

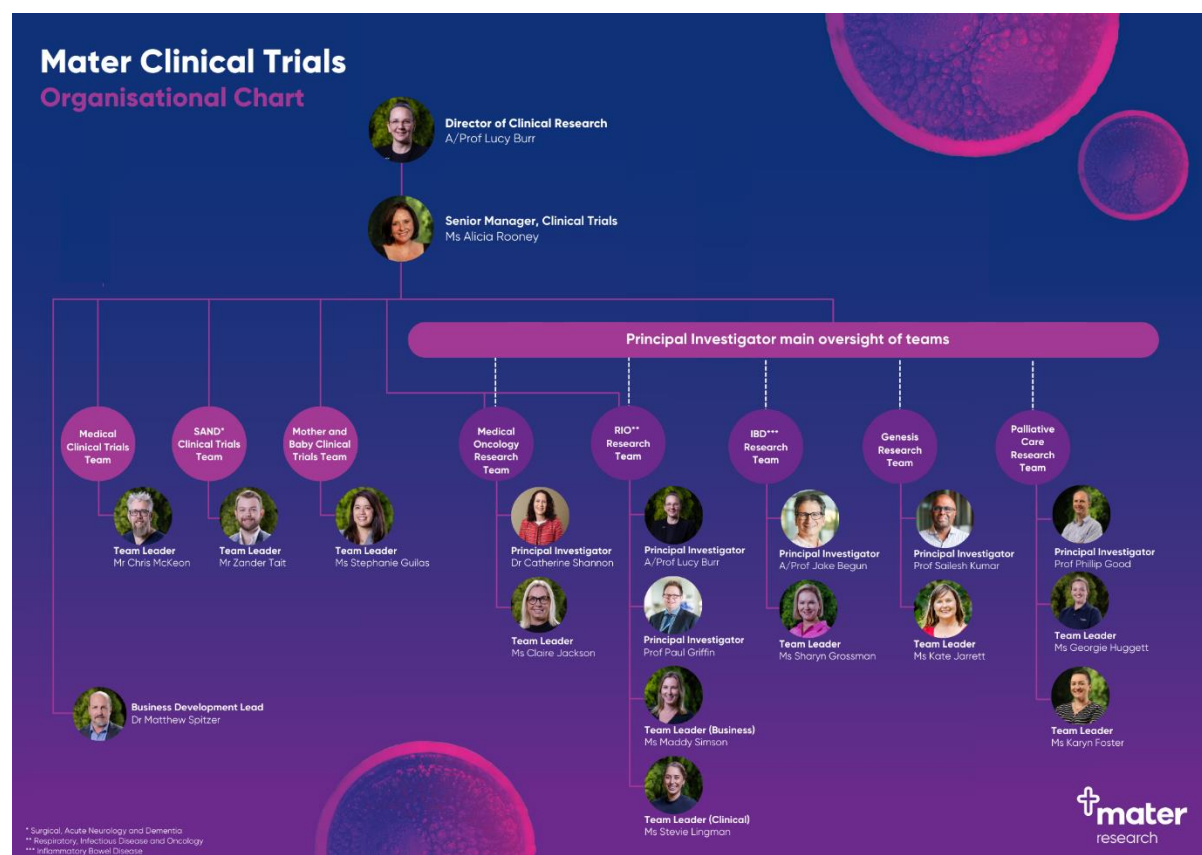
Mater Clinical Trials Site CV

March 2025

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About Mater Clinical Trials



Mater Clinical Trials (MCT) is the clinical trial service of Mater Research Limited. MCT supports clinical trials in therapeutic focus areas of Mater Hospital Brisbane, in the state of Queensland, Australia. MCT recruits clinical trial participants to trials from Mater Adults Hospital (public), Mater Mothers Hospital, Mater Private Hospital and Mater Private Clinics. Mater recognises that clinical trials are an integral part of healthcare. Knowledge gained through clinical trials is essential to support evidence-based practice. Clinical trials also give Mater patients access to the latest investigational therapies and provide alternative treatment options to patients with unmet needs under the current standard of care. Mater Principal Investigators are supported by teams of experienced clinical trials staff, organised by therapeutic area.

