Human Research Ethics Committee

Terms of Reference

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1. Committee Membership and Objectives

1.1 Membership

Name	Category*
Voting Members	
1. Professor Ross Pinkerton	*Category (a) Chairperson*
2. *Ms Odette Petersen*	*Category (b) Lay Member - Female, Deputy Chairperson*
3. *Mr John Larkin*	*Category (b) Lay Member – Male*
4. *Ms Genevieve Waldie*	*Category (b) Lay Member – Female*
5. *Ms Lucy Lai*	*Category (b) Lay Member – Female*
6. *Ms Maree Patane*	*Category (b) Lay Member – Female*
7. *Professor Sailesh Kumar*	*Category (c) Senior Staff Specialist, Maternal Fetal*
8. *A/Professor Simon Bowler*	*Category (c) Director Respiratory Medicine*
9. *Ms Alanna Jacoby*	*Category (d) Chief of Mission*
10. *Ms Courtney Coyne*	*Category (e) Lawyer, external to the organisation*
11. *Ms Katrina Chambers*	*Category (e) Lawyer, external to the organisation*
12. *Dr Adam Ewing*	*Category (f) Researcher TRI*
13. *Ms Sonia Hancock*	*Category (f) Researcher Compliance MS HHS*
14. *Dr Bridget Pratt*	*Category (f) Senior Lecturer Healthcare Ethics*
15. *Dr Simon Denny*	*Director Mater Young Adult Health Centre*
16. *Professor Michael Kimlin*	*Professor of Epidemiology, QUT*
Ex Officio	
17. Dr Amber Salman Popattia	HREC Liaison Officer (minutes)

* Mandatory membership categories for NHMRC registered human research ethics committees

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

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

1.1.1 MML HREC Members [*National Statement* sections 5.1.29 – 5.1.36]

- Prospective members of Mater Misericordiae Ltd (MML) Human Research Ethics Committee (HREC) may be recruited by expressions of interest, direct approach, nomination and/or advertisement, and are appointed in accordance with the *National Statement* [Sections 5.1.34-5.1.36].
- Remuneration: Members are appointed on a voluntary basis. All essential and necessary expenses incurred by members carrying out their MML HREC duties will be reimbursed. Refreshments and parking or taxi vouchers are provided at face-to-face monthly meetings. Members may receive a small token of appreciation from the institution in the form of a Christmas gift.
- The membership of MML HREC is constituted according to the National Statement [Section 5.1.30] as described in the table* above.
- Not less than one third of the Committee should consist of members who are not employed by MML or Mater Research Ltd (MRL) [National Statement section 5.1.29 (b)].
- Additional membership may be sought to enable the HREC to address ethical issues arising from the categories of research considered [National Statement section 5.1.33], taking into account:
  - The spread of disciplinary expertise across the Committee
  - Age and gender balance
  - The balance between institutional/non-institutional; medical/non-medical; researcher/non-researcher members.
- The Chairperson, Deputy Chairperson and other Committee members of MML HREC are appointed in the above categories by MML Board of Directors.

All changes to MML HREC membership are communicated to the NHMRC and other official research regulatory bodies as required.

1.1.2 Conditions of Appointment [*National Statement* sections 5.1.34 – 5.1.36; 5.2.3(c)]

- 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].

- Before appointment, members acknowledge in writing their acceptance of the Terms of Reference of MML HREC, specifically those concerning the confidentiality of Committee business and declaration of conflicts of interest as 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 a further three year period.
- Members should inform the Chairperson if a leave of absence is required. If regularly unable to attend meetings, members should consider their availability to remain on the Committee.
- Members agree to attend continuing education and training in research ethics at least every three years [*National Statement* section 5.2.3 (c)].
- 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, cab vouchers and refreshments will be provided at MML South Brisbane to facilitate members' attendance at meetings.

Expert reviewers appointed by the HREC Chairperson as non-member advisors to the Committee, must agree to the requirements of confidentiality and declaration of conflicts of interest set out in 1.8.1 and 1.8.2 below.

1.1.3 Induction, Mentoring and Training

- New members are provided induction material and mentoring by the Chairperson or other experienced members of the HREC [*National Statement* section 5.1.28(b)(i)].
- 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)].

1.1.4 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.

