

# 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.



**Director of Clinical Research**  
A/Prof Lucy Burr

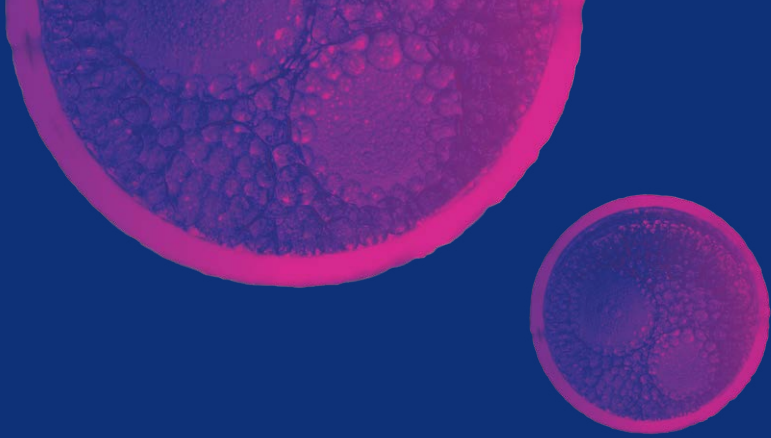


**Senior Manager, Clinical Trials**  
Ms Alicia Rooney



\* Surgical, Acute Neurology and Dementia  
^ Respiratory, Infectious Diseases and Oncology  
# Inflammatory Bowel Disease





Principal Investigator main oversight of teams

Medical  
Oncology  
Research  
Team



**Principal Investigator**  
Dr Catherine Shannon



**Clinical Trial  
Unit Manager**  
Ms Caitlin Bennett

RIO<sup>^</sup>  
Research  
Team



**Principal Investigator**  
A/Prof Lucy Burr



**Principal Investigator**  
Prof Paul Griffin



**Clinical Trial Unit  
Business Manager**  
Ms Maddy Simson



**Clinical Trial  
Unit Manager**  
Ms Stevie Anderson

IBD<sup>#</sup>  
Research  
Team



**Principal Investigator**  
A/Prof Jake Begun



**Team Leader**  
Ms Sharyn Grossman

Genesis  
Research  
Team



**Principal Investigator**  
Prof Sailesh Kumar



**Clinical Trial  
Unit Manager**  
Ms Kate Jarrett

Palliative  
Care Research  
Team



**Principal Investigator**  
Prof Phillip Good



**Team Leader**  
Ms Georgie Huggett



**Team Leader**  
Ms Karyn Foster

# 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.



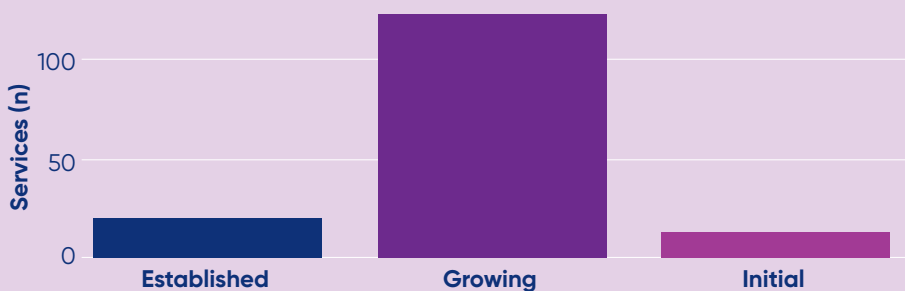


# MCT Site Capabilities

## 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
- Stem cell laboratory capability 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 Ruitenber

✉ Marc.Ruitenber@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](mailto:Maddy.Simson@mater.org.au)

**Stevie Anderson**

Clinical Lead

✉ [Stevie.Anderson@mater.org.au](mailto:Stevie.Anderson@mater.org.au)

### Team Contact

✉ [RIOClinicalTrials@mater.org.au](mailto: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 Kathryn Middleton**

Senior Medical Officer  
Oncology

**Dr Rebecca Moor**

Visiting Medical Officer  
Oncology

**Dr Niara Oliveira**

Senior Specialist  
Urological Cancers

### Unit Manager

**Caitlin Bennett**

✉ [Caitlin.Bennett@mater.org.au](mailto: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 eosinic 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 Nisbett**  
Queensland Lifespan  
Metabolic Medicine 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 Hurriion**

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](mailto:Stephanie.Guilas@mater.org.au)

### Team Contact

✉ [MBResearch@mater.org.au](mailto: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](mailto:Kate.Jarrett@mater.org.au)

### Team email

✉ [BirthTrials@mater.org.au](mailto: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**  
Visiting Medical Officer

