

Mater Clinical Trials Profile

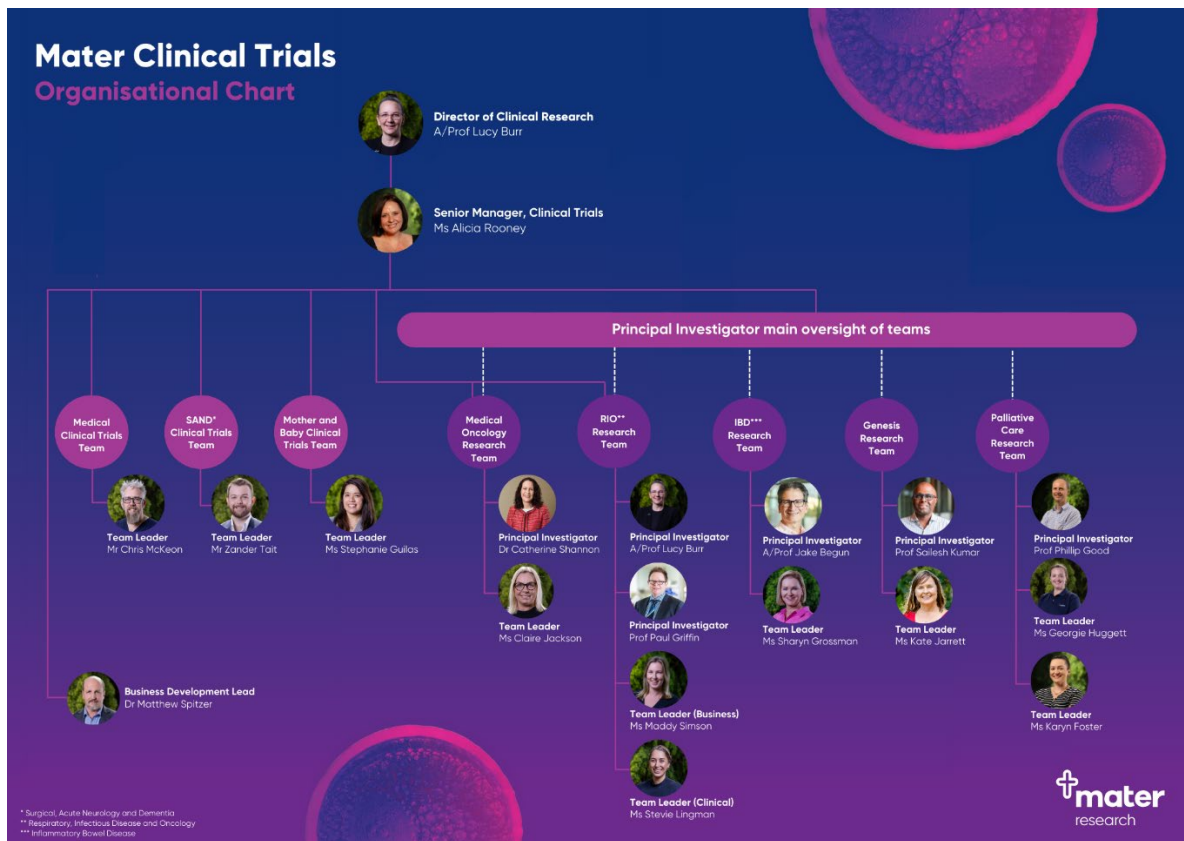
March 2025

Mater Clinical Trials (MCT) supports clinical trials within the Mater group of hospitals throughout Queensland, Australia. MCT is based on the campus of Mater Hospital, Brisbane.

