior to review by the HREC, the applicant must justify their request to the HREC Chairperson who then makes one of two determinations:
  - review of the study should proceed, or
  - the study should be withdrawn and resubmitted at a later date.

2.1.17 Withdrawal of applications

If an applicant withdraws an application at any time, the application should be treated as no longer valid and the 60 day time frame will no longer apply. If the applicant wishes to re-submit the application, it should be treated as a new submission.

2.2 MML HREC meetings

2.2.1 Meeting frequency [*National Statement* 5.1.37, 5.2.30-5.2.33]

- Meetings will be held monthly, except for January when there will be no scheduled meeting (National Statement section 5.1.37).
- A timetable for meetings will be prepared by MML HREC office and endorsed by MML HREC Chairperson and committee members prior to its circulation by November of the preceding year. Meeting dates, closing dates and checklist will be published on MML website.

2.2.2 Agenda

- The agenda will include the date, time and venue for the meeting or notice of virtual meeting should it be required.
- Members will be provided the agenda and the minutes of the previous meetings by email at least 11 days before the meeting.
- An electronic copy of the applications for consideration will be made available to members in ERM at least 11 days before the meeting, except in exceptional cases decided by the Chairperson where submissions or items for discussion may be tabled leading up to, or at, the meeting.
- All members may view all new applications in ERM via their "Reviews Next Meeting" tile.
- Members are also sent an email with a link to new studies on which they have been asked to provide a lead review.

2.2.3 Standing agenda items

1. Reflection
2. Apologies
3. Statements of disclosure
4. Confirmation of minutes
5. Items for discussion
6. Business arising from minutes
7. New Applications
8. Changes to approved projects
9. Investigator brochures – for information only
10. Applications granted exemption from full HREC review – for information only
11. Safety data review – for information only
12. Protocol Violations – for information only
13. Progress Reports – for information only
14. Items for Noting – for information only
15. General Business
16. Next Meeting

2.2.4 Lead reviewers

- MML HREC Liaison Officer in consultation with MML HREC Chairperson appoints two or more lead reviewers for each new application.
- The HREC Chairperson and Liaison Officer will determine if additional expert review may be required at the time of allocation of studies to lead reviewers.

2.2.5 Expert reviewers – internal or external

- MML HREC may seek the written advice of an expert reviewer on any aspects of an application that are relevant to the formation of an ethical decision, and which lie beyond the expertise of the members or on which the Committee is unable to agree. This may necessitate going outside the membership of the HREC. These expert reviewers may be specialists in ethics, specific diseases or methodologies, or they may be representatives of communities, patients or special interest groups.
- For multi-centre research, the opinion of the external expert may not be used to allow the HREC to review research outside of its NHMRC certification categories.
- For commercially sponsored studies, the cost of an external expert review (if applicable) may be borne if agreed, by the sponsor.
- Advice from expert reviewers may be sought at any time by the HREC.
- Expert reviewers are not voting members of the HREC, and will not be involved in the business of the Committee other than that related to the application on which their advice is sought.
- Communication between MML HREC and the expert reviewer about the substance of the study is conducted by MML HREC Chairperson or MML HREC Liaison Officer after first ensuring that the reviewer does not have any conflicting interests or other matters to declare which would affect their ability to objectively review the submission.

- A signed Confidentiality Agreement and Conflict of Interest Disclosure Statement are required prior to an expert advisor being appointed. Conflicts of interest should be disclosed as they arise or are recognised.
- A copy of the advice received will be made available to members prior to the meeting on ERM or tabled at the meeting. The substance of the advice should be recorded in the minutes.

2.2.6 Attendance of the PI or CPI at the meeting

- At the request of the HREC, after discussion with the Chairperson, the CPI or PI may be invited to attend a meeting (in person or remotely) at which his/her application is to be reviewed, or at a subsequent meeting. The purpose of this meeting is for the CPI or PI to respond directly to requests from the Committee for further information, clarification or reassurance but would be required to leave the meeting before a decision is made on the outcome. It is not the purpose of the CPI or PI's attendance to make a formal presentation of the study,
- Where the CPI or PI is unable to attend, it is acceptable for another key investigator or collaborator to attend in their place. It is not ethically acceptable for a representative of the sponsor to attend in place of the CPI or PI. Other members of the research team or representatives of the sponsor may also express an interest in attending alongside the CPI or PI and may do so at the discretion of the Chairperson.
- In the case of applications submitted by students, the HREC should consider inviting the academic or clinical supervisor.

2.2.7 Minimum membership requirements and meeting attendance [*National Statement* 5.1.29 – 5.1.30]

- The minimum membership is made up from six (6) categories (a to f):

a. a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement

b. at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work

c. at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional

d. at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion

e. at least one lawyer, where possible one who is not engaged to advise the institution, and

f. at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

- Where there is less than full attendance of the minimum membership at a meeting, the Chairperson must be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.

- MML HREC Chairperson can reschedule a meeting, convene additional meetings to consider urgent matters or as workload necessitates, or cancel a meeting if there is insufficient business or if unable to constitute a quorum.
- All applications may be reviewed on ERM. Members can submit their reviews for all other members to read and make comment on.
- Members who are unable to attend a meeting will be encouraged to contribute and advise their opinion via electronic submission on ERM or by email to the Chairperson or HREC Liaison Officer prior to the meeting.
- If members are unable to attend meetings regularly they should consider their availability to remain on MML HREC.
- Members must contact the HREC Chairperson to request a leave of absence.

2.2.8 Conflict of interest

2.2.8.1 Committee Members / Observers

- Members of the Committee and observers will be required to declare any conflict of interest prior to or at any time during a meeting.
- When a research application involves a Committee member or observer, that member or observer will be required to leave the meeting prior to discussion taking place.
- Members are required to disclose any actual or potential conflicts of interest, which exist or may arise during tenure on MML HREC, and that bears on any research coming before the review body [National Statement section 5.2.4]. This includes any:
  - Personal involvement or participation in the research
  - Financial or other interest or affiliation, or
  - Involvement in competing research [National Statement section 5.4.5].
- Declarations of any conflicts of interest by members, expert reviewers and observers are called for at the beginning of each meeting.
- Where such disclosure is made the Chairperson will determine, with the assistance of the Committee, the action to be taken, including exclusion from the meeting, or from some or all of the deliberations [National Statement section 5.4.5].
- The outcome and the action taken by the Committee are recorded in the Minutes.

