Researcher Handbook

Contents

Part 1. Introduction

1.1 Purpose

This handbook provides guidance for researchers seeking approval and authorisation to conduct projects involving patients, staff, data, biological samples, or other resources across any Mater location.

New to research? Start with *Research at Mater: A practical guide to help you get started* for an overview of the research process, key approvals and available support – available as a resource on our website.

1.2 Scope and context

Mater incorporates Mater Health, Mater Education, Mater Research and Mater Foundation under a single, unified banner.

If your project involves Mater patients, staff, data, samples, or resources, you will need the right kind of approval before you start. For research application purposes:

- Mater Misericordiae Ltd (Mater) = the research site
- Hospitals/facilities = facilities within the site

See Appendix 1 for a full list of Mater facilities (current as of August 2026).

Research projects conducted by private doctors in their private consulting rooms located on the Mater campus are generally *not* considered to be projects at the Mater site. However, if these projects involve access to hospital records or procedures performed within Mater hospitals or clinics, they may require Mater site authorisation.

1.3 Research application system

All submissions to Mater must be made through the Ethics Review Manager (ERM) system. A comprehensive suite of ERM help documents, user guides, and FAQs is available on the Mater Research website to assist with this process.

ERM training and support are available for Mater researchers - please contact the Research Quality Management team. Refer to Section 6.1 for all contact information.

Part 2. Planning your project

2.1 Research principles, policies and procedures

All research at Mater needs to follow important national and international standards that guide how projects are conducted responsibly and ethically, including:

- National Statement on Ethical Conduct in Human Research: Explains how to respect and protect people who take part in research.
- Australian Code for the Responsible Conduct of Research: Sets out how researchers should act with honesty, integrity, and accountability.
- Good Clinical Practice (GCP): Provides international standards for running clinical trials safely and reliably.
- Privacy Act 1988: Protects how personal information is collected, used and disclosed.

Alongside these frameworks, researchers must also follow the Mater Research Governance Framework and Mater's relevant policies and procedures at every stage of planning and conducting a study. These cover not only research-specific requirements but also broader governance requirements and can be found in the Mater Policies and Procedures Library (MPPL). MPPL is only accessible to Mater staff. External researchers can seek guidance from their Mater contacts or investigators.

To locate the research-specific policies and procedures:

1. Access the MPPL via the Mater intranet.
2. Navigate to the Published Library Search section.
3. Use the Ministry filter to select Mater Research.

2.2 Is your project research?

It is important to determine whether your project qualifies as research and whether ethical review is required. Different project types have distinct submission requirements and ongoing responsibilities. Research typically aims to generate new generalisable knowledge, while Quality Assurance (QA) and evaluation activities focus on improving existing processes within the hospital. Refer to Section 2.8 for more information on different types of QA and evaluation activities.

For guidance:

- Research – National Statement on Ethical Conduct in Human Research (NS)
- QA and evaluation activities – Ethical considerations in quality assurance and evaluation activities

If you are still unsure if your project is research, please reach out to the Research Navigator for guidance. The Navigator offers tailored support and advice, including early pre-review of study documentation, to help you prepare high-quality submissions and avoid common compliance barriers. Refer to Section 6.1 for all contact information.

2.3 Types of research

Research can take many forms, each with its own purpose, methodology, and compliance considerations.

Identifying the type of research you are conducting will help you plan your project effectively.

Common research types:

- Clinical Trials: Research projects that test whether a medical intervention (like a drug, device, or procedure) is safe and effective in humans
- Quantitative Research – Uses numerical data and statistical analysis to measure variables and test ideas (hypotheses)

- Qualitative Research: Explores experiences, opinions, and feelings through non-numerical data such as interviews, groups, or observations
- Mixed Methods Research: Combines both quantitative (numbers) and qualitative (words) approaches to get a fuller picture
- Observational Research: Researchers observe and collect data without changing anything or giving treatments
- Epidemiological Research: Looks at patterns of health and disease in large groups of people to understand causes and effects
- Biomedical Research: Laboratory-based research that studies cells, tissues, or animals to understand diseases and develop new treatments

2.4 Risk profiles of research

Understanding the level of risk in your research is important because it determines the ethics review pathway.

Lower Risk		**Higher Risk** (individual, group, community, societal or global)	
Minimal	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

Note. Adapted from National Statement on Ethical Conduct in Human Research 2025 (p. 13), by the National Health and Medical Research Council, the Australian Research Council, and Universities Australia, 2025. Copyright 2025 by the National Health and Medical Research Council.

2.4.1 Lower Risk research

Lower risk research projects are those where the foreseeable risk to participants is no greater than discomfort (for example, answering personal questions or giving a blood sample).

At Mater, these applications can be submitted at any time and are usually reviewed between HREC meetings by a smaller group (sub-committee) of the HREC.

If your project requires a waiver of consent (meaning participants won't be asked for consent for one or more elements of the project), the review may take longer. Refer to Section 3.3 for more information.

2.4.2 Higher Risk research

Higher risk research projects are those where the foreseeable risk to participants is more than discomfort (for example, risk of harm or significant stress). These applications must be reviewed by the full HREC at one of their scheduled meetings.

To find the dates of Mater's monthly HREC meetings and submission deadlines, check the HREC meeting calendar available from the Resources section of our website.

2.4.3 Research eligible for exemption

Research that may be eligible for an exemption from ethics review is lower risk research that satisfies one or more of the following:

Use of data where all identifiers have been removed.

Using collections of information where all personal details have been removed before researchers receive them. Researchers must agree:

- not to try to re-identify individuals,
- to take reasonable steps to prevent unauthorized re-identification or access, and
- to ensure that sharing data during or after the project does not create new risks of re-identification.