Contents

About Mater Clinical Trials.....	2
MCT Site Capabilities	3
MCT Contacts.....	4
Allied Health.....	5
Gynaecological Oncology - Surgery.....	5
Inflammatory Bowel Disorders	5
Medical Trials	5
Medical Oncology	6
Mother and Baby	6
Neuroscience	7
Palliative Care	8
Respiratory, Infectious Disease and Oncology (RIO)	8
Surgical and Acute Care	9
Experience.....	10
Qualifications	10
Facilities	10
Informed Consent	10
Participants Without Capacity to Consent.....	11
Monitoring	11
Documentation	11
Early Phase Clinical Trials.....	12
Investigational Product	13
Investigational Product Administration and Monitoring.....	14
Local Laboratory.....	14
Imaging Services.....	15
Study Start-Up.....	15

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

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

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

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	Team Leads	Bronwyn Alchin Clinical Trial Project Manager bronwyn.alchin@mater.org.au
	Dr Naven Chetty Senior Staff Specialist	Address for Kits	Level 2, Aubigny Place Raymond Terrace South Brisbane QLD 4101
	Dr Nisha Jagasia Staff Specialist		

Inflammatory Bowel Disorders

Principal Investigators	Dr Jakob Begun Director of Gastroenterology Senior Research Fellow IBD	Team Leads	Sharyn Grossman Senior Clinical Research Coordinator Sharyn.Grossman@mater.org.au
	Dr Yoon-Kyo An Head of IBD	Team Contact	Deborah Gietzel Regulatory & Start Up Officer Deborah.gietzel@mater.org.au
			ibdtrials.coordinator@mater.org.au
		Address for Kits	Level 2, Aubigny Place Raymond Terrace South Brisbane QLD 4101

Medical Trials

Principal Investigators	Endocrinology	Team Lead	Chris McKeon Chris.McKeon@mater.org.au
	Dr Liza Phillips Director of Endocrinology	Team Contact	Medical.trials@mater.org.au
	Dr Janelle Nisbett Queensland Lifespan Metabolic Medicine Service		
	Haematological Oncology	Address for Kits	Level 2, Aubigny Place Raymond Terrace South Brisbane QLD 4101
	Dr Naadir Gutta Director of Haematology		
	Dr Mohammed Shanavas Research Director		
	Dr Emma Taylor		

	<p>Staff Specialist</p> <p>Dr Stephen Boyle Staff Specialist</p> <p>Dr Heshani Mediwake Staff Specialist</p> <p>Haemoglobinopathies Dr Mimi Yue Staff Specialist</p> <p>Hepatology Dr Paul Clark Senior Staff Specialist</p> <p>Dr Mazhar Haque Senior Staff Specialist</p> <p>Dr Katerina Liew Staff Specialist</p> <p>Dr Aidan Woodward Senior Medical Officer</p> <p>Nephrology Dr Michael Burke Director Renal and Dialysis</p>	
--	---	--

Medical Oncology

Principal Investigators	<p>Dr Catherine Shannon Senior Staff Specialist Oncology Research Director Breast & Gynaecological Cancers</p>	Team Lead	<p>Claire Jackson Team Lead Claire.Jackson1@mater.org.au</p>	
	<p>Dr Niara Oliveira Senior Specialist Urological Cancers</p>		Address for Kits	<p>Level 2, Aubigny Place Raymond Terrace South Brisbane QLD 4101</p>
	<p>Dr Kathryn Middleton Senior Medical Officer Oncology</p>			
	<p>Dr Rebecca Moor Visiting Medical Officer Oncology</p>			

Mother and Baby

Principal Investigators	<p>Neonatology Prof Helen Liley Senior Staff Specialist Mother & Baby Research</p>	Team Lead	<p>Stephanie Guilas Lead Clinical Research Coordinator Stephanie.Guilas@mater.org.au</p>
--------------------------------	--	------------------	--