MCT Site Capabilities

Nationally and internationally recognised investigators with expertise in:

- Inflammatory Bowel Disorders
- Haematology
- Hepatology
- Endocrinology and Metabolic Medicine
- Kidney Disease
- Oncology and Cancer Surgery
- Maternal and Neonatal Health
- Neurology and Neurosurgery
- Cancer Palliative and Supportive Care
- Respiratory Medicine and Infectious Disease
- Surgery and Medical Devices
- Intensive Care and Emergency Medicine
- Anaesthetics.

Multi-disciplinary clinical trial teams:

- Therapeutic area-specific
- Study Coordinators, Research Nurses, Clinical Trial Assistants
- Managed by experienced Team Leads.

SiteDocs Portal:

- Real time remote monitoring of site core documents and study-specific investigator site files.

Access to Mater Health facilities and services:

- Mater Pathology
- Clinical Trials Pharmacy
- Imaging Services
- Intensive Care Unit
- Specialty Clinics
- Overnight Hospitalisation.

MCT Contacts

Institution Details

Mater Misericordiae Ltd (MML) and
Mater Research Limited (MRL)
collectively referred to as
“Mater”

MML ABN: 83 096 708 922
MRL ABN: 28 109 834 719

Address

Level 10, 14 Stratton Street
Newstead QLD 4006

MCT Details

Mater Clinical Trials

Aubigny Place
Raymond Terrace
South Brisbane QLD 4101
Clinical.Trials@mater.org.au

Kits and Supplies Address

See study team listings

Executive

**Executive Director – MRL
Research Delegate - MML**
Prof. Allison Pettit
Allison.Pettit@mater.uq.edu.au

**Director of Clinical Research –
MRL**
TBA

Director of Operations – MRL
Emily Bailey
Emily.bailey@mater.uq.edu.au

Senior Staff

Senior Manager Clinical Trials

Alicia Rooney
Alicia.Rooney@mater.org.au

Business Development Lead

Matthew Spitzer
Matthew.Spitzer@mater.org.au

Allied Health

Principal Investigators

A/Prof Liisa Laakso
Principal Research Fellow
Allied Health

Team Lead

Matthew Hunt
Research Assistant
Matthew.Hunt@mater.org.au

Address for kits

Level 2, Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

Gynaecological Oncology - Surgery

Principal Investigators

Prof Lewis Perrin
Director of
Gynaecological
Oncology

Dr Naven Chetty
Senior Staff Specialist

Dr Nisha Jagasia
Staff Specialist

Team Lead

Bronwyn Alchin
Clinical Trial Project Manager
bronwyn.alchin@mater.org.au

Address for kits

Level 2, Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

Inflammatory Bowel Disorders

Principal Investigators

Dr Jakob Begun
Director of
Gastroenterology
Senior Research Fellow
IBD

Dr Yoon-Kyo An
Head of IBD

Team Lead

Sharyn Grossman
Senior Clinical Research
Coordinator
Sharyn.Grossman@mater.org.au