Public Surveys or Observations

Conducting surveys or observing public behaviour, if the information is collected without personal identifiers and is very unlikely to cause distress to anyone involved.

Educational Training Projects

Research carried out as part of an educational program, where the activity is only for training purposes and any results or documents are used only within the program.

Use of publicly available information

Using information that is already publicly available under law or regulation, such as mandatory reporting data, registries of births/deaths, coronial reports, or statistics published by the Australian Bureau of Statistics.

At Mater, these applications can be submitted at any time and are reviewed by the HREC Chairperson or Deputy Chairperson rather than the full committee.

2.5 Protocol development

A detailed protocol (for research) or project plan (for non-research) is required for all applications. The protocol or project plan should contain sufficient detail to ensure the project can be conducted consistently by any suitably trained member of the project team.

For research projects, any changes to the protocol must be submitted as formal amendments to the reviewing HREC and relevant Research Governance Office/s for review. These changes must not be implemented until HREC approval and site authorisation have been obtained.

Templates are available from our website. You are encouraged to engage with the Research Navigator for support in refining protocol drafts before submission. Refer to Section 6.1 for all contact information.

2.6 Data Management Plan

At Mater, all research applications must include a Data Management Plan (DMP) to support the planning and documentation of how research data will be managed throughout the project lifecycle. The DMP should be submitted with your Mater SSA application.

A Mater template and supporting guidance document are available:

- Through Mater internal resources
    - Mater Policy and Procedure Library (MPPL-08277)
    - Mater Research SharePoint page – Research Compliance – Resources Library
- By contacting Mater Research Ethics and Governance

Alternative templates will also be accepted, however additional site-specific questions may be asked.

2.7 Participant information sheet and consent form (PICF)

For projects including written consent, the PICF is a critical document. It should be clear, simple and transparent, providing participants with sufficient information about the purpose, procedures, risks, benefits and alternatives of the research to support an informed decision. Mater Research and the Mater HREC recommend the use of the InFORMed PICF template, although other templates may be used

All PICFs must meet the following Mater requirements.

2.7.1 General information

Barcodes: If research participants are also Mater patients, the first page of the PICF should include a barcode to allow scanning into the health record where required.

Logos: Most Mater PICFs should include the Mater Research logo on the first page, apart from external projects where Mater's involvement is limited.

Version control:

- The footer should include version number, date and page numbering
  e.g. Mater PICF Version 1 dated 01 January 2020 *Page 1 of 4*
- Site versions of PICFs that have been created from a Master PICF should clearly state this in the footer and reference both version details.
  e.g. Mater PICF Version 1 dated 01 January 2020 based on Master Version 1 dated 01 December 2019 *Page 1 of 4*
- Ensure section breaks are correctly formatted to maintain consistent page numbering and footers.

HREC contact details: For projects reviewed by Mater HREC, include the following:

Name of committee	Mater Misericordiae Ltd Human Research Ethics Committee (EC000332)
Contact	HREC Coordinator or HREC Chairperson
Telephone	(07) 3163 1585
Email	research.ethics@mater.uq.edu.au

Research Governance contact details: For projects reviewed by an external HREC, include the following:

Name	Research Ethics and Governance Officer
Telephone	(07) 3163 3769
Email	research.governance@mater.uq.edu.au

2.7.2 Management of participant data

The PICF must clearly inform the participant about how their data will be used, stored, and shared. The following key points must be included in Mater PICFs:

- Identifiability of the data:
  - Provide details about how data will be collected, de-identified/coded, and in what form it will be shared with external collaborators (if applicable).
  - Best practice is to share only de-identified data. If identifiable data is to be collected or shared, the PICF should be explicit about what identifiable data is being shared.
  - Sharing of identifiable data requires review by Mater Privacy Office and Mater Legal.
- Who data will be shared with - each external institution/organisation must be listed.
- Where the information will be shared/sent to – including storage systems/databases and location. If data is to be shared outside of Australia or on international servers, this must be clear and will require review by Mater Privacy Office and Mater Legal.

2.7.3 Requirements as a Catholic healthcare service

For projects that include information about pregnancy avoidance or reproductive risks, the following wording is recommended for inclusion in the PICF:

"Because of the unknown risks of this study medication, it is important that you do not become pregnant during this study. For legal reasons, the study sponsor requires us to provide you with information about methods of avoiding pregnancy and relating to assisted reproduction. Not all of this information is endorsed by Mater nor reflects its ethical standards as a Catholic hospital. You must discuss with your own doctor or study doctor an effective way for you to avoid pregnancy. If for reasons of faith, beliefs, or values you decide not to use one of these methods to avoid pregnancy you are advised not to participate."

Instructions for use of this wording in the Mater site PICF:

- Projects reviewed by Mater HREC:
    - Include the recommended Mater wording as a preliminary paragraph before the standard wording relating to pregnancy avoidance/reproductive risks.
- Projects reviewed by external HRECs - there are two options:
    - Option 1 (***preferred***): Include the recommended Mater wording as a preliminary paragraph before the standard (non-Catholic) wording relating to pregnancy avoidance/reproductive risks.
        - Do not remove any of the non-Catholic wording if using this option.
        - Mater will accept the insertion as a site-specific change; however, you should consult with the reviewing HREC to determine their requirements.
    - Option 2: If the HREC has approved specific wording for Catholic institutions in the Master PICF, that wording will be reviewed by Mater Research Ethics and Governance Officers (REGOs) to ensure it is appropriate. Changes may be required to meet Mater's obligations, which may require further HREC review and approval.

If these options aren't suitable for your PICF, please contact the Research Navigator for guidance. Refer to Section 6.1 for all contact information.