2.2.8.2 Researchers [*National Statement* 5.2.11, 5.4.3]

A researcher should disclose to the HREC any actual or potential conflicts of interest, including financial or other interest or affiliation, which bears on the research. Where applicable, that disclosure should specify:

- Any business, financial or other similar association between a researcher and the supplier of a drug or surgical or other device to be used in the research, and
- Any restrictions on publication or dissemination of research findings.

Any such reported conflicts of interest should be managed by measures that may include requiring that:

- the information be disclosed to research participants
- a person other than the researcher make the initial approach to participants
- the information be disclosed in any report of the research
- the research be conducted by another researcher, or
- the research not be conducted.

2.2.8.3 Institution

- In its review of new research applications, should the HREC become aware of any conflict of interest involving the institution it should notify the Mater Group CEO.
- If the institution is aware of a conflict of interest bearing on a research project that is to be reviewed by the HREC it should inform the HREC prior to its review of the project.
- Once aware of a conflict of interest, management of the conflict should be determined by the HREC.

2.2.9 Confidentiality of proceedings

- The Agenda; content of applications, documents associated with submissions, proceedings and all discussions of the meeting, or HREC sub-Committees of the full Committee; expert reviews and identity of reviewers, and Minutes will remain confidential and confined to the Committee, those responsible for the administration of the HREC Office and those with authority to access ERM.
- Before appointment to MML HREC, members acknowledge in writing their acceptance of the Terms of Reference of the Committee and any requirements for confidentiality required by MML.
- Members are required to sign an agreement and declaration at the time of appointment and thereafter every three (3) years or earlier should their situation change, undertaking that all matters of which members, observers or expert reviewers become aware in the course of involvement with MML HREC will be kept confidential.
- Observers are required to sign a declaration prior to the commencement of the meeting undertaking that all matters of which they become aware of in the course of the meeting will be kept confidential.
- Expert reviewers are required to sign an agreement to maintain confidentiality of all documents provided to them by the HREC office.

2.2.10 Conduct of business and decision-making

- The Chairperson is responsible for the conduct of business and for ensuring that the Committee reaches clearly agreed decisions on all matters. In the absence of the Chairperson, the Deputy Chairperson will perform the duties of the Chairperson: i.e. chairing the meeting and/or fulfilling the other duties of the Chairperson as set out in the Position Description.

- In the absence of both the Chairperson and Deputy Chairperson, the Chairperson or HREC Liaison Officer may appoint an Acting Chairperson to chair the HREC meeting.
- Reviews provided by lead reviewers in the lead up to the meeting will be presented to Members at the meeting in the Reviews and Tabled Items document.
- All members present, both expert and lay, should be allowed reasonable opportunity to express relevant views on matters on the agenda. As per Section 5.2.32 of the *National Statement*, the written opinions of absent members should be tabled at the meeting and considered as part of the deliberation of a research project.
- The HREC should endeavour to reach decisions by general agreement (Section 5.2.33 of the *National Statement*). Generally, the minutes will record discussion of significant issues and the decision given.
- Where any member wishes to record his/her formal dissent from the Committee's decision, this should also be recorded in the minutes.

2.2.11 Decisions available to the HREC [*National Statement* 5.2.23]

The National Statement advises, "a review body may approve, request amendment of, or reject a research proposal on ethical grounds".

- It is the role of the HREC Chairperson to ensure one of these decisions has been reached.
- It is the role of the HREC Liaison Officer to clearly minute the decisions reached and record or collate any further information requested by the Committee.
- Questions or issues raised should be linked by members and reviewers to the relevant section of the National Statement.
- Decisions by the Committee about whether the research project meets the requirements of the National Statement must be informed by the exchange of opinions from each of the members that constitute the minimum membership of MML HREC.

2.2.12 Reporting responsibilities of the HREC Chairperson

- MML HREC Chairperson reports to MML CEO regarding the constitution and function of the Committee, associated processes and the ethical acceptability of research applications submitted for consideration
- MML HREC Chairperson operationally liaises with the Executive Director Mater Research relating to Mater researchers and research services and functions where the Chairperson considers no material conflict of interest exists.

2.2.13 Responsibilities of the HREC Liaison Officer

- Primary point of contact for researchers contacting the HREC office.
- Promote open communication with researchers including meetings, email and phone conversations and having an open-door policy.
- Promote to researchers the use of the National Statement when preparing their research project.

- Responsibilities in relation to HREC meetings includes the following activities:
  - publish the schedule of HREC meetings
  - manage the preparation of the agenda
  - allocate lead reviewers, in conjunction with the HREC Chairperson
  - arrange for distribution of the agenda and meeting documents
  - invite CPI's, PI's and, where appropriate, supervisors to attend the meeting and making the necessary arrangements
  - manage the preparation of the venue
  - record apologies for absence prior to the meeting
  - raise with the Chairperson any concern that a meeting may not be quorate
  - record attendance by members and referees for the discussion of each application for ethical review
  - advise the meeting as necessary on compliance with Terms of Reference, relevant policy or Standard Operating Procedures
  - take the Minutes of the meeting for review and approval at the following meeting
  - forward draft Minutes to the Chairperson for approval
  - forward HREC recommendations, usually in the form of the relevant meeting minute, via ERM email to researchers within four (4) working days of the HREC meeting, or notify researchers of a delay and the expected timeframe for completion of the review/minute
  - advise the researcher/s how to submit their response i.e. by submitting a response in ERM, providing both tracked and clean documents with revised version details.

2.2.14 Responsibilities of the HREC Coordinator

- Manage Committee Member recruitment, training and membership.
- NHMRC reporting including annual compliance reports, continuous certification requirements and ad hoc reporting of changes to Committee composition.
- Review of progress and final reports for approved projects in ERM.
- In conjunction with the HREC Chairperson, management of applications related to Authorised Prescriber; Serious Adverse Events; Safety Reports, Investigational Brochures and other updates.
- When required, and as able, attend the HREC meeting in the HREC Liaison Officer's absence to record proceedings and resolutions, prepare collated minutes for the HREC Chairperson review and approval prior to electronic notification of outcomes to researchers.

2.2.15 Minutes

- The minutes of the HREC meeting should be prepared by the HREC Liaison Officer in consultation with the Chairperson and other members as necessary and approved by the HREC Chairperson.