1.1.5 Relationship to Non-Affiliated Researchers

- MML HREC may review research that is not being conducted at MML, is to be undertaken by non-affiliated researchers, and/or where an MML or MRL employee has not been nominated as a Principal Investigator or contact, in accordance with the conditions of NHMRC certification.
- In such cases:

- MML and its 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 the MML HREC.

1.2 Reporting

- MML HREC is a Committee established by MML and is responsible to MML Board via the Group Chief Executive Officer.
- MML HREC provides unconfirmed minutes of each committee meeting to Mater Ltd Group Executive Committee, once approved by the Committee Chairperson for distribution.
- MML is accountable for its HREC to the NHMRC under registration requirements (NHMRC Registration No: EC00332), and through NHMRC certification as a lead HREC under the National Approach to Single Ethical Review of Multi-Centre Research.
- MML HREC submits annual compliance reports to the NHMRC and complies with continuous certification requirements.

1.3 Purpose

- MML HREC is established, constituted and practices in accordance with the *National Statement*.
- The Committee conducts the ethical review and oversight of human research to protect the mental and physical welfare, rights, dignity and safety of participants in research and to promote ethical standards in human research at MML.
- Before granting approval of a research study involving humans, MML HREC reviews study documentation to satisfy itself that the study complies with relevant guidance and legislation as detailed in 3.3 References below.
- The objectives of MML HREC are to ensure human research submitted for review:
  - is designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results [*National Statement* section 1.1 (d)]
  - is justifiable by its potential benefit, which may include its contribution to knowledge and understanding, to improved social welfare and individual wellbeing, and to the skill and expertise of researchers. What constitutes potential benefit and whether it justifies research may sometimes require consultation with the relevant communities [*National Statement* section 1.1(a)]
  - meets the requirements of the *National Statement*
  - complies with the Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia, 2001
  - complies with all relevant Commonwealth and State/Territory statutory and legislative requirements.

1.4 Purview / Scope of the Committee

MML HREC on behalf of MML Board of Directors is responsible for the effective discharge of responsibilities and duties in relation to:

- conducting ethical review of submitted research and monitoring research in accordance with the *National Statement* and the NHMRC certification requirements
- complying with the scope of the Committee certification for single ethical review of studies in clinical trials of drugs and devices – Phase 0, I, II, III, IV; Justice Health, Clinical Interventional Research other than Clinical Trials; Qualitative Health Research; Mental Health; Paediatrics; Population Health and / or Public Health Research
- complying with EQuIP National Standards: Standard 15 – Corporate Systems, Criterion 4 - Research Governance.

1.5 Duties and Responsibilities of Members [*National Statement* Chapter 5.2]

The role of the committee is to:

- Review all submitted research and reach a decision on the ethical acceptability of:
  - all single site research to be conducted at MML and MRL
  - other single site research where that site does not have its own HREC
  - multi-centre research including projects submitted by MML and MRL affiliated and non-affiliated researchers in line with the institution's certification for single ethical review of multi-centre research and in accordance with MML policies and procedures, and the Memorandum of Understanding between Queensland Health, QIMR Berghofer and MML.
- Ensure that proposed research protocols for studies being carried out within MML and MRL sites comply with the Catholic moral principles relating to the delivery of health care outlined in Code of Ethical Standards for Catholic Health and Aged Care Services in Australia Catholic Health Australia (2001)
- Consider the need for additional external expert review [*National Statement* section 5.1.31 and 5.1.33]; from internal and external reviewers, on scientific, technical and clinical aspects of human research protocols and clinical trials and on compliance with regulatory requirements
- Advise the responsible principal investigator and, as necessary, MML Group CEO and Executive Director of Mater Research, of advice on the ethical acceptability of submitted research
- Review and approve, request amendment of, or reject research proposals on ethical grounds
- Monitor and review amendments and progress and safety reports and, if necessary, withdraw approval for previously submitted research project
- Provide advice to MML and MRL on matters of research ethics including policy requirements relating to *the National Statement*, and any other relevant State, Territory and Commonwealth legislation relating to human experimentation

- Support, subject to Australian legislation and guidelines, requirements where the conditions of a grant involve compliance with any other regulatory agency (for example, U.S. Department of Health & Human Services and compliance with Federal Wide Assurance (FWA) for the protection of human subjects).