2.7.4 Research with Aboriginal and Torres Strait Islander People

The following wording is recommended for inclusion in the PICF:

"If you are an Aboriginal and/or a Torres Strait Islander person, you have the opportunity to yarn with an independent Aboriginal Research Liaison support person (Nicole Hewlett, yarning@mater.uq.edu.au) before agreeing to participate in this research project. If you would like to connect with Nic, please contact her email or let a team member know."

2.7.5 Research involving ionising radiation

When research involves exposing participants to ionising radiation, the PICF must clearly explain this exposure in line with regulatory requirements. The Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposes (2005) (ARPANSA Radiation Protection Series No. 8) sets the standards that must be followed.

For projects where radiation exposure is no more than standard clinical care, the PICF should state this.

For projects where radiation exposure goes beyond standard clinical care, a Radiation Safety Report is required with the ethics and governance applications, and the Mater PICF must include the recommended radiation wording provided in that report.

2.8 Non-research projects

Not all projects undertaken within a health service or academic setting meet the formal definition of *research*. However, some activities still require oversight or approval to ensure they are conducted ethically, responsibly, and in line with institutional policies.

Common examples include:

- **Quality assurance (QA) and audit activities**
  These projects evaluate or improve services, processes or standards of care.
- **Service evaluations**
  Projects that assess the effectiveness, efficiency, or acceptability of a service without generating new generalisable knowledge.
- **Case reports**
  A case report describes an individual patient's condition, treatment and outcome, with the aim of sharing clinical knowledge and lessons learned with other clinicians.
- **Case series**
  Generally, a case series of up to five cases is acceptable. Five cases is the standard limit, although special consideration may be given to larger case series. Larger case series may be considered research, particularly where the aim is to draw generalisable conclusions or make assumptions beyond the cases described.

How to submit your application

At Mater, these are submitted anytime in ERM using the Mater Quality Assurance Projects and Case Reports Form. You are strongly encouraged to contact the Research Navigator if you are unsure whether your project is considered research or which submission pathway is appropriate. Refer to Section 6.1 for all contact information.

2.9 Required approvals

Before commencing any research project at Mater, the following approvals are required:

1. **Ethics approval from a NHMRC-certified Human Research Ethics Committee (HREC**) – ensuring that a research project is planned and carried out in line with the National Statement, keeping participants safe, respecting their rights, and looking after their wellbeing.

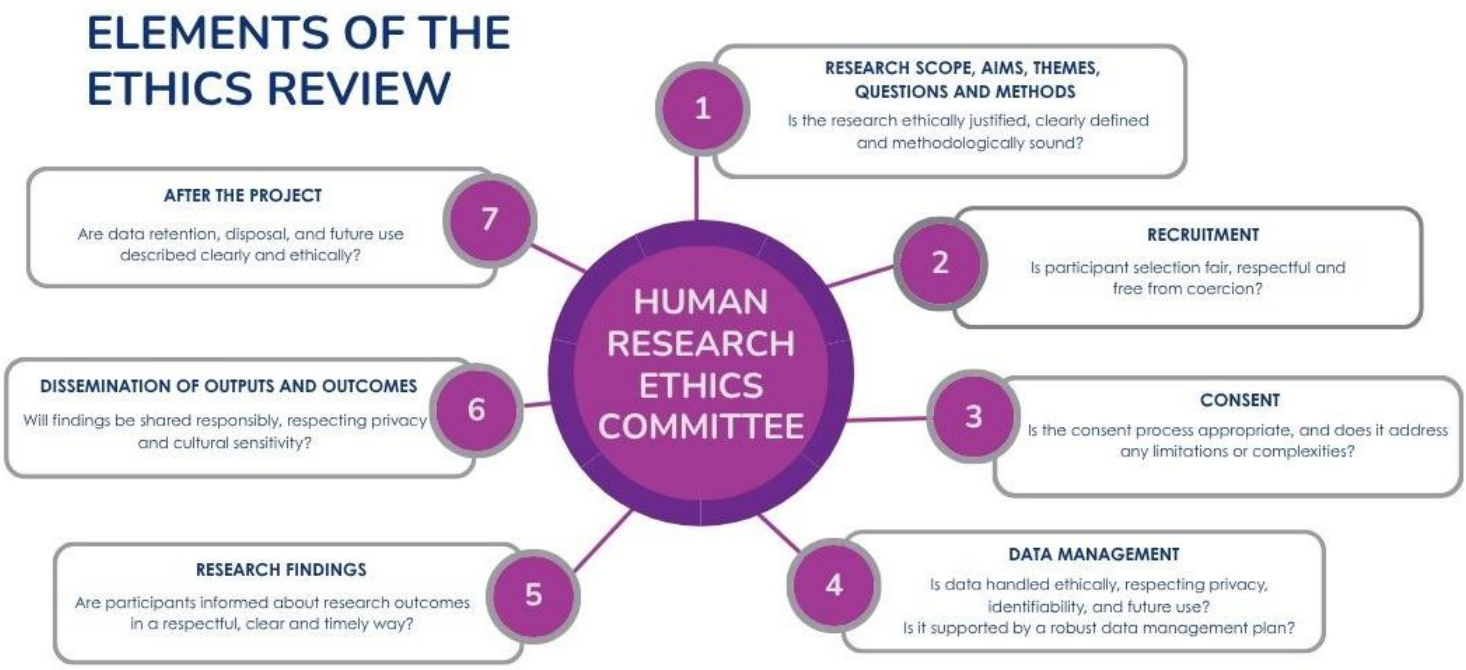
   In exceptional circumstances, where Mater's involvement is limited to advertising for an external project, a non-certified HREC approval may be acceptable, however this should be confirmed with Mater Research Ethics and Governance prior to submitting.

2. **Governance (site) authorisation –** ensuring that the site has the right resources, participants are protected, and that legal, financial, and risk requirements are all met according to the institutional and national standards.