Deborah Gietzel
Regulatory & Start Up Officer
Deborah.gietzel@mater.org.au

ibdtrials.coordinator@mater.org.au

Team Contact

Address for kits

Level 2, Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

Medical Trials

Principal Investigators

Endocrinology

Dr Liza Phillips

Director of Endocrinology

Dr Janelle Nisbett

Queensland Lifespan
Metabolic Medicine
Service

Haematological Oncology

Dr Naadir Gutta

Director of Haematology

Dr Mohammed Shanavas

Research Director

Dr Emma Taylor

Staff Specialist

Dr Stephen Boyle

Staff Specialist

Dr Heshani Mediwake

Staff Specialist

Haemoglobinopathies

Dr Mimi Yue
Staff Specialist

Hepatology

Dr Paul Clark

Senior Staff Specialist

Dr Mazhar Haque

Senior Staff Specialist

Dr Katerina Liew

Staff Specialist

Dr Aidan Woodward

Senior Medical Officer

Nephrology

Dr Michael Burke

Director Renal and
Dialysis

Team Lead

Chris McKeon

Chris.McKeon@mater.org.au

Team Contact

Medical.trials@mater.org.au

Address for kits

Level 2, Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

Medical Oncology

Principal Investigators

Dr Catherine Shannon

Senior Staff Specialist
Oncology Research
Director
Breast & Gynaecological
Cancers

Dr Niara Oliveira

Senior Specialist
Urological Cancers

Dr Kathryn Middleton

Senior Medical Officer
Oncology

Dr Rebecca Moor

Visiting Medical Officer
Oncology

Team Lead

Claire Jackson

Team Lead

Claire.Jackson1@mater.org.au

Address for kits

Level 2, Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

Mother and Baby

Principal Investigators

Neonatology

Prof Helen Liley

Senior Staff Specialist
Mother & Baby Research
Program Lead

Dr Pita Birch

Director of Neonatology

Dr Luke Jardine

Staff Specialist

Dr Maureen Dingwall

Senior Specialist

Dr Judith Hough

Physiotherapist
Consultant
ICN/Research

Dr Elizabeth Hurron

Growth & Development
Lead

Endocrinology

Dr Josephine Laurie

Clinical Director Obstetric
Medicine

Dr Liza Phillips

Director of Endocrinology

Maternal Fetal Medicine

Dr Glenn Gardener

Director Maternal Fetal
Medicine

Prof. Sailesh Kumar

Senior Staff Specialist
Mayne Professor and
Head of Mayne
Academy of Obstetrics
and Gynaecology
Genesis Research Group
Lead

Team Lead

Stephanie Guilas

Lead Clinical Research
Coordinator

Stephanie.Guilas@mater.org.au

Team Contact

MBResearch@mater.org.au

Address for kits

Level 2, Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

Genesis Team Lead

Kate Jarrett

Trial Coordinator

Kate.Jarrett@mater.org.au

Team Email

BirthTrials@mater.org.au

Neuroscience

Principal Investigators

Epilepsy

Prof Aileen McGonigal

Epilepsy Unit Director

Dr Donald Craig

Staff Specialist Neurology

Intellectual Disability & Autism

Dr Cathy Franklin

Director Mater Intellectual Disability & Autism Service

Neurology

Dr Andrew Swayne

Director of Neurology

Dr Rodrigo Tomazini Martins

Senior Medical Officer

Dr Reuben Beer

Senior Medical Officer

Neurosurgery

Dr Robert Campbell

Neurosurgeon

Dr Anthony Chau

Neurosurgeon

Team Lead

Zander Tait

Lead Clinical Trial Coordinator

Zander.Tait@mater.org.au

Address for kits

Level 2, Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

Palliative Care

Principal Investigators

Prof Phillip Good

Cancer Research

Program Lead

Director of Cancer

Services

Director of Palliative Care

Research Coordinators

Karyn Foster

Karyn.Foster@mater.org.au

Georgie Huggett

georgie.huggett@mater.org.au

Team Contact

palcareresearch@mater.org.au

Respiratory, Infectious Disease and Oncology (RIO)

Principal Investigators

Infectious Disease

Prof Paul Griffin

Director of Infectious Diseases
Head – Mater Clinical Unit,
University of Queensland School of Medicine