1.6 Duties and 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 of Mater Research relating to Mater researchers and research services and functions where the Chairperson considers no material conflict of interest exists.
- MML HREC Chairperson provides leadership and guidance to the Committee and is responsible for the proper conduct of meetings and fulfilling the other duties of the Chairperson as set out in the position description, the National Statement, MML values, and these Terms of Reference. The conduct of each meeting is by rule of the Chairperson.
  - Responsibilities of the Chairperson include:
  - assisting members to fulfil their duties as described in these Terms of Reference;
  - determining, with the HREC Liaison Officer, the level and nature of review of submitted applications
  - conducting reviews of studies submitted for consideration of exemption from HREC review
  - reaching a decision on the requirement for additional expert advice
  - ensuring the meeting documents are distributed in time for consideration by members
  - ensuring that there is quorum of members present to conduct the meeting, or where attendance is not quorate, ensuring that, before a decision is reached, the views of those absent who belong to the minimum membership have been received and considered [*National Statement* section 5.2.32]
  - ensuring that an accurate record of the meeting is documented in the minutes of the meeting
  - ensuring the Committee meets its reviewing, decision-making and reporting requirements.

1.7 Duties and Responsibilities of the HREC Liaison Officer

- The HREC Liaison Officer provides administrative advice on the Institution's processes of ethical review of research projects.
- The HREC Liaison Officer reports to the Chairperson of MML HREC on matters related to the activities and pertinent to the functions of the Committee, and to Mater Research Compliance Manager in matters related to supporting the HREC Office.
- The primary role of the HREC Liaison Officer is to provide leadership in managing all new research proposals submitted to MML HREC Office in accordance with the *National Statement*,

other relevant policies, guidelines and legislation pertaining to human research in Australia, these Terms of Reference and the Standard Operating Procedure of the HREC Office. This includes proactive liaison with researchers to promote high quality project submissions.

1.8 Duties and Responsibilities of the HREC Coordinator

- The HREC Coordinator provides administrative advice on the Institution's processes of ethical review of research projects.
- The HREC Coordinator reports to the Chairperson of MML HREC on matters related to the activities and pertinent to the functions of the Committee, and to Mater Research Compliance Manager in matters related to supporting the HREC Office.
- The primary role of the HREC Coordinator is to provide leadership in NHMRC reporting requirements and duties pertinent to the ongoing certification of MML HREC in accordance with the *National Statement*, other relevant policies, guidelines and legislation pertaining to human research in Australia, these Terms of Reference and the Standard Operating Procedure of the HREC Office.

1.9 Responsibilities of MML HREC Office

The HREC Office is responsible for:

- The administration of applications made by researchers to the HREC, and for the support of the HREC, its sub-Committees and expert reviewers
- Maintaining a record in accordance with the *National Statement* within the local database, Ethical Review Manager (ERM), of all research applications submitted to the HREC, which includes details such as date of approval, protocol amendments and progress and safety reporting [*National Statement* section 5.2.26]
- Facilitating the HREC monitoring of research in accordance with the *National Statement*, the Australian Code for the Responsible Conduct of Research 2018, TGA guidance, and NHMRC guidance for multi-centre research
- Communicating HREC decisions and advice to principal investigators and to the Institution, and reporting in accordance with these Terms of Reference
- Completion and submission of annual compliance and certification reports to the NHMRC;
- Liaising with Queensland Health Hospital and Health Services, and other research facilities within Queensland and nationally, and research personnel as appropriate to progress the administration of applications
- Notifying the Institution of applications for which a fee may be levied to the sponsors of commercial research for the processing and consideration of research documentation, research monitoring, and/or review of amendments.

1.10 Conduct of Members

Committee members are expected to discharge their responsibilities in an ethical and responsible manner consistent with the National Statement, MML Values and the Code of Conduct.

In addition:

- Each member of an ethical review body is responsible for deciding whether, in his or her judgement, a proposal submitted to the review body meets the requirements of the *National Statement* and is ethically acceptable [*National Statement* section 5.2.2]
- In order to fulfil the responsibility for deciding whether, in his or her judgement, the reviewed research meets the requirement of the *National Statement* and is ethically acceptable, each member should become familiar with the *National Statement*, and consult other guidelines relevant to the review of specific research proposals [*National Statement* section 5.2.3 (a)]
- Committee members are expected to prepare for and attend scheduled meetings or, if unavailable, provide opinions on the ethical acceptability of research proposals before meetings [*National Statement* section 5.2.3 (b)].

