

Mater

Clinical Trials Profile





The Heart to Heal, The Strength to Grow.

Our spirit is strong, it thrives as we embrace those whom we must always care for. Our journey has been long and we will continue to flourish as we open our hearts to those who walk with us. Always.

This artwork concept and narrative was developed by David Williams. David is a proud Wakka Wakka artist at Gilimbaa.

Acknowledgement of Country

Mater acknowledges Aboriginal and Torres Strait Islander peoples as the Traditional Custodians of the lands and waters where we live and work. We respect their historical and continuing spiritual connections to country and community and pay our respects to their Elders, past, present and emerging. As health, education and research ministries, we commit ourselves to the ongoing journey of reconciliation.



Mater Clinical Trials (MCT) supports clinical trials across Mater's network of public and private hospitals throughout metropolitan and regional Queensland. MCT is based at Mater Hospital Brisbane.



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About Mater Clinical Trials

Mater Clinical Trials (MCT) is the clinical trial service of Mater Research.

MCT supports clinical trials in therapeutic focus areas at Mater Hospitals in South East Queensland. MCT recruits clinical trial participants from Mater's hospitals in Brisbane and Springfield, including Mater Hospital Brisbane, Mater Mothers' Hospital, Mater Private Hospital Brisbane and Mater Hospital Springfield.

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.

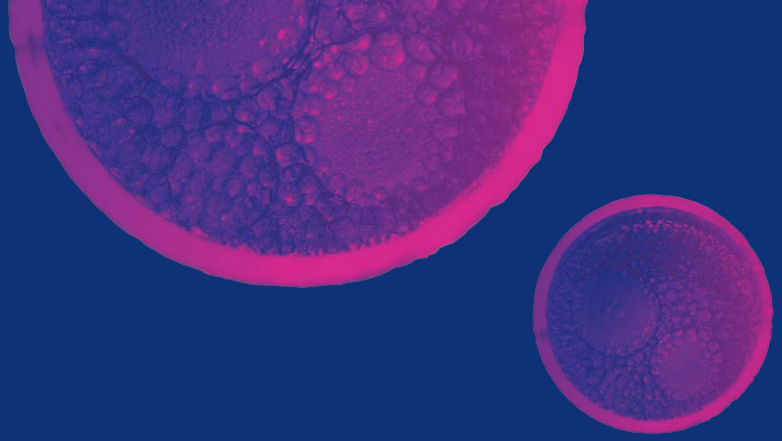
Mater Principal Investigators are supported by teams of experienced clinical trials staff, organised by therapeutic area.



* Surgical, Acute Neurology and Dementia

^ Respiratory, Infectious Diseases and Oncology

* Inflammatory Bowel Disease



Mater network

MCT currently manages approximately 120 active, industry-sponsored studies, recruiting from Mater Hospitals in Brisbane and Springfield. Expansion of trial services to other Mater hospital locations is planned for 2026 and beyond.



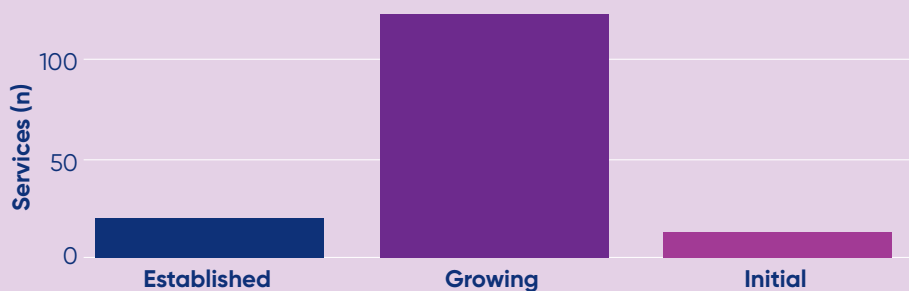


MCT *Site Capabilities*

Validated high quality clinical trial service delivery

Mater Clinical Trials now ranks in the top 13 per cent of Australian hospital-based clinical trial services after all three of Mater's Brisbane hospitals earned the highest possible rating (3 – Established Systems) during the inaugural Safety and Quality Commission accreditation against the National Clinical Trials Governance Framework.

Number of assessed services, by Maturity Rating



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
- Mental Health.

First-in-Human studies

- Healthy volunteer studies
- First in patient studies
- Overnight confinement
- Experienced investigators
- Advanced practice nursing staff
- Emergency management protocols
- Rapid access to ED, ICU, crash team
- Early phase clinical trials governance framework.

Multi-disciplinary clinical trial teams:

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

SiteDocs Portal and RealTime eSource:

Real time remote monitoring of source documents, 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 and confinement.