- Individual reviews taken from the minutes should be emailed to the researcher within four (4) days following the meeting.
- In relation to applications for ethical review or notices of substantial amendment, the minutes should contain an accurate record of the following, whether in the main text of the minutes or in attachments:
  - the members and external expert reviewers present for the review
  - any conflicts of interest declared, and the decision of the Committee regarding the allowable level of participation of the member concerned
  - the submission of reviews by members
  - the substance of any advice given by an expert reviewer
  - the decision of the HREC regarding the application
  - a summary of the main ethical issues considered and referenced to the *National Statement*
  - in the case of further information being requested, any special approval conditions or additional advice to be given to the applicant; as well as the arrangements for considering the information and confirming the final decision of the HREC
  - where a deficiency is identified by the HREC or additional information is required, the HREC may recommend the HREC Chairperson or another delegate approve the proposal on behalf of the full Committee when the HREC Chairperson or delegate is satisfied that the deficiency has been addressed or the additional information has been provided
  - in the case of a "Not Approved" decision (also known as rejected), the reasons for the decision with reference to the *National Statement*
  - where the opinion of an external expert is sought, the issues on which further advice is required, and
  - any formal dissent from the decision of the HREC by a named member, with reasons for their dissent.
- MML HREC provides unconfirmed minutes of each Committee meeting to MML Board of Directors, once approved by the Committee Chairperson for distribution.
- The minutes should be submitted to the next meeting of the HREC for ratification and to be signed by the Chairperson as a true record. Any necessary revisions should be incorporated in the final version of the minutes, which should be signed and dated by the HREC Chairperson.
- Where a deficiency is identified by MML HREC or additional information is required, MML HREC may recommend the HREC Chairperson or another delegate to approve the minutes as confirmed on behalf of the full Committee when the HREC Chairperson or delegate is satisfied that the deficiency has been addressed or the additional information has been provided.
- The minutes are confidential to the HREC and should not be disclosed to applicants, sponsors or host organisations.

2.2.16 Delegation of responsibility by MML HREC

- Where MML HREC requests further information from the researcher/s it should decide at the meeting the process for reviewing the response i.e. the Chairperson or delegate (i.e. Deputy or Acting Chairperson) may approve on behalf of the Committee; a sub-Committee of the HREC may review responses either electronically on ERM or in a face-to-face meeting with or without the researcher/s present; or further full Committee review at the next available meeting after the researcher/s have provided responses.

2.2.17 Meetings with researchers

- MML HREC and HREC Office encourages informal communication with researchers and face-to-face meetings to promote good understanding of research ethics, submission requirements and avoid delays in approval due to miscommunication or misunderstanding of these requirements.
- If it is deemed necessary after review by the HREC, researchers may be invited to meet with the Chairperson or with a sub-Committee to discuss and plan a way forward with their research.
- The HREC Chairperson and/or Liaison Officer will make themselves available for ad hoc meetings with researchers as and when they are requested.

2.2.18 60 day clock – time period to HREC approval

- The clock starts when a new application is validated. The clock runs until the study has been approved and the approval letter sent. If the researcher is asked questions the clock stops when those questions are sent. The clock will re-start immediately upon receiving a "response to further information" in ERM. All research ethics applications should be approved within this 60 day time period.
- LNR applications may be completed in a shorter time frame as they are reviewed between meetings, however this is not the case for all LNR applications as some require full Committee review.
- Applications for exemption from the requirement of full HREC review should generally have a decision made within a two (2) week time frame.

2.2.19 Approval of an application

- MML HREC approval letter is based on the NHMRC templates.
- The letter includes standard conditions of approval and:
  - a list of all documents approved and the sites where the research will be conducted in the case of a multi-centre application or when the research is not being conducted at MML or MR
  - period of approval
  - date of first progress report and any specific reporting requirements, and
  - specific approval such as a waiver of consent in accordance with the Privacy Act.

- The letter is signed by the HREC Chairperson or delegate (i.e. Deputy or Acting Chairperson).

2.2.20 When the application is not approved

- MML HREC provides a detailed explanation referencing the *National Statement*. The researcher/s is/are invited to a meeting to discuss.
- Researcher/s may choose to submit a new application taking into account the HREC recommendations.
- Researcher/s may choose to submit to another HREC however in accordance with questions raised in the HREA, should provide the new reviewing HREC a copy of the initial review.

2.3 Other considerations

2.3.1 Studies requiring Queensland Civil and Administrative Tribunal (QCAT) opinion

- Sections 65, 68, 72 and 74 of the *Guardianship and Administration Act 2000 (Qld)* cover participation in "special medical research or experimental health care".
- In accordance with the designation of the study under this definition, the PI (or CPI for multi-centre research) is required to obtain approval from the Queensland Civil and Administrative Tribunal (QCAT) in circumstances where the participant of the trial may be, by reason of physical or mental incapacity, incompetent to give informed consent to participate in the study. This approval process occurs after HREC approval and forms part of the governance process.
- The *National Statement* provides guidance on obtaining consent where capacity to provide consent is limited or non-existent, whether it is considered to be temporary or permanent.
- For persons under the legal age of consent, written approval must be obtained from the person's parent(s) or guardian(s). Where a person is over the legal age of consent but is unable to provide informed consent for participation, written application to the QCAT must be undertaken.
- Approval from QCAT does not provide consent for a person who has impaired decision making capacity to participate in a research project. QCAT Approval determines whether a clinical trial is appropriate for a person of impaired decision making capacity to participate in. However, consent for participation is still required from the Legally Authorised Representative (Substitute Decision Maker).

2.3.2 Clinical Trial Notification Scheme (CTN) and Clinical Trial Exemption Scheme

- HREC's play an important role in the regulation of the supply of unapproved goods under the *Therapeutic Goods Act 1989* in connection with the operation of clinical trials (both CTN and CTX schemes), the "Special Access Scheme" and approval of "Authorised Prescribers".
- Unapproved therapeutic goods have undergone little or no evaluation of quality, safety or efficacy by the Therapeutic Goods Administration (TGA). These products are considered to be

experimental and potentially carry some risks that have not been defined in the Australian context. HREC's should be guided by the principles outlined in the *National Statement* in assessing the risks and precautions in research involving humans.

- HREC roles and responsibilities are in accordance with the Therapeutic Goods legislation.
- This section should be read in conjunction with the *National Statement* and *Good Clinical Practice (GCP) Guidelines.*

2.3.3 Research involving coronial material

- Research involving access to coronial material must be referred to the Queensland Forensic and Scientific Services Human Research Ethics Committee for ethical and legal approvals.