1.10.1 Confidentiality

Information acquired in the course of carrying out Committee work is to be treated confidentially. The Chairperson shall determine which, if any, meeting documents and items of business can be disseminated outside of the Committee membership.

1.10.2 Conflicts of Interest

Conflicts of interest must be dealt with in accordance with Mater Misericordiae Ltd By-Laws. When any conflict of interest is disclosed to the Committee, the Committee notes the conflict and the Chairperson shall make a determination that may include, but is not limited to, that the member or person will not be present in the meeting when the matter is being considered or that the member or person may be present but will not participate in the meeting discussion while the matter is being considered.

The name of the member, the nature of the conflict and the manner of how it was dealt with must be recorded in the minutes.

1.11 Consumer Engagement

The objectives of this Committee relate to consumers in the following ways:

- The requirement for the ethical principle of respect for human beings to be *the common thread through all the discussions of ethical values. [National Statement,* section 1]
- Consideration of research by non-affiliated lay members who represent consumers both of Mater Misericordiae Ltd and of research as participants
- Researchers are encouraged to consider the benefits of actively engaging consumers in their proposed research. The Consumer Health Forum (CHF) and NHMRC Statement on Consumer and Community Involvement in Health and Medical Research 2018 provides guidance.

- Researchers are encouraged to engage with consumers through Mater Consumers in Care and Mater Cultural Diversity Unit.
- Ethical approval of all recruitment material, such as information sheets.

1.12 Committee Evaluation

The Committee will evaluate itself against the purpose and objectives set out in these Terms of Reference in keeping with the governing policy and procedures and NHMRC requirements [at least every 2 years] using the Committee Evaluation Template found on Mater Document Centre.

2. Conduct of Meetings

2.1 Meeting Frequency and Length [*National Statement* sections 5.1.37, 5.2.28 – 5.2.31]

- 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 circulated by November of the preceding year and published on MML website.
- 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.

2.2 Standing Agenda Items

Standing agenda items include:

- Reflection
- Apologies
- Statements of Disclosure
- Confirmation of Minutes
- Items for Discussion
- Business arising from Minutes
- New Applications
- Changes to approved projects
- Investigator's Brochures – for information only
- Applications granted exemption from full HREC review – for information only
- Safety Data Review – for information only

- Protocol Violations – for information only
- Progress Reports – for information only
- Items for Noting – for information only
- General Business
- Next Meeting

2.3 Committee Quorum & Proxies

- A meeting quorum is established when a representative of each of the categories designated in the *National Statement* [section 5.1.30] is present. When core members cannot be present, they may provide written comments prior to the meeting. 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 those absent who belong to the minimum membership have received all meeting documents and have had an opportunity to contribute their views and that these have been recorded and considered [*National Statement* section 5.2.32].
- The appointed Chairperson will chair every meeting when present. On occasions when the Chairperson is absent or excluded because of a conflict of interest, the meeting will be chaired by the Deputy Chairperson or an appointed Acting Chairperson.

2.4 Committee Documents and Conduct

- Each study will be allocated to two MML HREC members and depending on the nature of the study and HREC membership, and if considered necessary for adequate ethical review, one or two non-member reviewers from MML, MRL, QH or other institution or consumer group [*National Statement* sections 5.1.33, 5.2.19].
- Expert reviews will be provided to the Committee prior to, or tabled at, the subsequent meeting.
- Members who are unable to attend a meeting will be encouraged to contribute and advise their opinion via electronic submission to the Chairperson or HREC Liaison Officer prior to the meeting.
- Meetings will generally be held in the Level 2 Boardroom in Aubigny Place, with Committee members attending in person or via teleconference linkage as and when required.
- The Principal Investigator or a representative of the investigator may be invited to attend the relevant meeting to address questions on an application but will be required to leave the meeting before the ethical decision is formulated.
- Members of the Committee will be required to declare any conflict of interest prior to or at any time during a meeting. The Chairperson will determine the action to be taken.
- Members of the Committee associated with a research protocol being considered by the Committee will be excluded from the meeting for consideration of that particular application.
- 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.
- In general, decisions of MML HREC will be reached by general agreement rather than by a majority vote.
- The decision will be to approve, request amendment or reject a research proposal on ethical grounds [*National Statement* section 5.2.23].
- The Agenda, content of applications, documents associated with submissions, sub-Committees of the full HREC, expert 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 the HREC ERM database.