	<p>Program Lead</p> <p>Dr Pita Birch Director of Neonatology</p> <p>Dr Luke Jardine Staff Specialist</p> <p>Dr Maureen Dingwall Senior Specialist</p> <p>Dr Judith Hough Physiotherapist Consultant ICN/Research</p> <p>Dr Elizabeth Hurrion Growth & Development Lead</p> <p>Endocrinology</p> <p>Dr Josephine Laurie Clinical Director Obstetric Medicine</p> <p>Dr Liza Phillips Director of Endocrinology</p> <p>Maternal Fetal Medicine</p> <p>Dr Glenn Gardener Director Maternal Fetal Medicine</p> <p>Prof. Sailesh Kumar Senior Staff Specialist Mayne Professor and Head of Mayne Academy of Obstetrics and Gynaecology Genesis Research Group Lead</p>	<p>Team Contact</p> <p>Address for Kits</p> <p>Genesis Team Lead</p> <p>Team email</p>	<p>MBResearch@mater.org.au</p> <p>Level 2, Aubigny Place Raymond Terrace South Brisbane QLD 4101</p> <p>Kate Jarrett Trial Coordinator Kate.Jarrett@mater.org.au</p> <p>BirthTrials@mater.org.au</p>
--	--	--	---

Neuroscience

<p>Principal Investigators</p>	<p>Epilepsy</p> <p>Prof Aileen McGonigal Epilepsy Unit Director</p> <p>Dr Donald Craig Staff Specialist Neurology</p> <p>Intellectual Disability & Autism</p> <p>Dr Cathy Franklin Director Mater Intellectual Disability & Autism Service</p> <p>Neurology</p> <p>Dr Andrew Swayne Director of Neurology</p> <p>Dr Rodrigo Tomazini Martins Senior Medical Officer</p> <p>Dr Reuben Beer</p>	<p>Team Lead</p> <p>Address for Kits</p>	<p>Zander Tait Lead Clinical Trial Coordinator Zander.Tait@mater.org.au</p> <p>Level 2, Aubigny Place Raymond Terrace South Brisbane QLD 4101</p>
---------------------------------------	--	--	--

	<p>Senior Medical Officer</p> <p>Neurosurgery Dr Robert Campbell Neurosurgeon</p> <p>Dr Anthony Chau Neurosurgeon</p>	
--	---	--

Palliative Care

Principal Investigator	<p>Prof Phillip Good Cancer Research Program Lead Director of Cancer Services Director of Palliative Care</p>	Research Coordinators	<p>Karyn Foster Karyn.Foster@mater.org.au</p> <p>Georgie Huggett georgie.huggett@mater.org.au</p>
		Team Contact	<p>palcareresearch@mater.org.au</p>

Respiratory, Infectious Disease and Oncology (RIO)

Principal Investigators	<p>Infectious Disease Prof Paul Griffin Director of Infectious Diseases Head – Mater Clinical Unit, University of Queensland School of Medicine</p> <p>Respiratory Medicine A/Prof. Lucy Burr Director Respiratory/Sleep Medicine</p> <p>A/Prof Simon Bowler Director Medical Services</p> <p>Dr Ardian Barnett Respiratory Physician</p> <p>Lung and Colorectal Cancer Dr Vikram Jain Director of Oncology</p> <p>Dr Connor O'Leary Staff Specialist Medical Oncology</p>	Team Leads	<p>Maddy Simson Business/Finance Lead Maddy.Simson@mater.org.au</p> <p>Stevie Anderson Clinical Lead Stevie.Anderson@mater.org.au</p>
		Team Contact	<p>RIOClinicalTrials@mater.org.au Ph: 07 3163 1369</p>
		Clinic Location/ Address for Kits	<p>Level 3 Aubigny Place Raymond Terrace South Brisbane, QLD 4101</p>