While applications for ethics and governance review can be submitted concurrently, governance authorisation will only be granted once HREC approval has been obtained.

Part 3. Obtaining ethics approval

3.1 Overview of ethics approval



Mater accepts ethics approvals from any NHMRC-certified HREC.

The Mater Misericordiae Limited HREC (Mater HREC) [EC00332] is NHMRC-certified to review and approve projects in the following categories:

- clinical trials of drugs and devices: phase 0, I, II, III, IV
- clinical interventional research other than clinical trials
- qualitative health research
- mental health
- paediatric research
- population health and/or public health research

Mater HREC can provide ethics approval for most sites. However, some sites have their own requirements about which HREC approvals they will accept.

If your project involves more than one site, you should contact your preferred HREC **before you submit your application**. They will confirm whether they can review and approve the project on behalf of all the sites involved. Doing this early helps avoid delays and ensures you follow the correct approval pathway.

3.2 How to submit your application

Once you have determined which HREC will review your project, you should contact that HREC directly or consult their website to obtain details about their application processes and specific requirements. The following information describes the requirements for submission to Mater HREC.

3.2.1 Mater HREC Applications

All applications must be submitted through ERM using the Human Research Ethics Application (HREA) form.

3.2.2 Study documents

The study documents required for submission with your ethics application will vary depending on the type and nature of your project. To help you prepare, refer to Appendix 3 for a checklist of required documents.

3.3 When is a waiver of consent required?

If you plan to use patient information or biospecimens for anything other than the primary purpose it was collected, you must either obtain consent from the patient or apply to the HREC for a waiver of consent.

A waiver of consent means an ethics committee allows researchers to use people's information without asking them first. An ethics committee may approve a waiver when all the following conditions are met:

- The research is lower risk
- It's genuinely not possible to get consent
- The research is important and can't be done properly if consent is required
- People's privacy is protected and only the minimum necessary information is used
- No one has previously said "don't use my data"

Refer to the National Statement (Section 2.3.9 – 2.3.11) for more information.

Prior consent

If participants have already given their consent for their data or samples to be used in future research (for example, through a biobank or another study), you do not need to apply for a waiver of consent. However, you must confirm that the scope of their original consent covers your proposed use. If this prior consent does not cover your research, you will need to seek new consent or apply for a waiver.

How to apply

You must provide a clear justification demonstrating that the waiver meets the requirements of the National Statement section 2.3.10 and the Guidelines approved under section 95A of the Privacy Act 1988. Refer to Appendix 2 for guidance when preparing your justification; this information is also embedded within our retrospective research protocol template. If you are unsure whether a waiver of consent is appropriate for your project, please contact the Research Navigator for guidance. Refer to Section 6.1 for all contact information.

3.4 Ethics review timelines

Every effort is made to review ethics applications without delay. To support timely review:

- Submit a complete and well-prepared application
- Ensure participant-facing documents are clear, accurate and consistent
- Respond promptly to requests for clarification or amendment
- Use tracked changes when submitting revised documents

Mater HREC (Ethics review)

Benchmark: 60 calendar days from receipt of a valid application to approval (excluding time taken by researchers to respond to queries).

Part 4. Obtaining governance (site) authorisation

4.1 Overview of governance authorisation

4.2 How to submit your application

4.2.1 Site-Specific Assessment (SSA)

All applications for governance review must be submitted through ERM.

The Mater SSA is submitted as a sub-form in ERM, either from a HREA (if submitted to a HREC that uses ERM) or from a Minimal Data Form (MDF). For further information, refer to the ERM user guides available on our website.

4.2.2 Study document

Mater HREC-reviewed projects: Study documents submitted with the HREA do not need to be uploaded with the SSA.

Externally reviewed projects: Study documents must be uploaded with the SSA application (not within the MDF). Refer to Appendix 3 for a checklist of required documents.

4.3 Privacy and cybersecurity approval

Research projects involving access to Mater patient data require approval from the Mater Privacy Office, even if the researcher already has clinical access. Additionally, in some cases, use of certain systems or software require review by Mater Cybersecurity Office. The REGO will coordinate this process as part of the SSA review. Any feedback or additional requirements will be communicated to the research team.

4.4 Agreements

Projects involving external parties may require a legal agreement. These agreements outline responsibilities related to collaborations, student involvement, data/sample sharing, funding arrangements, intellectual property or service provision.

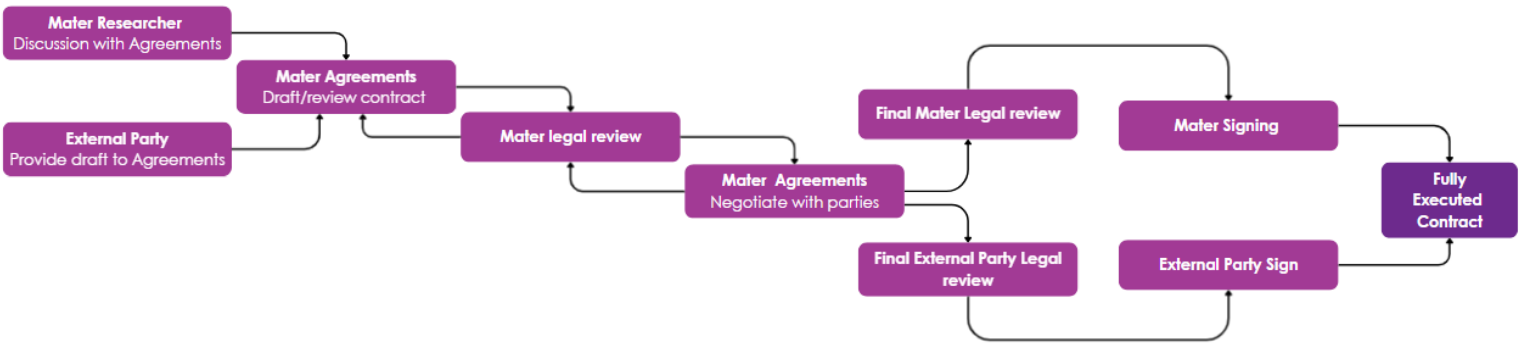
At Mater, all agreements must be processed through Mater Research Agreements and reviewed by Mater Legal. The Mater Research Agreements office is also responsible for arranging signature/s from the appropriate person/people at Mater.