**Dr Anthony Chau**  
Visiting Medical Officer

**Dr Robert Campbell**  
Visiting Medical Officer

#### Psychiatry

**Dr Tatjana Ewais**  
Staff Specialist

### Team Lead

**Chris McKeon**  
✉ [Chris.McKeon@mater.org.au](mailto:Chris.McKeon@mater.org.au)

### Team Contact

✉ [Medical.trials@mater.org.au](mailto:Medical.trials@mater.org.au)

### Address for kits

Level 2, Aubigny Place  
Raymond Terrace  
South Brisbane QLD 4101



## Surgical and Acute Care



- 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](mailto:Zander.Tait@mater.org.au)

### Team Contact

✉ [Acute.research@mater.org.au](mailto:Acute.research@mater.org.au)

### Address for kits

Level 2, Aubigny Place  
Raymond Terrace  
South Brisbane QLD 4101

## Palliative



- 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

### Research Coordinator

**Karyn Foster**

✉ [Karyn.Foster@mater.org.au](mailto:Karyn.Foster@mater.org.au)

**Georgie Huggett**

✉ [georgie.huggett@mater.org.au](mailto:georgie.huggett@mater.org.au)

### Team Contact

✉ [palcareresearch@mater.org.au](mailto:palcareresearch@mater.org.au)

# MCT *Contacts*

## Gynaecological Oncology – Surgery

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### Key Capabilities

- Intratumoural drug administration
  - Perioperative pain management studies
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### Principal Investigators

**Prof Lewis Perrin**  
Director of Gynaecological  
Oncology

**Dr Naven Chetty**  
Senior Staff Specialist

**Dr Nisha Jagasia**  
Staff Specialist

### Team Lead

**Raj Kaur**  
Clinical Trial Project Manager  
✉ [raj.kaur@mater.org.au](mailto:raj.kaur@mater.org.au)

### Address for kits

Level 2, Aubigny Place  
Raymond Terrace  
South Brisbane QLD 4101

## Allied Health

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### Key Capabilities

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

**A/Prof Liisa Laakso**  
Principal Research Fellow  
Allied Health

### Team Lead

**Matthew Hunt**  
Research Assistant  
✉ [Matthew.Hunt@mater.org.au](mailto:Matthew.Hunt@mater.org.au)

### Address for kits

Level 2, Aubigny Place  
Raymond Terrace  
South Brisbane QLD 4101





## Experience

<b>Trial Phase Capabilities</b>	Pharmaceutical: FIH, I, II, III, IV Medical Device: Pilot, Pivotal, Post-Market
<b>Research Experience</b>	Industry, Collaborative Group, Investigator-Initiated, Biomedical
<b>Patient Population</b>	Neonates   Young adults 16+   Adults 18+
<b>Open Studies</b>	200+
<b>Audit History</b>	Sponsor initiated audits within the last two years with no critical findings. Reports cannot be provided due to confidentiality.

## Qualifications

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

## Facility

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

## Informed consent

<b>Policy</b>	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
<b>Catholic Wording</b>	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

<b>Approval</b>	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.
<b>Policies and Application Form</b>	Policies and forms are available on the QCAT website: <a href="https://www.qcat.qld.gov.au/">https://www.qcat.qld.gov.au/</a>

## Monitoring

<b>Policy</b>	SOPs available on SiteDocs: <ul style="list-style-type: none"><li>• MPPL-04810 Monitoring Research Projects Procedure</li><li>• MPPL-04748 Remote Monitoring of Research Procedure</li></ul>
<b>Onsite Monitoring</b>	Three monitoring rooms available
<b>Onsite Facilities</b>	eISF access via Site Docs, photocopier, phone
<b>Bookings</b>	Onsite visits 6 weeks in advance
<b>Remote Monitoring</b>	Monitoring of eISFs is available via Site Docs