Respiratory Medicine

A/Prof. Lucy Burr

Director
Respiratory/Sleep Medicine

A/Prof Simon Bowler

Director Medical Services

Dr Ardian Barnett

Respiratory Physician

Lung and Colorectal Cancer

Dr Vikram Jain

Director of Oncology

Dr Connor O’Leary

Staff Specialist Medical Oncology

Team Leads

Maddy Simson

Business/Finance Lead

Maddy.Simson@mater.org.au

Stevie Anderson

Clinical Lead

Stevie.Anderson@mater.org.au

Team Contact

RIOClinicalTrials@mater.org.au

Ph: 07 3163 1369

Clinic location/Address for kits

Level 3 Aubigny Place
Raymond Terrace
South Brisbane, QLD 4101

Surgical and Acute Care

Principal Investigators

Orthopaedic Surgery

Dr John Radovanovic

Director of Orthopaedics

Dr Anubhav Sathu

Orthopaedic Surgeon

Dr Ali Kalhor

Orthopaedic Surgeon

Team Lead

Zander Tait

Zander.Tait@mater.org.au

Team Contact

Acute.research@mater.org.au

Address for kits

Level 2, Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

**Principal
Investigators
(cont.)**

**Gynaecological
Oncology Surgery**

Prof Lewis Perrin

Director of Gynaecological
Oncology

Dr Naven Chetty

Senior Staff Specialist

Dr Nisha Jagasia

Staff Specialist

Breast Surgery

Prof Chris Pyke

Director Medical Services
Chief Medical Officer

Dr Emma Clarkson

Breast and Endocrine
Surgery

Dr Heidi Peverill

Breast and Endocrine
Surgery

Dr Ben Lancashire

Breast and Endocrine
Surgery

Acute Care

Prof Anne Leditschke

Research Lead
Senior Specialist ICU

Dr Nai An Lai

Director ICU

Dr Loki Johnk

Intensivist

Dr Sadie Callahan

Intensivist

Anaesthetics

Dr John Riordan

Research Lead
Staff Anaesthetist

Dr David McCormack

Director Anaesthesia

Experience

Trial Phase Capabilities	Pharmaceutical: FIH, I, II, III, IV Medical Device: Pilot, Pivotal, Post-Market
Research Experience	Industry, Collaborative Group, Investigator-Initiated, Biomedical
Patient Population	Age 16 years and older, Neonates
Open Studies	200+
Audit History	Sponsor initiated audits within the last two years with no critical findings. Reports cannot be provided due to confidentiality.

Qualifications

Policies	Standard Operating Procedures available on SiteDocs
Staff Training	TransCelerate accredited GCP certification on SiteDocs IATA biospecimen transport certification on SiteDocs
Curriculum Vitae	Investigator and trial staff CVs available on SiteDocs
Medical Licenses	Available on AHPRA website
Staffing	Therapeutic area specific trial teams are staffed with senior lead coordinators supervising clinical trial coordinators, clinical trial assistants and shared administrative support resources.

Facilities

Type	Private Catholic Hospital
Hours	24/7 Emergency Department 24/7 Inpatient care Monday to Friday 8 am to 4 pm ambulatory care
Government Affiliation	None
Affiliated Clinical Trial Sites/Satellite Sites	Mater Hospital Brisbane (Mater Adults Hospital, Mater Mothers Hospital, Mater Private Hospital, Mater Private Clinic), Mater Hospital Springfield, Mater Hospital Redlands

Informed Consent

Policy	Institutional SOP MPPL-04666 Informed Consent for Research Procedure complies with NHMRC National Statement on Ethical Conduct in Research 2023, ICH GCP Guideline E6(R3). Standard Operating Procedure available on SiteDocs
Catholic Wording	Participant Information and Consent Forms must comply with Catholic Health Australia guidelines on research on humans of reproductive age. Mater PICF guidance is available on SiteDocs

Participants Without Capacity to Consent

Approval

Clinical trials involving recruitment of adult participants without capacity to consent require approval from the Queensland Civil and Administrative Tribunal (QCAT). Applications for Approval to Conduct Clinical Research (Form 16) may be lodged with QCAT by a Principal Investigator at any participating Queensland site. A single application covers all trial sites in Queensland.