To support efficient processing of research agreements, researchers must use the approved request forms when initiating an agreement. These forms ensure the Mater Research Agreements team receives the information required to commence review, helping to reduce delays and minimise requests for additional information. Request forms are available on SharePoint (accessible to Mater staff). External researchers can contact the Mater Research Agreements Office.

The need for an agreement may be identified during the Research Governance review process or through engagement with the Mater Research Agreements team. In practice, agreement requirements are often identified collaboratively, with Research Governance flagging potential needs and the Research Agreements Office confirming, refining, or identifying additional requirements.

An example process diagram for two-party agreements is shown below.

Note: Multi-party agreements are more complex and may require additional time for review and execution.



4.4.1 Institution details for legal documents

Institution	Mater Misericordiae Ltd (MML) and Mater Research Ltd (MRL) collectively referred to as "Mater"
Address	Level 10, 14 Stratton Street, Newstead 4006 QLD
ABN	MML: 83 096 708 922 MRL: 28 109 834 719
Contact for Notices	Executive Director Mater Research
Email for Notice	Executive@mater.uq.edu.au (copied to research.agreements@mater.uq.edu.au)
Phone Number	+61 7 3163 8008

4.4.2 Insurance

For some research projects, external institutions will require evidence of insurance held by Mater. The Mater Research Agreements team can arrange insurance certificates if requested.

For commercially sponsored clinical trials, Mater requires the other party (i.e., Local Sponsor) to hold clinical trial, public liability, and product liability insurance of $20 mil AUD each.

4.5 Service providers

4.5.1 Mater Support Services

If your research project requires the use of any Mater Support Services, you must obtain approval from the relevant service area. Most services will incur a fee.

A signed quote from the service provider must be included with your SSA submission and is required before governance authorisation can be granted.

Commonly used Mater services:

- Mater Pharmacy: pharmacy.clinicaltrialsteam@mater.org.au
- Mater Pathology: pathologyclinicaltrialsteam@mater.org.au

4.5.2 External services

If Mater engages an external provider to deliver research-related services (e.g. sample analysis, investigational product manufacturing, or clinical assessments), a service agreement is required.

These agreements ensure legal and operational clarity around scope of services, data/sample handling, intellectual property, and funding and payment terms.

All service agreements must be reviewed and processed through Mater Research Agreements and Mater Legal. Refer to Section 6.1 for all contact information.

4.6 Clinical trials

4.6.1 Early phase clinical trials

Early Phase (phase 1) clinical trials conducted at Mater require additional expert review to ensure Mater patient safety. The REGO will coordinate this process as part of the SSA review. Any feedback or additional requirements will be communicated to the research team.

4.6.2 Clinical Trial Notification (CTN)

If a clinical trial involves the use of an unapproved therapeutic good, the sponsor must notify the Therapeutic Goods Administration (TGA), typically via the CTN scheme.

Externally sponsored trials	Mater-sponsored trials
• A copy of the submitted CTN must be provided as part of the SSA review. • A copy of the acknowledged CTN is required before any site activities involving the unapproved therapeutic drug can commence.	• The REGO will assist the research team in preparing the draft CTN during the SSA review. • The CTN must be approved by the Mater Principal Investigator (PI) before submission to the TGA. • The TGA fee must be paid from the Mater researcher's cost centre. • Mater-sponsored trials are subject to ongoing monitoring by the Research Monitor.

Mater Approving Authority Details:

- Entity: Mater Misericordiae Ltd and Mater Research Ltd (collectively referred to as Mater)
- Approving Officer: Prof Allison Pettit
- Position: Executive Director, Mater Research Ltd (Research Delegate for MML)
- Phone: 07 3163 3769
- Email: research.governance@mater.uq.edu.au

4.6.3 Insurer notification

Some categories of clinical trials require notification to Mater's insurers. The REGO or Mater Research Agreements will coordinate this process as part of the agreement or SSA review. Any feedback or additional requirements will be communicated to the research team.

4.7 Registries

4.7.1 Clinical Quality Registries

Clinical registries collect information about patients' diagnoses and treatments. Clinical quality registries (CQRs) are a type of clinical registry that monitors the quality of healthcare in specific areas by regularly collecting, analysing and reporting health data. They use this information to set benchmarks, identify significant outcome differences and improve healthcare quality.

HREC approval is required for participation in a CQR. At Mater, the site approval is granted by Mater Clinical Governance on behalf of Mater Health. Contact Mater Clinical Governance for advice on the application process.

4.7.2 Research Registries

Research registries retrospectively and/or prospectively collect and store data to answer specific research questions, or to use for future research.

HREC approval is required for all research registries. At Mater, the site authorisation is managed through the research process. Applications for research registries are submitted as a Mater SSA form in ERM.

4.8 Research involving animals

Animal research undertaken by Mater staff and students must be approved by a University of Queensland Animal Ethics Committee before commencing. Details are available from the UQ Animal Ethics Unit.

4.9 Governance review timelines

Every effort is made to review governance applications without delay. To support timely review:

- Submit all required site-specific documentation and institutional approvals
- Ensure regulatory, contractual and funding requirements have been considered
- Respond promptly to requests for additional information

Mater REGO (Governance Review)

Benchmark: 33 calendar days from SSA submission to authorisation (excluding time taken for researcher responses to queries, execution of legal agreement, HREC review and approval, other Mater-specific approvals).