MCT *First-in-Human Trial Capabilities*

Study types:



Healthy volunteer



Vaccine studies



First in patient



Cell therapy and cellular immunotherapies

Experienced Investigators

A/Prof Lucy Burr – Respiratory medicine, healthy volunteer studies, vaccines

A/Prof Jake Begun – IBD and gastroenterology

Dr Stephen Boyle – CAR-T, cellular immunotherapies

Dr Catherine Shannon – Women's cancers

Prof Ju-Lee Oei – Neonatal intensive care

Dr Glenn Gardener – Maternal-foetal medicine, vaccines

Prof Paul Griffin – Infectious disease, healthy volunteer studies, vaccines

A/Prof Anne Leditschke – Acute care

Dr Vikram Jain, Dr Connor O'Leary – Solid tumours

Dr Mohamed Shanavas – Haematological oncology

Dr Niara Oliveira – Urological cancers

Site Capabilities

- Overnight and extended participant confinement
- ALS-trained, advanced practice nursing staff
- Emergency management protocols
- Hospital setting with direct access to ED, ICU, crash teams
- Apheresis and stem cell laboratory capabilities for cell therapy trials
- Early phase clinical trials governance framework



MCT *Contacts*



Institution

**Mater Misericordiae Ltd (MML)
and Mater Research Limited (MRL)
collectively referred to as "Mater"**

📍 14 Stratton Street
Newstead QLD 4006

MML ABN: 83 096 708 922

MRL ABN: 28 109 834 719

Executive

Executive Director – MRL

Research Delegate – MML

Prof Allison Pettit

✉ Allison.Pettit@mater.uq.edu.au

Director of Clinical Research – MRL

A/Prof Lucy Burr

✉ Lucy.Burr@mater.org.au

Director of Operations – MRL

Emily Bailey

✉ Emily.bailey@mater.uq.edu.au

**Director of Biomedical
Research – MRL**

Prof Marc Ruitenberg

✉ Marc.Ruitenberg@
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

Respiratory, Infectious Disease and Oncology (RIO)



Key Capabilities

- Key Opinion Leaders in respiratory and sleep medicine, infectious disease and oncology
- First-in-human studies – healthy volunteer, first-in-patient
- Large bronchiectasis patient cohort
- Cystic fibrosis, COPD, IPF, bronchiectasis, pulmonary hypertension, vaccines, asthma

Principal Investigators

Respiratory Medicine

A/Prof Lucy Burr
Director Respiratory/
Sleep Medicine

Dr Adrian Barnett
Respiratory Physician
Dr Olivia Dixon
Respiratory Physician

Infectious Disease

Prof Paul Griffin
Director of Infectious Diseases Head – Mater Clinical Unit,
The University of Queensland School of Medicine

Lung and Colorectal Cancer

Dr Vikram Jain
Director of Oncology

Dr Connor O'Leary
Staff Specialist Medical Oncology

Team Lead

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
☎ 07 3163 1369

Address for kits

Level 3, Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

Medical Oncology



Key Capabilities

- Key Opinion Leaders in women's cancers, urological cancers
- Queensland's largest breast cancer cohort
- One of QLD's two tertiary referral centres for gynaecological cancers

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

Unit Manager

Caitlin Bennett
✉ Caitlin.Bennett @
mater.org.au

Address for kits

Level 2, Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

MCT *Contacts*

Inflammatory Bowel Disorders



Key Capabilities

- International Key Opinion Leaders in IBD
- Leading recruiters in IBD, coeliac and eosinophilic oesophagitis studies

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 and Start Up Officer
✉ Deborah.gietzel@mater.org.au

Team Contact

✉ ibdtrials.coordinator@mater.org.au

Address for kits

Level 2, Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

Medical Trials



Key Capabilities

- Endocrinology – statewide service for inborn errors of metabolism
- Endocrinology – large T1D patient population
- Haematology – BiTE and CAR-T studies, accredited stem cell lab
- Confinement studies

Principal Investigators

Endocrinology

Dr Liza Phillips
Director of Endocrinology

Dr Janelle Nisbet
Clinical Lead – Queensland
Lifespan Metabolic Service

Dr Stephanie Teasdale
Staff Specialist

Haematological Oncology

Dr Heshani Mediwake
Director of Haematology

Dr Mohammed Shanavas
Staff Specialist

Dr Emma Taylor
Staff Specialist

Dr Stephen Boyle
Staff Specialist

Dr Naadir Gutta
Staff Specialist

Dr Julian Grabek
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

Mother and Baby

★ Key Capabilities

- Australia's largest maternity service, > 10,000 births per year
- Australia's largest stand-alone NICU, 81 beds

Principal Investigators

Neonatology

Prof Helen Liley

Senior Staff Specialist
Mother & Baby Research
Program Lead

Dr Pita Birch

Director of Neonatology

Prof Ju-Lee Oei

Chair of Neonatology

Endocrinology

Dr Josephine Laurie

Clinical Director
Obstetric Medicine

Maternal Fetal Medicine

Dr Glenn Gardener

Director Maternal
Fetal Medicine

Dr Luke Jardine

Staff Specialist

Dr Judith Hough

Physiotherapist Consultant
ICN/Research

Dr Elizabeth Hurron

Growth & Development Lead

Dr Liza Phillips

Director of Endocrinology

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

✉ 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



MCT *Contacts*

Neuroscience



Key Capabilities

- Queensland's only Level 4 epilepsy unit
- Statewide service for adults with autism and intellectual disability
- Neuroimmunology specialists and patient cohorts
- Neurosurgical studies