## Documentation

<b>Policies</b>	<p>Institutional SOPs available on SiteDocs:</p> <ul style="list-style-type: none"> <li>• MPPL-04749 Research Documentation Requirements</li> <li>• MMPL-04675 Research Master File and Essential Documents</li> <li>• MPPL-07058 Research Data Collection, Entry, Storage Movement and Destruction</li> <li>• MPPL-04677 Documentation of Research Site Staff Qualifications</li> </ul>
<b>Templates</b>	<ul style="list-style-type: none"> <li>• Investigator Site File Table of Contents</li> <li>• Delegation Log</li> <li>• Training Log</li> <li>• CV Template</li> </ul>
<b>Investigator Site File</b>	From January 2024 all records stored centrally in study specific eISF on SiteDocs
<b>Patient Source Data Location</b>	VERDI Scanned Record System and paper files stored in Mater Clinical Trials Offices, Aubigny Place, Raymond Terrace, South Brisbane, QLD 4101, Australia
<b>EDC</b>	Monitoring of eISFs is available via Site Docs
<b>Safety Reporting Procedure</b>	<p>Mater endorses the NHMRC guidance on Safety monitoring and reporting in clinical trials involving therapeutic(2016)</p> <p>Institutional SOPs available on SiteDocs:</p> <ul style="list-style-type: none"> <li>• MPPL-05219 Safety Reporting for Research Studies Including Serious Adverse Events</li> </ul>
<b>Archiving</b>	<p>Institutional SOP available on SiteDocs:</p> <ul style="list-style-type: none"> <li>• MPPL-04749 Research Documentation Requirements</li> </ul>
<b>Archiving Facilities</b>	<p>Pharmacy study documents are archived onsite at:            Pharmacy Department            Mater Hospital Brisbane            Raymond Terrace            South Brisbane QLD 4101</p> <p>All other study documents are archived at:            Grace Information Management            420 Sherbrooke Rd            Willawong QLD 4110</p>

## Early Phase Clinical Trials

<b>Early Phase Clinical Trials</b>	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.
<b>Policies</b>	<p>Policy and SOPs available on SiteDocs:</p> <ul style="list-style-type: none"> <li>• MPPL-07779 Mater Research Governance Framework</li> <li>• MPPL-07692 Early Phase Clinical Trials Risk Assessment Procedure</li> <li>• MPPL-07689 Early Phase Clinical Trials Risk Assessment Review Policy</li> </ul>
<b>Monitoring</b>	EPCT are monitored by Mater, in addition to trial sponsors
<b>Patient Safety</b>	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

<b>Policies</b>	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.
<b>Clinical Trial Pharmacy</b> Address for Delivery of Investigational Product	<b>Pharmacy Department – Clinical Trials</b> Mater Hospital Brisbane Level 3, Salmon Building Raymond Terrace South Brisbane, QLD 4101
<b>Pharmacy Contact</b>	<b>Clinical Trials Pharmacist</b> ☎ 07 3163 2451 ✉ pharmacy.clinicaltrials@mater.org.au
<b>IV Infusion Capability</b>	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.
<b>IP Storage</b>	<ul style="list-style-type: none"> <li>• Secured with controlled access.</li> <li>• Ambient temperature monitored storage.</li> <li>• Refrigerated (2°C to 8°C) temperature monitored storage.</li> <li>• Frozen (-20°C and -80°C) temperature monitored storage.</li> <li>• Digital continuous temperature monitoring of all storage areas</li> <li>• Alarmed systems in the event of temperature excursions</li> </ul>
<b>Backup Power</b>	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.
<b>Blinded IP Procedure</b>	Trained and experienced CT staff to perform blinded IP procedures including randomisation of treatment and blinding of parenteral aseptic products.
<b>Controlled Substances</b>	Schedule 8 medicines and Schedule 4 Diversion Risk medicines are stored in a dedicated Pharmacy Clinical Trials S8 safe.

## Investigational Product Administration and Monitoring

<b>Specialist Clinics</b>	<ul style="list-style-type: none"> <li>• Mater Cancer Care Centre – Oncology and Haematology</li> <li>• Mater Hospital Infusion Clinic – Neurology and General Medicine</li> <li>• Queensland X-Ray – Image-guided IP administration</li> <li>• Mater Anaesthetics – Intrathecal IP administration</li> </ul>
<b>Overnight Admissions</b>	Clinical trial participants can be hospitalised as private admissions for observation and treatment as required by study protocols
<b>Emergency Response</b>	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.
<b>ICU</b>	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

<b>Local Laboratory</b>	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.
<b>Laboratory Address</b>	Mater Pathology Level 6, Mater Hospital Brisbane Raymond Terrace South Brisbane, QLD 4101
<b>Local Lab Contact</b>	Clinical Trials Pathology ☎ 07 3163 2075 ☎ 07 3163 6632 ✉ pathologyclinicaltrialsteam@mater.org.au
<b>Address for Lab Kits</b>	Mater Clinical Trials Attn: [Team Lead] Level 2, Aubigny Place Raymond Terrace South Brisbane, QLD 4101
<b>Accreditation</b>	Certificates available on SiteDocs: <ul style="list-style-type: none"><li>• NATA ISO15189:2007</li><li>• NPAAC</li><li>• GCP</li></ul>
<b>Reference Ranges</b>	Available on SiteDocs
<b>Local Laboratory Capabilities</b>	<ul style="list-style-type: none"><li>• Phlebotomy services</li><li>• Monitored storage at -20°C and -80°C</li><li>• Chemical Pathology</li><li>• Haematology</li><li>• Immunology</li><li>• Genetics</li><li>• Cytology</li><li>• Anatomical Pathology</li><li>• Microbiology</li><li>• Cryostorage</li></ul>