2.3.4 Indemnity

- MML Board of Directors accepts legal responsibility for decisions made and advice given, and indemnifies all members of the HREC, sub-Committees of the HREC and expert reviewers appointed to advise the HREC against liabilities incurred as a result of carrying out authorised HREC tasks.
- For research which is not being conducted at MML, which is being undertaken by non-affiliated researchers, and where an MML or MR employee has not been nominated as a Principal Investigator or Mater contact, in accordance with the conditions of NHMRC certification:
  - MML HREC must be provided with independent legal indemnity;
  - Documentation of legal indemnity must be provided to MML legal counsel prior to the external study receiving independent ethics review by MML HREC.

2.4 After approval

2.4.1 Updated safety information

- *The principles of ICH GCP state:* "Amendments, safety and other reports may be reviewed and approved, actioned or noted by the Chairperson between meetings. Substantial amendments *or serious safety issues may require full Committee review and / or subsequent ratification*".
- *MML HREC acts in accordance with the NHMRC Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research, January 2012, Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods, November 2016, Mater policies and other external guidance.*
- *Amendments or safety reports requiring an urgent review to identify, reduce, expose or eliminate a real or potential risk or burden to participant safety or wellbeing are reviewed in accordance with this Procedure section 2.1.6 Exceptional Circumstances.*
- *National Statement section 5.5.6 directs that the researcher/s* "(d) inform the review body as soon as possible of any new safety information from other published or unpublished research that may have an impact on the continued ethical acceptability of the research or that may indicate the need for modification of the project", and

- *National Statement section 5.5.7 directs that* (f)"Researchers should inform the relevant institution/s, the review body/ies that approved the research and, wherever possible, the research participants, if the research project is to be discontinued before the expected due date of completion, and why".

2.4.2 Expansion of approval

Multi-centre amendment to include another site

Required documents:

- Covering letter briefly outlining the expansion to additional site/s and reasons for expansion
- CV/s for additional investigator/s
- Documents that have been changed as a result of the added site, in both tracked change and clean copies including new version numbers and date in the footer of these documents.

2.4.3 Substantial amendments

- Substantial amendments will be carefully considered by the HREC Chairperson for validity.
- If an amendment will fundamentally alter the nature of the research e.g. change in the primary purpose, and the extent of the involvement of, or risk to, existing and / or potential participants, the HREC may recommend the amendment not be approved and a new application be submitted.
- Substantial amendments that can be validated may be added to the next available HREC agenda for full Committee consideration and / or ratification of the HREC Chairperson's recommendation.

2.4.4 Urgent safety amendments

Refer to sections 2.4.1 and 2.1.6

2.5 Other types of applications

2.5.1 Authorised prescriber

The HREC may review 'other' applications in accordance with the Therapeutic Goods Administration (TGA) Guidelines, Human Research Ethics Committees and the Therapeutic Goods Legislation June 2001. The following categories of 'other' application include but are not limited to:

- Submission to Access Unapproved Products
- Requests to become Authorised Prescriber, and
- Request for ethics review of Special Access Scheme applications.

2.6 Monitoring research [*National Statement* Chapter 5.5]

2.6.1 Reporting

Where MML HREC is the reviewing (lead) Committee, the CPI or site PI is required to conform to conditions set out in the formal approval letter as outlined below:

Study commencement

- Research should commence within 12 months of HREC approval. Researchers are responsible for notifying the HREC of their commencement date (post research governance authorisation) e.g. advertising or screening for participants, commence data collection.
  - If the research has not commenced within 12 months the CPI/PI should provide the HREC with a written explanation for the delay. The HREC may decide to extend the approval period, or not.

Progress

- At a minimum, researchers must submit an annual progress report or more frequently as directed by the HREC.
- The progress report is due on the anniversary date of the HREC approval, rather than 12 months after commencement of the study at any of the sites.
- In investigator initiated research the role of the CPI is to submit a collated annual report including information from all sites listed in the HREC approval letter.

If the research is sponsored it is the role of the sponsor or CRO to collate the progress from each site and submit to the CPI for review by the HREC.

SAE / SUSAR / Safety

The NHMRC advises in Safety monitoring and reporting in clinical trials involving therapeutic goods:

The sponsor, through their independent safety monitoring arrangements, has the primary responsibility for monitoring the ongoing safety of the investigational medicinal product. The HREC should be satisfied that the sponsor's arrangements are sufficiently independent and commensurate with the risk, size and complexity of the trial.

The HREC should:

g. assess the safety of proposed trials, including whether the evaluation of the anticipated benefits and risks is satisfactory and ensure that the sponsor has proportionate systems in place to mitigate and manage any identified risks

h. satisfy itself that the sponsor's ongoing safety monitoring arrangements are adequate, including the justification for appointing/not appointing a Data Safety Monitoring Board and any 'stopping rules' or criteria for withdrawing individual participants from the trial

i. keep under review the adequacy and completeness of the informed consent process and documentation in the light of new information about risks and benefits

j. assess whether changes to the risk-benefit ratio that are reported by the sponsor are compatible with continued ethical approval

k. advise the TGA, investigators and their institutions of any decision to withdraw approval

Note: While HRECs must keep approvals under review in light of safety information it receives, the responsibility for proactively monitoring the ongoing risk-benefit ratio of the trial remains with the sponsor at all times.

Investigators should assess all local safety events and should act on any events as clinical care dictates. The role of the investigator with regard to safety reporting is to provide the sponsor with all relevant information so that an appropriate safety analysis can be performed.

The Principal Investigator should:

a. capture and assess all AEs that occur at the site as required and in accordance with the protocol

b. report to the sponsor **within 24 hours of becoming aware of the event**:

   i. all SAEs, except those that are identified in the protocol as not needing immediate reporting

   ii. any occurrences of congenital anomaly/birth defect arising from any pregnancy of a participant (or partner)

   iii. all urgent safety measure instigated by the site

c. report to the sponsor as specified in the protocol:

   i. all safety critical events

   ii. any additional requested information relating to reported deaths

d. report to the institution **within 72 hours** of becoming aware of the event:

   i. all significant safety issues

   ii. SUSARs20 arising from the local site.

An institution's responsibilities and oversight of safety information in clinical trials will differ depending on whether they are hosting externally sponsored clinical trials or sponsoring locally led non-commercial trials. In both cases they should help ensure that their site(s) understands and complies with sponsor requirements. Institutions should have oversight of any issues that may require management, such as disputes or litigation resulting from trials. Where the institution is also named as the trial sponsor, the institution will also assume the sponsor responsibilities set out in this document.