Policies and Application Form

Policies and forms are available on the QCAT website:
<https://www.qcat.qld.gov.au/>

Monitoring

Policy

SOPs available on SiteDocs:

- MPPL-04810 Monitoring Clinical Research Studies Procedure
- MPPL-04748 Remote Monitoring of Research Procedure

Onsite Monitoring

Three monitoring rooms available

Onsite Facilities

eISF access via Site Docs, photocopier, phone

Bookings

Onsite visits 6 weeks in advance

Remote Monitoring

Monitoring of eISFs is available via Site Docs

Documentation

Policies	<p>Institutional SOPs available on SiteDocs:</p> <ul style="list-style-type: none">• MPPL-04749 Research Documentation Requirements• MMPL-04675 Research Master File and Essential Documents• MPPL-0111 Procedure for Human Research Data Entry Collection Storage Movement and Destruction• MPPL-04677 Documentation of Research Site Staff Qualifications
Templates	<p>Investigator Site File Table of Contents</p> <p>Delegation Log</p> <p>Training Log</p> <p>CV Template</p>
Investigator Site File	<p>From January 2024 all records stored centrally in study specific eISF on SiteDocs</p>
Patient Source Data Location	<p>VERDI Scanned Record System and paper files stored in Mater Clinical Trials Offices, Aubigny Place, Raymond Terrace, South Brisbane, QLD 4101, Australia</p>
EDC	<p>Experience with Medidata Rave, Inform, Oracle, RedCap. Certificates available on SiteDocs</p>
Safety Reporting Procedure	<p>Mater endorses the NHMRC guidance on Safety monitoring and reporting in clinical trials involving therapeutic(2016)</p>
Archiving	<p>Institutional SOPs available on SiteDocs:</p> <p>MPPL-05219 Safety Reporting for Research Studies Including Serious Adverse Events</p>
Archiving Facilities	<p>Institutional SOP available on SiteDocs:</p> <p>MPPL-04749 Research Documentation Requirements</p> <p>Pharmacy study documents are archived onsite at:</p>

Pharmacy Department
Mater Hospital Brisbane
Raymond Terrace
South Brisbane QLD 4101

All other study documents are archived at:
Grace Information Management
420 Sherbrooke Rd
Willawong QLD 4110

Early Phase Clinical Trials

Early Phase Clinical Trials

Mater has capacity and experience to run Early Phase Clinical Trials (EPCT). EPCT are conducted within the context of the EPCT Governance Framework and require the PI to submit a risk assessment to be approved by an independent Expert Advisory Committee.

Policies

Policy and SOPs available on SiteDocs:

- MPPL-00100 Early Phase Clinical Trials Governance Framework
- MPPL-01150 Risk Assessment, Expert Advisory Committee Review and Conduct of Early Phase Clinical Trials Procedure
- MPPL-00022 Early Phase Clinical Trials Expert Advisory Committee Terms of Reference

Monitoring

EPCT are monitored by Mater, in addition to trial sponsors

Patient Safety

EPCT are conducted in medical facilities equipped for medical emergencies and accessible to Mater crash teams, with direct access to the Emergency Department and ICUs. Trial teams conducting EPCT are required to rehearse medical emergency scenarios annually.

Investigational Product

Policies

Institutional SOP available on SiteDocs:

- MPPL-06127 Medication Storage, Supply, Distribution and Disposal
- MPPL-04992 Receipt and Handling of Research Investigational Product Procedure
- WH-PHA-CT06 Handling and Management of Investigational Medicinal Product Work Instruction
- WH-PHA-CT01 Disposal of Investigational Medicinal Product Work Instruction

Clinical Trial Pharmacy

Address for Delivery of Investigational Product

Pharmacy Department – Clinical Trials

Mater Hospital Brisbane
Level 3, Salmon Building
Raymond Terrace
South Brisbane, QLD 4101

Pharmacy Contact

Clinical Trials Pharmacist

Phone: 07 3163 2451

Email: pharmacy.clinicaltrials@mater.org.au

IV Infusion Capability

Aseptic production unit is equipped with Laminar Flow cabinets and Cytotoxic Drug Safety Cabinets with capabilities for the sterile compounding and preparation of parenteral chemotherapy, biologic, cytotoxic, immunotherapy, vaccine, and antibiotic products.