Mater Research Agreements (contract review)

Benchmark: 14 calendar days from receipt of a valid request to Mater approval (excluding time taken by researchers and other parties to respond to queries). Complex contracts and negotiations of contract clauses will likely require additional time.

Mater Priority Trial Reviews

Mater Research offers a fee-for-service express review model for clinical trials, designed to expedite the site authorisation process within 2 to 4 weeks. This model includes an initial review of Research Governance and Agreements within five business days, dedicated governance/agreement officers assigned to the study, and parallel review pathways. Terms and conditions apply. Further information can be found on our website.

Part 5. Managing your research project

5.1 Amendments

An amendment should be submitted and approved prior to the implementation of any change that alters the conduct, scope, oversight, or approved documentation of the research project.

Amendments should be submitted through the ERM system using the 'Mater Amendment Form'. Submissions should include:

- A summary of the amendment
- Any new documents
- Amended documents (tracked and clean versions)
- HREC approval letter (for projects reviewed by external HRECs)

5.2 Progress reporting

An annual progress report must be submitted through the ERM system using the 'Mater Progress and Final Report Form'**.** This is a condition of ongoing HREC approval and/or governance authorisation. Failure to submit progress reports may result in your HREC approval/site authorisation being suspended at Mater. In rare cases, a project may be closed if no action is taken to address the suspension.

Reviewing HREC	Due dates	Submission requirements
Mater HREC	Anniversary of HREC approval	• Any relevant supporting documents
External HREC	As per HREC deadline	• Any relevant supporting documents • Progress report submitted to the reviewing HREC* • HREC acknowledgement*

*Mater progress reports can be submitted without these documents, which can be provided once available.

5.3 Safety reporting

Safety reporting requirements are summarised in the table below. Refer to the Mater Clinical Trials Safety Reporting Framework (MPPL-07986) for further details.

ERM form	Purpose	Submission requirements
Mater Deviations and Breaches	Notify Mater HREC/REGO of deviations, suspected breaches and serious breaches to the protocol or Good Clinical Practice.	• Relevant supporting documents • HREC acknowledgement (external HRECs only)
Mater Annual Safety Report form	Notify Mater HREC/REGO of any changes to safety information for projects that involve the use of an investigational product.	• Development Safety Update Report (DSUR), if available • Relevant supporting documents • HREC acknowledgement (external HRECs only)

Mater DSMB Recommendations	Notify Mater HREC/REGO of Data Safety Monitoring Board (DSMB) letters of recommendation. Note: Projects reviewed by external HRECs - DSMB recommendations to "continue as planned" are not required to be submitted to Mater REGO	• DSMB Letter of recommendation • Relevant supporting documents • HREC acknowledgement (external HRECs only)
Mater SAE/SUSAR/USADE	Notify Mater REGO of an individual: • SAE/SAR/SADE/SUSAR/USADE (Mater-sponsored trials) • SUSAR/USADE that occurred at a Mater location (Externally sponsored trials)	• Relevant supporting documents
Mater Significant Safety Issue	Notify Mater HREC/REGO of any significant safety issues, including urgent safety measures, temporary halts or early terminations.	• Relevant supporting documents

5.4 Monitoring

All research projects conducted at Mater may be subject to internal monitoring. The scope and frequency of monitoring are determined by the level of risk associated with each project, along with other relevant factors. This process helps ensure the integrity, safety, and regulatory compliance of research activities at Mater.

5.5 Final report

A final report must be submitted through the ERM system using the 'Mater Progress and Final Report Form' upon project completion or abandonment. This allows for formal closure of the project and/or Mater site.

When can a project be closed?

Research projects approved by Mater HREC:

Note: *Multi-site research projects approved by Mater HREC cannot be closed until all sites can be closed.*

- ☑ All primary objectives published or presented → Include publication, presentation or summary of results
- ☑ All results available but not yet published → Include draft publication
- ☑ All results available but not planning to publish → Provide summary of results
- ☑ Discontinued, abandoned, or never commenced → Provide details of study activity

Research projects at Mater approved by an external HREC:

- ☑ All activity at Mater ceased (including access to Mater data)

5.6 After project closure

Research data should be stored securely and retained according to your Data Management Plan, including timelines for archiving or disposal. Any future use must align with participant consent and comply with Mater policies regarding confidentiality, privacy and protection information.

Part 6. Supporting information

6.1 Key contacts

Mater Research Ethics: research.ethics@mater.uq.edu.au

Mater Research Governance: research.governance@mater.uq.edu.au

Mater Research Agreements: research.agreements@mater.uq.edu.au

Mater Research Monitoring: research.monitoring@mater.uq.edu.au

Mater Research Navigator: research.navigator@mater.uq.edu.au

Mater Research Quality Management: researchqualitymanagement@mater.org.au

6.2 Appendix 1 – Mater locations

Mater facilities (current as of August 2026):

- Mater Research, South Brisbane Campus
- Mater Research, Translational Research Institute Campus
- Mater Hospital Brisbane
- Mater Private Hospital Brisbane
- Mater Private Hospital Brisbane, Annerley Road Campus
- Mater Cancer Care Centre
- Mater Mothers' Hospital
- Mater Mothers' Private Brisbane
- Catherine's House for Mothers, Babies and Families
- Mater Children's Private Brisbane
- Mater Hospital Springfield
- Mater Private Hospital Springfield
- Mater Mothers' Springfield
- Mater Private Hospital Redland
- Mater Private Hospital Bundaberg
- Mater Private Hospital Rockhampton
- Mater Mothers' Private Rockhampton
- Mater Private Hospital Mackay
- Mater Private Hospital Mackay, Wellington Street Campus
- Mater Mothers' Private Mackay
- Mater Private Hospital Townsville
- Mater Private Hospital Townsville, Hyde Park Campus
- Mater Mothers' Private Townsville
- Mater Private Hospital Gold Coast
- Mater Mothers' Private Gold Coast