The Institution should:

a. assess whether any safety reports received impact on medico-legal risk, the responsible conduct of research, adherence to contractual obligations or the trial's continued site authorisation and, where applicable, facilitate the implementation of corrective and preventative action

b. develop clear guidance for investigators detailing the requirements for safety reporting and monitoring in clinical trials. This document(s) should cover the requirements for both externally sponsored clinical trials and, if applicable, internally sponsored investigator/initiated or collaborative group trials.

Investigator initiated trials where MML will take responsibility as the Sponsor:

The NHMRC guidance on Safety Monitoring indicates that 'The sponsor, through their independent safety monitoring arrangements, has the primary responsibility for monitoring the ongoing safety of the investigational medicinal product'.

Before the HREC provides ethical approval of a clinical trial it must be assured that 'the sponsor (MML) has proportionate systems in place to mitigate and manage any identified risks' and "assess the safety of proposed trials, including whether the evaluation of the anticipated benefits and risks is satisfactory" and "ensure that satisfy itself that the sponsor's ongoing safety monitoring arrangements are adequate, including the justification for appointing/not appointing a Data Safety Monitoring Board and any 'stopping rules' or criteria for withdrawing individual participants from the trial" **are in place. (**3. Responsibilities of the HREC**). This information should be included in the HREC application.**

Protocol violations (***NHMRC Framework for Monitoring, January 2012***)

'The distinction between protocol violations and protocol deviations is neither clearly understood nor consistently applied amongst Australian HRECs, but, for the purposes of this document, protocol violations are those variations to a protocol that implicate participant consent, participant safety or data integrity that compromises the ethical acceptability of the project, and, thus, require retrospective notification to or review by a HREC, whereas protocol deviations relate to other matters and do not require notification to or review by a HREC. This definition is consistent with ICH/GCP taxonomy.'

- The definition of protocol violation applicable to this Procedure is consistent with the extract above and with ICH GCP taxonomy which emphasises the potential for safety or efficacy implications, rather than a requirement for them to eventuate.
- The CPI/PI is responsible for reporting all protocol violations to the reviewing HREC.

MML HREC should consider these violations at the next HREC meeting and determine whether any further action is required in regard to participant safety or research misconduct and consider if further action is required.

2.6.2 Study discontinuation

- Where a research project is terminated or suspended by the Principal Investigator prematurely, MML HREC must be promptly informed and provided with a detailed written explanation of the circumstances, having regard to the ongoing safety and welfare of any research participants who may be receiving study treatment.
- Notification of early termination of a study should be included on the next HREC agenda for noting and / or recommendation.

2.6.3 Suspension of approval

- MML HREC may suspend its ethical approval for a study if it is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with its ethical approval and that, as a result, the welfare and rights of participants are not or will not be protected.
- Where MML HREC considers it appropriate that the serious adverse event/s and / or monitoring report requires the immediate suspension or discontinuation of the research ethics approval, the HREC should immediately notify MML CEO.

- The CEO must instruct the CPI (or site PI for single site studies) to:
    - Immediately cease all study related activities
    - Ensure the health and wellbeing of participants are not compromised
    - Notify any study sponsor of MML HREC's decision, and
    - Notify the authorising RGO.

2.7 Storage and retention of records

In accordance with National Statement sections 5.2.26-29, MML HREC will maintain a record of all research proposals received and reviewed, including the protocol and any information sheets, consent forms, or relevant correspondence, in the form in which they were approved. These records will include at least the:

- Name/s of the institution/s to which the research approval is provided
- Project identification number/s
- Name/s of principal researcher/s
- Title of the project
- Correspondence between the review body and the researcher about the review
- Acceptance or rejection of any changes to the proposal
- Proposed date of completion of the proposal
- Formal advice of final ethical approval or non-approval, with date
- Terms and conditions, if any, of approval of any proposal
- Duration of the approval
- Name of any other review body whose opinion was considered
- Mechanisms to be used to monitor the conduct of the research, and
- Relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information
- Decisions about approval, amendment, or rejection of proposals, with reasons for those decisions, linking those reasons to the National Statement
- Where more than one review body has reviewed the research proposal: details of the other review body/ies involved the decision/s of each other review body and details of any amendments required by each other review body.

Records described above are maintained in ERM.

Greater than low risk studies submitted prior to Wednesday 1 January 2020 will have a corresponding hard copy file:

- MML HREC hard copy records are stored in Room 293, Level 2, Aubigny Place, Mater Misericordiae Ltd, South Brisbane.
- Hard copy files for completed studies are stored off site at GRACE Records Management.

In accordance with *The Code* and TGA requirements clinical trial records to be stored for a minimum of 15 years. In the case of paediatric research records are stored for up to 33 years

(participant reaching the age of 18 years plus 15 years for a clinical trial). In addition, if legal action has been taken the files are stored for 10 years after the legal action has been completed. Further information can be found at Queensland State Archives.

2.8 Schedule of fees

MML HREC schedule of fees is publicly available on MML HREC website.

2.9 HREC management

2.9.1 Appointing members [*National Statement* 5.1.34 – 5.1.36]

- Prospective members should forward an Expression of Interest (EOI) to MML HREC Office. Vacancies may be filled from the persons who have submitted an EOI or by internal or external advertisement.
- Membership must reflect the *National Statement* minimum membership requirements as listed in sections 5.1.29 and 5.1.30.
- Members are appointed as individuals for their knowledge, qualities, expertise and relevant experience, and not as representatives of any organisation, group or opinion (*National Statement* Section 5.1.35).
- Members are not to be appointed in more than one of the categories listed in 5.1.30 of the *National Statement*.
- Before appointment, members acknowledge in writing their acceptance of the terms of reference and relevant policies of MML HREC and any requirements for confidentiality and conflict of interest required by MML.
- Members will be provided a letter of appointment including the date of appointment, length of tenure, assurance that indemnity will be provided by MML in respect of the conduct of their duties as a HREC member, HREC meeting attendance responsibilities and general responsibilities as a HREC member.
- Membership appointments to MML HREC will be considered for review every three years (*National Statement* Section 5.1.34).
- A member may be re-appointed for further three year periods.
- Members are appointed by MML Board of Directors. All changes to MML HREC membership are communicated to the NHMRC and other official research regulatory bodies as required.
- Members should inform the Chairperson if leave of absence is required. If unable to attend meetings regularly, members should consider their availability to remain on the Committee.