IP Storage

- Secured with controlled access.
- Ambient temperature monitored storage.
- Refrigerated (2o to 8o) temperature monitored storage.
- Frozen (-20o and -80o) temperature monitored storage.
- Digital continuous temperature monitoring of all storage areas
- Alarmed systems in the event of temperature excursions.

Backup Power

All Pharmacy clinical trial fridges, cold room and freezers are connected to essential power points (red emergency power points). In the event of a mains power outage or power failure, the power supply will automatically switch to back up generator power.

Blinded IP Procedure

Trained and experienced CT staff to perform blinded IP procedures including randomisation of treatment and blinding of parenteral aseptic products.

Controlled Substances

Schedule 8 medicines and Schedule 4 Diversion Risk medicines are stored in a dedicated Pharmacy Clinical Trials S8 safe.

Investigational Product Administration and Monitoring

Specialist Clinics

- Mater Cancer Care Centre – Oncology and Haematology
- Mater Hospital Infusion Clinic – Neurology and General Medicine
- Queensland X-Ray – Image-guided IP administration
- Mater Anaesthetics – Intrathecal IP administration

Overnight Admissions

Clinical trial participants can be hospitalized as private admissions for observation and treatment as required by study protocols

Emergency Response

All treatment areas have full emergency equipment available, including crash carts, are readily accessible by the Mater Hospital MET team, and are in close proximity to the Emergency Department.

ICU

In case of medical emergency, clinical trial patients may be transferred to the ICU Department in Mater Adults Hospital (public), Mater Private Hospital, or the Neonatal Intensive Care Unit, as appropriate.

Local Laboratory

Local Laboratory	Mater Pathology provides comprehensive pathology testing and local laboratory services across all disciplines, as well as providing access to a statewide network of collection centres.
Laboratory Address	Mater Pathology Level 6, Mater Hospital Brisbane Raymond Terrace South Brisbane, QLD 4101
Local Lab Contact	Clinical Trials Pathology T: 07 3163 2075 F: 07 3163 6632 pathologyclinicaltrialsteam@mater.org.au
Address for Lab Kits	Mater Clinical Trials Attn: [Team Lead] Level 2, Aubigny Place Raymond Terrace South Brisbane, QLD 4101
Accreditation	Certificates available on SiteDocs: <ul style="list-style-type: none">• NATA ISO15189:2007• NPAAC• GCP
Reference Ranges	Available on SiteDocs
Local Laboratory Capabilities	<ul style="list-style-type: none">• Phlebotomy services• Monitored storage at -20o and -80o• Chemical Pathology• Haematology• Immunology• Genetics• Cytology



- Anatomical Pathology
- Microbiology
- Cryostorage

Imaging Services

Imaging Services on Campus
Queensland X-Ray Address
Queensland X-Ray Contact
Qscan Address
Qscan Contact
Imaging Services Available

Queensland X-Ray, contracted as Mater Radiology Department
Qscan

Level 3
Mater Hospital Brisbane
Raymond Terrace
South Brisbane, QLD 4101

Emma Harriman
Clinical Trial Coordinator
P: 07 3422 8837
Emma.Harriman@qldxray.com.au

Qscan Radiology Clinic
Level 6, Mater Private Clinic
550 Stanley Street
South Brisbane, QLD 4101

Breanna Rooke
Operations Support Lead
e: clinicaltrials@qscan.com.au
p: 07 35399488

- XRay
- CT Scan



- MRI
- PET
- Nuclear Medicine
- DXA
- Interventional Radiology

Study Start-Up

Start-Up Contacts

Study start-ups are managed by clinical trial team leads, listed above. The team lead can direct sponsors to the start-up contacts within their teams.