6.3 Appendix 2 - Waiver of consent guidance

Purpose of the waiver request

Provide a brief description of why a waiver of consent is required for the project. For example:

- Retrospective data collection
- Pre-screening potential participants before approaching them for consent
- Comparing a retrospective patient cohort with an interventional group
- Other (please specify)

Details of the records to be accessed

Include the following information:

- The organisation holding the records.
- The type of records to be accessed
- The estimated number of records/charts to be accessed

Justification against the National Statement criteria

Address each criterion below, describing specifically how and why it applies to your study.

a) Involvement in the research carries no more than low risk to participants

b) The benefits from the research justify any risks of harm associated with not seeking consent
c) It is impracticable to obtain consent
d) There is no known or likely reason for thinking that participants would not have consented if they had been asked
e) There is sufficient protection of their privacy
f) There is an adequate plan to protect the confidentiality of data
g) In case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them
h) The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled
i) The waiver is not prohibited by State, federal, or international law

Declaration

Include the following statement:

We believe this request satisfies the criteria for providing a waiver of consent as outlined in Section 2.3.10 of the National Statement on Ethical Conduct in Human Research and is also in accordance with Section 95A of the Privacy Act 1988.

6.4 Appendix 3 – Submission checklists

6.4.1 HREA checklist

HREA Checklist for MML HREC
All HREAs
☐ **Protocol**
☐ **Curriculum Vitae (CV)** – Submit a current CV (within 2 years) for each site Principal Investigator (PI) – For multi-site projects, also submit a, current (within 2 years) CV for the Coordinating Principal Investigator (CPI) – Other CVs are not required unless requested in HREC review
☐ **HREA declaration** – For multi-site projects the CPI must sign. For single site projects, the PI for the site must sign
…If applicable
☐ **Patient Information and Consent Forms (PICFs)** – For multi-site projects, submit Master PICFs only
☐ **Waiver of consent justification** – *e.g., for use of patient data for a secondary purpose without consent* – Only include a separate justification document if not embedded in the Protocol
☐ **Data collection tools** – *e.g., Case Report Forms (CRFs)*
☐ **Instruments, tools and measures** – *e.g., surveys, questionnaires, interviews and focus group guides*
☐ **Investigator Brochures (IB), Product information or Device information**
☐ **Advertising materials** – *e.g., flyers, brochures, posters, websites, letters/emails of invitation and telephone transcripts*
☐ **Participant diaries and wallet cards**
☐ **Institutional Biosafety Committee (IBC) and Office of the Gene Technology Regulator (OGTR) licences and approvals** – Submit license for dealings with a Genetically Modified Organism (GMO)
☐ **Radiation Safety Reports** – Submit a report for each site to be approved by MML HREC where radiation is involved
☐ **Other recruitment material** – *e.g., template letter/email invitations, recruitment videos, video transcripts, phone transcripts*
☐ **Other study-specific supporting documents** – *e.g. correspondence or approval from other HRECs, expert independent reviews, peer reviews*

6.4.2 SSA Checklist

Mater SSA Checklist

All Mater SSAs - Please note: For Mater Priority Trial Review service, refer to the Mater Priority Trial Reviews Fact Sheet. Documents submitted to MML HREC do not need to be submitted with the Mater SSA.

☐ **Research Team section of the SSA**
- For externally sponsored clinical trials, list the PI for Mater; primary Clinical Trials Coordinator (CTC); Mater Contact; students; non-Mater people accessing Mater site, interacting with Mater participants or working with Mater data or samples (excl monitors)
- For all other research projects, also list all other investigators (including the CPI for multisite projects)

☐ **CV**
- Submit a current CV (within 2 years) for the PI for Mater

☐ **Budget**
- Submit a budget that lists actual funding, Mater costs, and in-kind support (dollar figure or an estimate of time commitment for staff)

☐ **Mater Data Management Plan (DMP)**
- Submit a Mater (site-specific) DMP (refer to Template). DMPs on other templates are accepted but will trigger additional SSA questions.
- Include version, date and page numbering (page x of x) in the footer

☐ **SSA declarations**
- For all projects, the PI for Mater, Mater Contact and relevant Head of Department and/or Head of Laboratory must sign
- For funded projects, a cost centre must be provided, and the Management Accountant must sign
- For projects where Mater's involvement extends beyond advertising an otherwise externally led research project, Facility Authorities must sign (refer to Fact Sheet)

… If applicable

☐ **Mater site PICFs**
- For multisite projects where Master PICFs have been HREC approved, submit clean and tracked copies (tracked from clean Master) with version, date and page numbering (page x of x), and Master version and date referenced in the footer
- Complete placeholders for site details (Mater Research logo, name of PI for Mater, the correct site name ["Mater Misericordiae Ltd"], clinical contact, and Mater research governance contact [if approved by an external HREC])

☐ **Mater site documents**
- For multisite projects where Master documents have been HREC approved, submit clean and tracked copies (tracked from clean Master) with version, date and page numbering (page x of x), and Master version and date referenced in the footer
- For projects where Mater site documents are created, but do not require HREC approval, submit clean version with version, date and page numbering (page x of x) in the footer
- Complete placeholders for site details

☐ **Evidence of Mater Marketing approval**
- For any advertising materials to be used at Mater

☐ **Clinical Trials Notification (CTN) and/or Clinical Trial Approval (CTA)**
- For externally sponsored projects, provide CTN and/or CTA with the correct Mater site and approving authority details
- For Mater-sponsored projects, the CTN and/or CTA will be drafted and submitted by Research Ethics and Governance during SSA review
- TGA acknowledgment required for site authorisation