2.9.2 Conditions of appointment

- Membership of MML HREC is publicly available on the website.
- All essential and necessary expenses incurred by members in carrying out their MML HREC duties will be paid for or reimbursed by MML on production of original receipts.

- Parking and refreshments will be provided at MML South Brisbane to facilitate members' attendance at face-to-face monthly HREC meetings.

2.9.3 Education and training

- New members are provided induction material and offered mentoring via the Chairperson or other members of the HREC (*National Statement* Section 5.1.28(b)).
- Throughout their tenure, members are given the opportunity to attend conferences and workshops, supported by MML, that are relevant to the roles and responsibilities of the HREC (*National Statement* section 5.1.28(b) (ii)).
- Members and HREC Office staff are asked to report back to the Committee on any course or conference attended.
- MML HREC Coordinator will record members' education training history for the purpose of NHMRC reporting.

2.9.4 Essential reading for HREC members

- Mater Misericordiae Ltd Human Research Ethics Committee (MML HREC) (EC00332) Terms of Reference
- National Statement on Ethical Conduct in Human Research, National Health & Medical Research Council, 2007 (Updated 2018) (herein referred to as the *National Statement*)
- The Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, World Medical Association, 2013
- Guideline for Good Clinical Practice ICH E6(R2) (2016)
- NHMRC guidance for multi-centre research
- Safety monitoring and reporting in clinical trials involving therapeutic goods (2016)
- Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia, 2001
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (NHMRC 2018)
- Australian Code for the Responsible Conduct of Research 2018 (the Code)
- Privacy Act, 1988; *Guidelines approved under Section 95 of the Privacy Act, 1988*; *Guidelines approved under Section 95A of the Privacy Act, 1988*; Guidelines approved under Section 95AA of the Privacy Act, 1988 (Cth); Australian Privacy Principles
- Coroners' Act 2003, Section 53.

2.10 NHMRC HREC certification and compliance

- MML HREC has current certification from the NHMRC as a lead HREC under the National Approach to Single Ethical Review of Multi-Centre Research. The Committee is certified for single ethical review of studies in clinical trials of drugs and devices – Phase 0, I, II, III, IV; Clinical

Interventional Research other than Clinical Trials; Qualitative Health Research; Mental Health; Paediatrics; Population Health and / or Public Health Research.

- MML HREC reports to the NHMRC under registration requirements (NHMRC Registration No: EC00332). MML HREC Coordinator submits an Annual Compliance Report to the NHMRC and complies with continuous certification requirements.

2.11 Complaints [*National Statement* Chapter 5.6]

- Research complaints can be about the conduct of research including the conduct of researcher/s and / or about the conduct of the HREC or Office.
- The process for receiving and resolving allegations of research misconduct at MML / MR is described in the Research Misconduct Policy (see Section **Error! Reference source not found. Error! Reference source not found.**).
- Participant Information Sheets must include contact details for MML HREC Office for complaints to be made.
- Complaints should be made in writing however may be sent by email or by telephone.
- All complaints will be dealt with by MML HREC Chairperson with assistance from MML HREC Liaison Officer or Coordinator.
- The Chairperson will notify MML CEO as soon as possible.
- The Chairperson will investigate the complaint and its validity, and make a recommendation to MML HREC / MML CEO on the appropriate course of action.
- The Institutional Research Governance Officer should also be informed by the Coordinating or site Principal Investigator.
- All complaints will be acknowledged within seven days.
- The complaint and the proposed action will be reported to the next meeting of MML HREC.
- Complainants will be advised of an outcome within 30 days.
- MML HREC Office may contact MML Clinical Governance Unit if considered helpful for the purpose of the investigation.
- If the complaint refers to care provided to a patient of Mater Health the Director of that Service and the Clinical Governance Unit should be advised as soon as details become available.
- If the complainant does not accept the decision of MML HREC the complaint may be forwarded to MML CEO.
- MML CEO will consider the need for further investigation.
- If it is decided there is to be a further investigation, MML CEO will convene an investigating committee to review the complaint, ensuring that both the complainant and MML HREC are afforded the opportunity to make submissions. In conducting its review, the panel shall be concerned with ascertaining whether MML HREC acted in accordance with the *National Statement*, Terms of Reference and Standard Operating Procedures.

- In situations where a conflict of interest is suspected the Conflict of Interest Policy is applied.

3. Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a research participant using an investigational product which does not necessarily have a causal relationship with the product. Therefore, an adverse event (AE) can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.
Amendment	A change to the Human Research Ethics Committee (HREC) approved application including the protocol or supporting documentation.
Applicant	For multi-centre studies the Coordinating Principal Investigator (CPI). For single site studies the Site Principal Investigator (PI).
Associate Investigator (AI)	Another term used for Sub-Investigator
(The Code)	The *Australian Code of for the Responsible Conduct of Research* (2007) (The *Code*). This guides institutions and researchers in responsible research practices and promotes integrity in research. It shows how to manage breaches of The Code and allegations of research misconduct, how to manage research data and materials, how to publish and disseminate research findings, including proper attribution of authorship, how to conduct effective peer review and how to manage conflicts of interest. It also explains the responsibilities and rights of researchers if they witness research misconduct.
Certified HREC	An HREC which has had its processes assessed and certified under the National Health and Medical Research Council (NHMRC) National Certification Scheme and remains compliant with continuous certification requirements. • Go to NHMRC Certification Scheme, for further information. • List of certified HRECs
Clinical Audits	Quality assurance programs may use planned clinical audits along with other monitoring tools to assure that standards are being met. A clinical audit is not research. • Clinical audit tells us whether we are doing what we should be doing and how well we are doing it. Clinical audit is about quality and finding out if best practice is being practised. • Research is about obtaining new knowledge and finding out what treatments are the most effective. Research tells us what we should be doing. There is a clear distinction between clinical audit and research and clinical audit does not need approval from a research ethics committee. Even if an ethical opinion is sought for a clinical audit and even if the project is to disclose non-identifiable confidential information without consent, clinical audits do not require research authorisation as they are not research activities.