Principal Investigators

Epilepsy

Prof Aileen McGonigal

Epilepsy Unit Director

Dr Donald Craig

Staff Specialist Neurology

Intellectual Disability and Autism

Dr Cathy Franklin

Director Queensland Centre of Excellence in Intellectual Disability and Autism Health (QCEIDAH)

Neurology

Dr Rodrigo Tomazini Martins

Senior Medical Officer

Dr Reuben Beer

Senior Medical Officer

Neurosurgery

Dr Martin Wood

Visting Medical Officer

Dr Anthony Chau

Visting Medical Officer

Dr Robert Campbell

Visting Medical Officer

Psychiatry

Dr Tatjana Ewais

Staff Specialist

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



Surgical and Acute Care



Key Capabilities

- Intensive care studies
- Surgical studies

Principal Investigators

Acute Care

A/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

Breast Surgery

Prof Chris Pyke

Director Medical Services
Chief Medical Officer

Dr Heidi Peverill

Breast and Endocrine Surgery

Dr Emma Clarkson

Breast and Endocrine Surgery

Dr Ben Lancashire

Breast and Endocrine Surgery

Orthopaedic Surgery

Dr John Radovanovic

Director of Orthopaedics

Dr Ali Kalhor

Orthopaedic Surgeon

Dr Anubhav Sathu

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

Palliative Care



Key Capabilities

- Key opinion leader in palliative care
- Telehealth trials

Principal Investigators

Prof Phillip Good

Cancer Research Program Lead
Director of Cancer Services
Director of Palliative Care

Karyn Foster

✉ Karyn.Foster@mater.org.au

Georgie Huggett

✉ georgie.huggett@mater.org.au

Team Contact

✉ palcareresearch@mater.org.au

MCT *Contacts*

Gynaecological Oncology - Surgery



Key Capabilities

- Intratumoural drug administration
- Perioperative pain management studies

Principal Investigators

Dr Naven Chetty

Senior Staff Specialist

Dr Nisha Jagasia

Staff Specialist

Team Lead

Raj Kaur

Clinical Trial Project Manager

✉ raj.kaur@mater.org.au

Address for kits

Level 2, Aubigny Place
Raymond Terrace
South Brisbane QLD 4101

Allied Health



Key Capabilities

- Medical device and non-pharmacological studies in musculoskeletal, neurological, pain and rehabilitation indications

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





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	Neonates Young adults 16+ Adults 18+
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.

Facility

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

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 Research Projects 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: • MPPL-04749 Research Documentation Requirements • MMPL-04675 Research Master File and Essential Documents • MPPL-07058 Research Data Collection, Entry, 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	Monitoring of eISFs is available via Site Docs
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: • MPPL-07779 Mater Research Governance Framework • MPPL-07692 Early Phase Clinical Trials Risk Assessment Procedure • MPPL-07689 Early Phase Clinical Trials Risk Assessment Review Policy
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	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.
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 ☎ 07 3163 2451 ✉ 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 (2°C to 8°C) temperature monitored storage. • Frozen (-20°C and -80°C) 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 hospitalised 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 Hospital Brisbane (public), Mater Private Hospital Brisbane, 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 ☎ 07 3163 2075 📠 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: • NATA ISO15189:2007 • NPAAC • GCP	
Reference Ranges	Available on SiteDocs	
Local Laboratory Capabilities	• Phlebotomy services • Monitored storage at -20°C and -80°C • 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 ☎ 07 3032 8457 ✉ Emma.Harriman@sonicradiology.com.au	
Qscan Address	Qscan Radiology Clinic Level 6, Mater Private Clinic 550 Stanley Street South Brisbane, QLD 4101	

Imaging Services

Qscan Contact	Breanna Rooke Operations Support Lead  07 35399488  clinicaltrials@qscan.com.au	
Imaging Services Available	• XRay • CT Scan • MRI • PET	• Nuclear Medicine • DXA • Interventional Radiology

Study Startup

Start-Up Contacts	• 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	
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  07 3163 3769  research.governance@mater.uq.edu.au  Starting your project – https://www.materresearch.org.au/researchers/for-researchers/ethics-and-governance/starting-your-project	
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  07 3163 1585  research.ethics@mater.uq.edu.au  Starting your project – https://www.materresearch.org.au/researchers/for-researchers/ethics-and-governance/starting-your-project	
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 contained in the Mater Clinical Trials Rate Card, 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. • Budget negotiation and legal review of CTRA are conducted in parallel, following HREC approval of the protocol	

Study Startup

Contracts Contact	Mater Research Agreements Office ☎ 07 3163 8008 ✉ research.agreements@mater.uq.edu.au
Other Approvals	Individual study protocols may require additional approvals including: • 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 • 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 submitted 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 standard 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. • Review of CTRA can commence in parallel with SSA preparation and review, upon receipt of complete HREC approval package. Legal review of CTRA and budget negotiation can proceed in parallel. Legal and budget review cannot commence prior to HREC approval. Budget review also requires complete study manuals and other documentation with budget implications. • Sponsors are advised to review Mater's insurance requirements, contained in the Mater Clinical Trials Rate Card, upon site selection to facilitate timely finalisation of the CTRA.