Surgical and Acute Care

Principal Investigators	Orthopaedic Surgery	Team Lead	Zander Tait
	Dr John Radovanovic Director of Orthopaedics	Lead	Zander.Tait@mater.org.au
	Dr Anubhav Sathu Orthopaedic Surgeon	Address for Kits	Level 2, Aubigny Place Raymond Terrace South Brisbane QLD 4101
	Dr Ali Kalhor Orthopaedic Surgeon	Team email	Acute.research@mater.org.au
	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: <ul style="list-style-type: none"> 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	Institutional SOPs available on SiteDocs: <ul style="list-style-type: none"> MPPL-04749 Research Documentation Requirements MMPL-04675 Research Master File and Essential Documents MPPL-01111 Procedure for Human Research Data Entry Collection Storage Movement and Destruction MPPL-04677 Documentation of Research Site Staff Qualifications
Templates	Investigator Site File Table of Contents Delegation Log Training Log CV Template
Investigator Site File	From January 2024 all records stored centrally in study specific eISF on SiteDocs

Patient Source Data Location	VERDI Scanned Record System and paper files stored in Mater Clinical Trials Offices, Aubigny Place, Raymond Terrace, South Brisbane, QLD 4101, Australia
EDC	Experience with Medidata Rave, Inform, Oracle, RedCap. Certificates available on SiteDocs
Safety Reporting Procedure	Mater endorses the NHMRC guidance on Safety monitoring and reporting in clinical trials involving therapeutic (2016) Institutional SOPs available on SiteDocs: MPPL-05219 Safety Reporting for Research Studies Including Serious Adverse Events
Archiving	Institutional SOP available on SiteDocs: MPPL-04749 Research Documentation Requirements
Archiving Facilities	Pharmacy study documents are archived onsite at: 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Secured with controlled access.• Ambient temperature monitored storage.• Refrigerated (2° to 8°) temperature monitored storage.• Frozen (-20° and -80°) 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	<ul style="list-style-type: none">• 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 31 63 2075 F: 07 31 63 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	<ul style="list-style-type: none">• Phlebotomy services

Capabilities	<ul style="list-style-type: none"> • Monitored storage at -20° and -80° • Chemical Pathology • Haematology • Immunology • Genetics • Cytology • Anatomical Pathology • Microbiology • Cryostorage
---------------------	--

Imaging Services

Imaging Services on Campus	Queensland X-Ray, contracted as Mater Radiology Department Qscan
Queensland X-Ray Address	Level 3 Mater Hospital Brisbane Raymond Terrace South Brisbane, QLD 4101
Queensland X-Ray Contact	Emma Harriman Clinical Trial Coordinator P: 07 3422 8837 Emma.Harriman@qldxray.com.au
Qscan Address	Qscan Radiology Clinic Level 6, Mater Private Clinic 550 Stanley Street South Brisbane, QLD 4101
Qscan Contact	Breanna Rooke Operations Support Lead e: clinicaltrials@qscan.com.au p: 07 35399488
Imaging Services Available	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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

	<p>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.</p> <ul style="list-style-type: none"> • RGO and HREC schedule of fees: SoF
RGO Contact	<p>Research Governance Officer Phone: 07 3163 3769 Email: research.governance@mater.uq.edu.au Website: Starting your project - Mater Research</p>
Research Ethics	<p>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.</p>
Research Ethics Contact	<p>HREC Liaison Officer Phone: 07 3163 1585 Email: research.ethics@mater.uq.edu.au Website: Starting your project - Mater Research</p>
Contracts and Budget	<ul style="list-style-type: none"> • 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	<p>Mater Research Agreements Office Phone: 07 3163 8008 Email: research.agreements@mater.uq.edu.au</p>
Other Approvals	<p>Individual study protocols may require additional approvals including:</p> <ul style="list-style-type: none"> • EPCT Expert Advisory Committee – Phase 1, 2a, device pilot studies • QCAT – Participants lacking capacity to consent • Institutional Biosafety Committee – GMO studies <p>Site Specific Applications can be reviewed in parallel with applications for Other Approvals.</p>
Documentation Requirements	<p>Mater requires the following documentation to be provided to commence study start-up:</p> <ul style="list-style-type: none"> • 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
- CTRA, including schedules – complete Schedule 1 details, draft budget and payment terms, Standard Indemnity, Certificate of Currency and any insurance terms

Site Initiation

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.