## Imaging Services

<b>Imaging Services on Campus</b>	Queensland X-Ray, contracted as Mater Radiology Department Qscan
<b>Queensland X-Ray Address</b>	Level 3 Mater Hospital Brisbane Raymond Terrace South Brisbane, QLD 4101
<b>Queensland X-Ray Contact</b>	Emma Harriman Clinical Trial Coordinator ☎ 07 3032 8457 ✉ Emma.Harriman@sonicradiology.com.au
<b>Qscan Address</b>	Qscan Radiology Clinic Level 6, Mater Private Clinic 550 Stanley Street South Brisbane, QLD 4101

## Imaging Services

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<b>Qscan Contact</b>	Breanna Rooke Operations Support Lead ☎ 07 35399488 ✉ clinicaltrials@qscan.com.au
<b>Imaging Services Available</b>	<ul style="list-style-type: none"><li>• XRay</li><li>• CT Scan</li><li>• MRI</li><li>• PET</li><li>• Nuclear Medicine</li><li>• DXA</li><li>• Interventional Radiology</li></ul>

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## Study Startup

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<b>Start-Up Contacts</b>	<ul style="list-style-type: none"><li>• Mater Cancer Care Centre – Oncology and Haematology</li><li>• Mater Hospital Infusion Clinic – Neurology and General Medicine</li><li>• Queensland X-Ray – Image-guided IP administration</li><li>• Mater Anaesthetics – Intrathecal IP administration</li></ul>
<b>Research Governance</b>	<ul style="list-style-type: none"><li>• Clinical trials at Mater require approval by the Mater Research Governance Office (RGO).</li><li>• Site Specific Applications (SSA) are submitted via ERM</li><li>• 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.</li><li>• RGO and HREC schedule of fees: SoF</li></ul>
<b>RGO Contact</b>	Research Governance Officer ☎ 07 3163 3769 ✉ research.governance@mater.uq.edu.au 📄 Starting your project - <a href="https://www.materresearch.org.au/researchers/for-researchers/ethics-and-governance/starting-your-project">https://www.materresearch.org.au/researchers/for-researchers/ethics-and-governance/starting-your-project</a>
<b>Research Ethics</b>	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.
<b>Research Ethics Contact</b>	HREC Liaison Officer ☎ 07 3163 1585 ✉ research.ethics@mater.uq.edu.au 📄 Starting your project - <a href="https://www.materresearch.org.au/researchers/for-researchers/ethics-and-governance/starting-your-project">https://www.materresearch.org.au/researchers/for-researchers/ethics-and-governance/starting-your-project</a>
<b>Contracts and Budget</b>	<ul style="list-style-type: none"><li>• 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"</li><li>• Mater Clinical Trials standard rates and standard terms for CTRA schedules are contained in the Mater Clinical Trials Rate Card, available on SiteDocs.</li><li>• 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.</li><li>• Budget negotiation and legal review of CTRA are conducted in parallel, following HREC approval of the protocol</li></ul>

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## Study Startup

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<b>Contracts Contact</b>	Mater Research Agreements Office ☎ 07 3163 8008 ✉ research.agreements@mater.uq.edu.au
<b>Other Approvals</b>	Individual study protocols may require additional approvals including: <ul style="list-style-type: none"><li>• QCAT – Participants lacking capacity to consent</li><li>• Institutional Biosafety Committee – GMO studies</li></ul> Site Specific Applications can be reviewed in parallel with applications for Other Approvals.
<b>Documentation Requirements</b>	Mater requires the following documentation to be provided to commence study start-up: <ul style="list-style-type: none"><li>• Notification of site selection</li><li>• Final versions of protocol and investigators' brochure</li><li>• Master PICF</li><li>• Final versions of study manuals – Pathology, Pharmacy, Imaging, any other service provider manuals</li><li>• HREC approval, if applicable – must include complete submission package and approved documents</li><li>• HREC review indemnity</li><li>• CTRA, including schedules – complete Schedule 1 details, draft budget and payment terms, Standard Indemnity, Certificate of Currency and any insurance terms</li></ul>
<b>Site Initiation</b>	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.
<b>Start-Up Timeline</b>	<ul style="list-style-type: none"><li>• Written notification of site selection is required to commence site start-up.</li><li>• 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.</li><li>• 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.</li><li>• 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.</li><li>• 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.</li><li>• 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.</li></ul>

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