Research Governance

- Clinical trials at Mater require approval by the Mater Research Governance Office (RGO).
- Site Specific Applications (SSA) are submitted via ERM
- SSAs must be accompanied by complete supporting documentation including: HREC Approval, Executed CTRA, Site Specific Documents, any Other Approvals required for the study, executed contracts with service providers or other external entities where study procedures are performed, supporting department quotes (Pharmacy, Pathology, Radiology), Privacy Office approval to access patient data.
- RGO and HREC schedule of fees: SoF

RGO Contact

Research Governance Officer

Phone: 07 3163 3769

Email: research.governance@mater.uq.edu.au

Website: [Starting your project - Mater Research](#)

Research Ethics

Clinical Trials at Mater require approval by an NHMRC accredited Human Research Ethics Committee (HREC). Mater is not a signatory to the NMA. Approval may be obtained from the Mater HREC, or any accredited external HREC that does not require private sites to execute an External Entity Agreement.

Research Ethics Contact

HREC Liaison Officer

Phone: 07 3163 1585

Email: research.ethics@mater.uq.edu.au

Website: Starting your project - Mater Research

Contracts and Budget

- Legal Entity Name: Mater Misericordiae Ltd (MML) ABN 83 096 708 922 and Mater Research Limited (MRL) ABN 28 109 834 719 collectively referred to as "Mater"
- Mater Clinical Trials standard rates and standard terms for CTRA schedules are available on SiteDocs.
- Budgets are negotiated by trial team budget contacts. CTAs and other contracts require review and approval by Mater Research Agreements. Electronic signature is available via DocSign, arranged through Agreements.

Contracts Contact

Mater Research Agreements Office

Phone: 07 3163 8008

Email: research.agreements@mater.uq.edu.au

Other Approvals

Individual study protocols may require additional approvals including:

- EPCT Expert Advisory Committee – Phase 1, 2a, device pilot studies
- QCAT – Participants lacking capacity to consent
- Institutional Biosafety Committee – GMO studies

Site Specific Applications can be reviewed in parallel with applications for Other Approvals.

Documentation Requirements

Mater requires the following documentation to be provided to commence study start-up:

- Notification of site selection
- Final versions of protocol and investigators' brochure
- Master PICF
- Final versions of study manuals – Pathology, Pharmacy, Imaging, any other service provider manuals
- HREC approval, if applicable - must include complete submission package and approved documents
- HREC review indemnity

Site Initiation

- CTRA, including schedules – complete Schedule 1 details, draft budget and payment terms, Standard Indemnity, Certificate of Currency and any insurance terms

Site initiation visit and site staff training must be timed to coincide with Research Governance approval and site activation. Site initiation visits well in advance of site activation are not permitted.

Start-Up Timeline

- Written notification of site selection is required to commence site start-up.
- HREC review and approval timeline varies between reviewing HRECs. The Mater HREC meets monthly. Complete applications must be submitting 2 weeks prior to the meeting date. The Mater HREC works to a benchmark of 60 days for review and approval. Timelines may be impacted by completeness of submissions and time taken by sponsors to respond to HREC queries.
- Time to prepare SSAs for submission to RGO varies subject to study complexity and workload of the trial team. SSA submission time can be facilitated by provision of complete study documentation, including final versions of study manuals.
- The Mater RGO works to a benchmark of 33 days for review and approval of SSAs, excluding time taken for PIs/Sponsors to respond to RGO queries. Mater Priority Trial Review is available for an additional fee to expedite RGO review time.
- CTRA review and approval are conducted in parallel with the HREC and RGO application processes and may commence upon notification of site selection. Legal review of the CTRA is also conducted in parallel with budget negotiation. Consequently, CTRA/budget negotiation time should not rate-limit start-up time.