☐ **Quotes**
- For projects that use Mater Pathology Services or Mater Pharmacy Services, submit a fully signed and in date (within 1 year) quote

☐ **External Service Provider section of the SSA**
- For projects that use external service providers, list each provider and the service they will provide

☐ **Mater site Radiation Safety Report**

☐ **IBC and/or OGTR licences and approval**

☐ **Queensland Civil and Administrative Tribunal (QCAT) approval**
- For projects including adults who lack the capacity to provide their own consent, QCAT approval may be required

External HREC – *additional submission requirements*

☐ **HREC approval letters**
- Submit initial and all subsequent approvals with "Mater Misericordiae Ltd" listed as an approved site
- If a waiver of consent is approved, provide evidence that s95A was considered during HREC review

☐ **Current HREC-approved documents**
- Submit all documents listed on the HREC approval letters. If a document is not relevant to Mater, this should be explained. Do not submit superseded documents.

☐ **Progress Report and Acknowledgement**
- For projects where the initial HREC approval was ≥12 months prior to SSA authorisation, submit the most recent progress report submitted to the HREC along with subsequent HREC acknowledgement as evidence of ongoing HREC approval

6.4.3 Amendment checklist

Amendment Checklist

Projects approved by MML HREC

- ☐ **Summary and rationale for changes**
  - Describe all project-level changes and rationale for the amendment
- ☐ **New documents**
  - Provide clean versions with version, date and page numbering (page x of x) in the footers
- ☐ **Amended documents**
  - Provide tracked and clean copies with updated version, date and page numbering (page x of x) in the footers
- ☐ **Research team**
  - List all new and removed members or members who have a change of project role or affiliation
  - Consider whether project documents need to be amended and consider impact on research agreements
- ☐ **Amendment declaration**
  - For projects where Mater is NOT a site, the CPI (for multi-site projects) or PI (for single site projects) must sign
  - For projects where Mater is a site, the PI for Mater must sign

Projects where Mater is a site

- ☐ **Summary and rationale for changes**
  - Describe all project-level changes and rationale for the amendment. Describe whether/how the amendment will affect the Mater site.
- ☐ **New Mater site documents**
  - Provide clean version with version, date and page numbering (page x of x) in the footer
- ☐ **New Mater site documents based on Master documents (new or amended)**
  - Provide clean and tracked versions (tracked from current approved Master document) with version, date and page numbering (page x of x) and Master version and date referenced in the footer
- ☐ **Amended Mater site documents**
  - Provide clean and tracked versions (tracked from previously authorised version) with updated version, date and page numbering (page x of x) in the footer
- ☐ **Changing the PI for Mater**
  - If the PI for Mater cannot provide oversight for ≥3 months, nominate a new or alternate PI, submit a CV for the new or alternate PI, submit an email/letter of support from outgoing PI and new or alternate PI. Consider effect on site documents, CTN and research agreements.
- ☐ **Changing the research team**
  - List all new/removed members or members who have a change of project role or affiliation
  - Consider whether project documents need to be amended and consider impact on research agreements
- ☐ **Amendment declaration**
  - The PI for Mater must sign

Projects approved by External HREC

- ☐ **Summary and rationale for changes**
  - Describe all project-level changes and rationale for the amendment and whether/how the amendment will affect the Mater site
  - If a document listed on a submitted HREC approval letter is not relevant to Mater, explain this in the amendment rationale
- ☐ **HREC approval letters**
- ☐ **HREC-approved documents (new)**
  - Submit clean versions of all new documents listed on the HREC approval letters with version, date and page numbering (page x of x) in the footers. Do not submit superseded documents.
- ☐ **HREC-approved documents (amended)**
  - Submit clean and tracked copies (tracked from previous HREC approved version) of all amended documents listed on the HREC approval letters with version, date and page numbering (page x of x) in the footers. Do NOT submit superseded documents.
- ☐ **IB updates**
  - Only submit if Mater is the TGA sponsor, the update is relevant to Mater participant safety or if requested by Research Ethics and Governance
- ☐ **Protocol Clarification or Dear Investigator Letters, memos**
  - Only submit if there is an impact on Mater participant safety, privacy, resourcing or if requested by REGO

6.4.4 Submission checklists - FAQs

When do I submit a Human Research Ethics Application (HREA)

- ✓ To obtain HREC approval for human research that is lower risk or higher risk
- × **Do not use this form for** Quality Assurance projects, case reports, case series, literature reviews or research using aggregate data

When do I submit a Mater Site-Specific Assessment (SSA)

- ✓ To obtain Mater research governance authorisation for research projects involving Mater facilities (state-wide), Mater data, samples, patients or staff (as collaborators or participants), clinical research (interventional or observational), or for biomedical research using human samples
- × **Do Not submit** this form for Quality Assurance projects, Clinical Quality Registries or biomedical research not using human samples

When do I submit a Mater Amendment - For projects approved by MML HREC:

- ✓ Adding sites to single or multi-site project approvals
- ✓ Adding or amending project documents
- ✓ Changes to the project team

When do I submit a Mater Amendment - For projects where Mater is a site:

- ✓ Adding a Mater facility
- ✓ Changes to project team (refer to research team list in the SSA Checklist above and Fact Sheet)
- ✓ Changes that affect contracts (e.g., sites, external services, Mater responsibilities, funding or sponsor)
- ✓ Changes that affect Mater approvals (e.g., cost centres, Mater branding, data management)
- ✓ Changes or updates to external approvals
- ✓ Changes to site processes (e.g., procedures, recruitment, participants, referrals)
- ✓ Changes to site documents (e.g., updates to site and/or Master documents, site data and sample management)