Term	Definition
Clinical Research Coordinator (CRC)	The CRC is the person designated by the CPI to be responsible for coordinating the conduct of the research project, including scheduling of participant visits, liaison with Sponsor management personnel and the HREC / Research Governance Office(r) (RGO). May also be known as the Site Coordinator or Contact Person.
Contact Person	The person designated by the Principal Investigator (PI) to be responsible for liaising with the HREC / RGO. May also be known as the Site Coordinator or Clinical Research Coordinator.
Clinical Research Associate (CRA)	The CRA is a representative of the Sponsor or Contract Research Organisation (CRO) employed to monitor clinical trials. The CRA ensures compliance with the clinical trial protocol, checks site activities, reviews Case Report Forms (CRFs) and acts as a communication conduit between sites and the sponsor organisation.
Confidential Information	Confidential information means any information that— is about a person who is receiving or has received health care and could identify the person.
Contract Research Organisation (CRO)	The CRO is an organisation (commercial, academic or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties or functions.
Coordinating Principal Investigator (CPI)	The CPI the investigator responsible for coordinating a multi-centre research study, and the submission and communication of all subsequent requests and notifications to the site PIs. The CPI and their team are responsible for coordinating the HREC applications and correspondence throughout a multi-centre study, on behalf of the Accepting PIs for which the CPI is responsible. For single site studies the terms CPI, Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are all synonymous.
ERM	Ethical Review Manager. A secure web-based research ethics database used by HREC Administrators to store ethics documents, applications and correspondence in relation to studies submitted to MML HREC. ERM provides separate applicant/researcher access and reviewer access.
Good Clinical Practice (GCP)	GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. May also be referred to as ICH GCP (International Conference on Harmonisation).
Human Research Ethics Application (HREA)	*"As part of the initiative to streamline ethics approval, NHMRC has developed the Human Research Ethics Application (HREA) as a replacement for the National Ethics Application Form (NEAF). The aim of the HREA is to be a concise application to facilitate efficient and effective ethics review for research involving humans. The application will assist researchers to consider the ethical principles of the National Statement on Ethical Conduct in Human Research (2007) in relation to their research, rather than focus on requirements for approval."*
Human Research Ethics Committee (HREC)	The HREC review research proposals that involve humans or their tissue or data. HRECs are established by organisations which register their HREC with the NHMRC. It may also be referred to as the Reviewing HREC in multi-centre research studies. "HREC" in this document means the Mater Misericordiae Ltd Human Research Ethics Committee established under MML HREC (EC00332) Terms of Reference.
HREC Liaison Officer	An employee of MML who provides administrative support and advice on MML / MR process of ethics review of research studies. The Liaison Officer reports to the Research Compliance Manager and consults with the Chairperson of the HREC in matters related to the activities of the HREC.

Term	Definition
HREC Coordinator	An employee of MML who provides administrative support and advice on the compliance of MML HREC including membership and certification. The Coordinator reports to the Research Compliance Manager and consults with the Chairperson of the HREC in matters related to the activities of the HREC.
Individually Identifiable Data	Where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth, or address.
HREC Checklist	The HREC checklist is available on MML HREC website. This checklist provides a guide to researchers on the types of attachments that may be included with a new research application.
Low and Negligible Risk (LNR)	Low and Negligible Risk Research is described in sections 2.1.6-7 of the *National Statement* as: • *Low risk - where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.* • Negligible risk - *where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.*
Mater Misericordiae Ltd (MML)	"MML" means Mater Misericordiae Ltd ACN 096708922 owner and operator of the Mater Hospitals South Brisbane, Redland, Springfield, Bundaberg, Gladstone, Mackay, Rockhampton and Townsville and other sites notified to the HREC.
Mater Research Ltd (MR)	"MR" means Mater Research Ltd ABN 28 109 834 719. MR is a wholly owned subsidiary of MML ABN 83 096 708 922.
Multi-Centre Research	Includes research conducted through the collaboration of at least two unique institutions that may be situated in more than one state or territory or within a single jurisdiction. It does not refer to research being conducted at several sites or locations of a single institution e.g. Mater Hospital Brisbane and Mater Private Hospital.
National Statement	The *National Statement on Ethical Conduct in Human Research (2007) Updated 2018*. A guidance document developed by the NHMRC, the Australian Research Council and the Australian Vice-Chancellors' Committee to provide guidelines for researchers, HRECs and others conducting ethical review of research. It also states institutions' responsibilities for the quality, safety and ethical acceptability of research that they sponsor or permit to be carried out under their auspices.
Personal Information	Information or an opinion, including information or an opinion forming part of a database, whether true or not and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.
Principal Investigator (PI)	The PI is the investigator responsible for the overall conduct of the research study at an individual site. • For multi-centre studies the PI may be known as the Accepting PI if they do not have CPI responsibilities. For single site studies the terms CPI, Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are used interchangeably.
Protocol	The protocol is the study working document. It is the formal design or specific plan for the research. It provides detail for the conduct of the research consistent with the scope of the template available on MML HREC website. If the study is amended after approval, a revised tracked protocol must be submitted and

Term	Definition
	approved. The protocol should include document identifier, version number and date.
Quality Assurance Activity (QA)	A clinical governance activity that is a requirement of the compulsory National Safety and Quality Health Service Standards and an associated Australian Health Service and Quality Accreditation (AHSSQA) Scheme. This includes patient satisfaction surveys, surveillance and monitoring and clinical audits. If there are research elements then it will be reviewed under the research review process, Ethical considerations apply to such work.
Research Governance Authorisation	Authorisation is issued by the Research Governance Office or delegate to conduct research at a site within their jurisdiction. Authorisation is contingent upon receiving HREC approval and completion of governance requirements which may include a Site Specific Assessment form (SSA).
Research Governance Office (RGO)	The Research Governance Office is the Office(r) or coordinated function within MML whose responsibilities are: • assessing the site-specific aspects of research applications, • making recommendations to the CEO or delegate as to whether a research study should be granted authorisation at the site; and monitoring authorised research at the site to ensure it meets appropriate standards.
Reviewing HREC	The certified HREC that reviews multi-centre research studies.
60-day clock	The period of 60 review days allowed for the deliberation of an ethical decision on an application. For research not requiring review at a full HREC meeting, the clock starts on receipt of a valid application. For research requiring review at a full HREC meeting the clock starts on the relevant HREC meeting closing date. The 60-day time limit excludes stop clock days. May also be called 60 Review Days.
Serious Adverse Event (SAE)	The definition of an SAE will be defined by the Sponsor and included in the protocol. Generally, an SAE in human drug trials is defined as any untoward medical occurrence that at any dose, results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage. Suspected Unexpected Serious Adverse Reactions (SUSARs) are considered a subset of SAEs.
Single Ethical Review Process	The mechanism to allow ethical review of multi-centre research by one NHMRC Certified HREC rather than submitting a study to multiple HRECs for review.
Single Site Research	Research to be conducted at one site only.
Site Coordinator	The person designated by the (PI) to be responsible for liaising with the HREC / RGO. May also be known as the Clinical Research Coordinator, Contact Person or Study Liaison Officer
Site-Specific Governance Amendment	An amendment request for an authorised research study that may be submitted by the applicant to the RGO only (for studies approved by an HREC other than MML). Examples would be changes to site contracts and changes to participating site staff other than the PI.
Site-Specific Assessment (SSA)	The SSA Form is a tool to assist RGOs in the research governance process to document the assessment of safety, privacy, legal, financial, insurance, regulatory, contractual issues to determine the level of support and level of support and suitability of a research study to be conducted at a site, irrespective of whether the study is multi-centre or single site.