2.5 Meeting Attendance Apologies

- All attendance apologies should be directed to the Research Ethics Office on 07 3163 1585 or emailed to research.ethics@mater.uq.edu.au

3. Definitions/Abbreviations

Term	Definition
HREC	Mater Misericordiae Ltd Human Research Ethics Committee established under these Terms of Reference
MML	Mater Misericordiae Ltd ACN 096708922 owner and operator of Mater Hospitals South Brisbane, Redland, Springfield, Bundaberg, Mackay, Rockhampton and Townsville and other sites notified to the HREC.
MRL	Mater Research Ltd ABN 28 109 834 719. MRL is a wholly owned subsidiary of Mater Misericordiae Ltd ABN 83 096 708 922

4. Documents related to these Terms of Reference

External documents

1.	National Statement on Ethical Conduct in Human Research, National Health & 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 ICH E6(R2) – Annotated with TGA Comments. Therapeutic Goods Administration
4.	NHMRC guidance for multi-centre research
5.	Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia, 2001
6.	Ethical Conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders, 2018
7.	Australian Code for the Responsible Conduct of Research, 2018
8.	The Consumer Health Forum (CHF) and NHMRC Statement on Consumer and Community Involvement in health and medical research
9.	Public Health Act 2005, Hospital and Health Boards Act 2011 and other relevant requirements of Commonwealth and State/Territory laws
10.	*Guidelines approved under Section 95 of the Privacy Act 1988*
11.	*Guidelines approved under Section 95A of the Privacy Act 1988*
12.	*Guidelines approved under Section 95AA* of the Privacy Act 1988 (Cth)

5. Document controls

5.1 Document revision history

Version	Release date	Description	Risk-rated Review date
1.	1 January 2000	(in accordance with the *National Statement* on Ethical Conduct in Research Involving Humans 1999)	
2.	22 August 2007	Approved by MML Board of Directors 11 September 2007	

Version	Release date	Description	Risk-rated Review date
3.	30 March 2011	(submitted to the National Health and Medical Research Council (NHMRC) for certification in 2011)	
4.	11 October 2011	Approved by MML Board of Directors 4 April 2012	
5.	24 July 2014	Submitted to MML Board of Directors for approval 24 July 2014	
6.	3 March 2015	Submitted to MML Board of Directors for approval	
7.	16 March 2017	Submitted to MML Board of Directors for approval	
8.	25 August 2020	"This version"	25 August 2021

5.2 Document review and approval

In accordance with Mater Committees Policy, this Terms of Reference must be reviewed at least every two years in conjunction with the Committee Evaluation (Sn 1.11). Committee Members must be given the opportunity to assess the current Terms of Reference and make any recommendations to the Committee Chair.

In accordance with the Document Management Policy, changes to this Terms of Reference may be authorised by the Committee Chair.

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

5.3 References

Internal Documents

Document Type	Document ID	Document Title
Governing	PY-IID-000002	Mater Committees Policy
	PR-IID-000003	Operation of Mater Committees Procedure
	FK-CLN-900000	Consumer and community engagement
Supporting	PY-RSH-300305	Human Research Ethics Review Policy
	CA-CEO-000001	Mater Misericordiae Ltd By-Laws
	PY-PAL-060000	Code of Conduct Policy

Document Type	Document ID	Document Title
	PY-RSH-300302	Responsible Conduct of Research Policy
	PY-RSH-300310	Research Misconduct Policy
Relating	PY-RSH-300304	Human Research Governance Review Policy
	PR-RSH-300017-05	Standard Operating Procedures for the Mater Misericordiae Ltd Human Research Ethics Committee Office Staff

5.4 Keyword indexing

Key words:	HREC, Terms of Reference, ToR, Ethical, Review, Human, Approval, Confidentiality, Monitoring, National Statement