Term	Definition
Site Start Date	The site start date refers to either the anticipated first point of recruitment (i.e. the date when the advertising or screening for participants begins) or start of data collection.
State Specific Modules	Victoria, Western Australia and the Australian Capital Territory have developed additional modules for HREC review that must be completed and submitted as part of the HREC review of clinical trials, when sites from those States / Territories are participating in multi-centre research. For further information go to: VIC: http://www.health.vic.gov.au/clinicaltrials/application-instructions.htm#vsm WA: http://www.health.wa.gov.au/researchdevelopment/home/hrec.cfm#ethics ACT: http://healthresearch.anu.edu.au/human-research-ethics-committee.html
Stop Clock Facility	For HREC applications, the time when the 60-day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the HREC for further information or clarification. The clock will re-start automatically when a response from the applicant is submitted in ERM.
Study Site	The location(s) under the control of the Institution where the study is actually conducted.
Sub Investigator	May also be called Associate Investigator (AI) or Associate Researcher. ICH GCP defines a sub-investigator as "any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial related procedures and/or to make important trial related decisions".
Therapeutic Goods Administration (TGA)	The TGA is the agency responsible for regulating therapeutic goods: Follow this link for further information.
Validation	An administrative check carried out by an HREC Administrator or RGO to verify that all applicable application documentation is submitted prior to review. Decisions on validation should be made within one week of receipt.
Validation Date	• For research not requiring review at a full HREC meeting, the date on which a valid application is received by the HREC Liaison Officer. • For research requiring review at a full HREC meeting, the relevant HREC meeting closing date.

4. Documents related to this procedure

Mater documents

Document Type	Document ID	Document Title
Committee Terms of Reference	CT-RSH-300000	Mater Misericordiae Ltd Human Research Ethics Committee (MML HREC) (EC00332) Terms of Reference
Governance	CA-CEO-000001	Mater Misericordiae Ltd By-Laws
Policy	PY-PAL-060000	Code of Conduct Policy
Policy	PY-RSH-300300	Ownership, Storage and Retention of Human Research Materials and Data Policy
Policy	PY-RSH-300301	Collection, Storage, Use and Disposal of Human Biospecimens in Research Policy

Document Type	Document ID	Document Title
Policy	PY-RSH-300302	Responsible Conduct of Research Policy
Policy	PY-RSH-300305	Human Research Ethics Review Policy
Policy	PY-RSH-300309	Conflict of Interest in Research Policy
Policy	PY-RSH-300310	Research Misconduct Policy
Policy	PY-RSH-300304	Human Research Governance Policy

External documents

1.	National Statement on Ethical Conduct in Human Research, National Health and Medical Research Council, 2007 (Updated 2018) (herein referred to as the *National Statement*)
2.	The Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, World Medical Association, 2013
3.	Guideline for Good Clinical Practice E6(R2) (2016)
4.	Human Research Ethics Committees and the Therapeutic Goods Legislation, June 2001
5.	NHMRC Guidance for multi-centre research
6.	Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia, 2001
7.	Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (NHMRC 2018)
8.	Australian Code for the Responsible Conduct of Research 2007 (herein referred to as The Code)
9.	Public Health Act 2005, Hospital and Health Boards Act 2011 and other relevant requirements of Commonwealth and State/Territory laws
10.	Privacy Act, 1988 *Guidelines approved under Section 95 of the Privacy Act, 1988, (March 2014)* *Guidelines approved under Section 95A of the Privacy Act, 1988, (March 2014)* Guidelines approved under Section 95AA of the Privacy Act, 1988 (Cth), *(March 2014)* Australian Privacy Principles, March 2014
11.	Sections 65, 68, 72 and 74 of the Guardianship and Administration Act 2000
12.	Memorandum of Understanding (MoU) between the Mater Misericordiae Ltd, Queensland Health and QIMR Berghofer in relation to mutual acceptance of ethical and scientific review of multi-centre research studies.
13.	Standard Operating Procedures (SOP) for Queensland Health (QH) HREC Administrators Version 4, November 2013
14.	Ethical considerations in Quality Assurance and Evaluation Activities
15.	Safety monitoring and reporting in clinical trials involving therapeutic goods
16.	Framework for Monitoring

5. Document controls

5.1 Document revision history

Version	Release date	Description	Risk-rated Review date
1.	July 2011	Standard Operating Procedures (SOP) for Mater Health Services HREC Secretariat	July 2011
2.	28 August 2013	Standard Operating Procedures (SOP) for Mater Health Services HREC Secretariat	August 2013
3.	1 Sept 2014	Mater Health Services Human Research Ethics Committee (HREC) (EC00332) Office Standard Operating Procedure (SOP)	September 2014
4.	3 March 2015	Mater Misericordiae Ltd Human Research Ethics Committee (MML HREC) (EC00332) Office Standard Operating Procedure (SOP)	3 March 2015
5.	16 March 2017	Procedure for Mater Misericordiae Ltd Human Research Ethics Committee (MML HREC) Office	
6.	25 August 2020	"This version"	

5.2 Document review and approval

Name Person/committee	**Position** If applicable	**Function** Owner/author/review/approve
Ms Jessica Pearson	HREC Coordinator	Author
Professor Ross Pinkerton	HREC Chairperson	Review/Approve

5.3 Keyword indexing

Keywords:	HREC, procedure, SOP, code, complaint, ethics, application, human, approval, conflict of interest, confidentiality, monitoring, National Statement