Government of South Australia

Health
Northern Adelaide Local Health Network

Clinical Trials Unit Site Information Guide

Lyell McEwin Hospital

Contents

Clinical Trials Unit

Introduction

Thank you for taking the time to consider the Lyell McEwin Hospital (LMH) Clinical Trials Unit (CTU) as a potential study site for your research project.

The following information is provided to assist you in the site selection.

The Lyell McEwin Hospital is part of the Northern Adelaide Local Health Network (NALHN) that provides care to more than 400,000 people living in the northern metropolitan area of Adelaide as well as people in regional area. LMH is recognised as a leading teaching institution which has affiliations with the University of South Australia, Flinders University and The University of Adelaide.

LMH is an accredited institution that complies with the 10 National Safety and Quality Health Services Standards. The LMH currently services the area of highest population growth in the South Australia.

At the LMH various health disciplines have been successfully involved in the conduct of clinical trials for more than 20 years. As the hospital capacity and demand in clinical trials have grown, the CTU was formally established in 2016.

The CTU runs Phase II – IV clinical trials for many of the world's leading pharmaceutical and biotechnology companies. We uphold stringent observation of the international regulatory requirements that facilitates the practice of the highest standards in clinical research. The unit has an extensive portfolio of over 40 active trials in a broad range of therapeutic areas.

We have extensive experience in the following:

- Use of various Electronic Data Capture (EDC) systems
- Administering Patient Reported Outcomes (PROs) questionnaires (paper and tablet based)
- Obtaining ECGs
- Vital signs assessments
- Intravenous Infusions
- Collection, processing and shipping of biological samples

A dedicated team of highly trained and experienced staff including medical personnel and registered nurses are involved in coordinating and conducting the clinical trials in the following disciplines:

- Endocrinology
- Gastroenterology & Hepatology
- Psychiatry
- Cardiology
- Renal
- Respiratory
- Rheumatology
- Infectious Diseases

The LMH has dedicated Cancer Clinical Trials Unit that specialises in various Oncology Trials.

For further information, please contact:
Victoria Tsagareli
Clinical Trials Unit Manager
Email: Health.LMHClinicalTrialsUnit@sa.gov.au
Phone: +61 (08) 8282 0219

CTU Address:
Lyell McEwin Hospital Level
2, Clinical Trials Unit
Haydown Road
ELIZABETH VALE SA 5112

Staff

CTU complies with SA Health Policy, Procedures and Guidelines and clinical trials are conducted under current ICH/GCP and NHMRS guidelines.

Medical Staff - Consultants

Name	Experience in Research (years)
ENDOCRINOLOGY	
A/Prof Peak Mann Mah	> 10
Dr Parind Vora	> 5
Dr Linda Watson	> 5
Dr Jessica Stranks	> 5
PSYCHIATRY	
A/Prof Dennis Liu	> 10
Prof Cherrie Galletly	> 10
Dr Anna Nowak	> 5
CARDIOLOGY	
A/Prof Margaret Arstall	>10
Dr Purendra Pati	> 5
Dr Sharmalar Rajendran	> 5
Dr Alicia Chan	> 5
Dr Rajiv Mahajan	> 5
Dr Devan Mahadavan	> 5
GASTROENTEROLOGY	
Dr Damian Harding	> 5
Dr Asif Chinnaratha	> 5
Dr Derrick Tee	> 10
Dr Hamish Philpott	> 5
Prof Rajvinder Singh	> 5
RESPIRATORY	
Dr James Geake	> 5

Trial Staff

Name	Position
Victoria Tsagareli	Clinical Trials Unit Manager
Jane Rose	Clinical Trials Coordinator
Bernie Hoffmann	Clinical Trials Coordinator
Brenda Trezona	Clinical Trials Coordinator
Beverley Hisee	Clinical Trials Coordinator

Unit Facilities

- Reception / Waiting area
- Three fully equipped clinic rooms designated for trial assessments / procedures
- Facilities for clinical trials monitoring
- Fully equipped Laboratory
- Secure Storage Rooms
- Conference Room
- Shared Kitchen facility

Equipment

The following equipment is available at the site for the clinical trials:

- ECG machine
- Blood Pressure Monitors
- Ophthalmoscope
- Scales
- Stadiometer
- Thermometer (tympanic)
- Glucometer
- Fibroscan
- Accurate measuring device for distance (6 minute walk test)
- Fridge (-200C) and freezer and (-700 C) fully monitored and alarmed
- Centrifuges (refrigerated and ambient)

  NOTE: The Clinical Trials Unit is unable to supply or source dry ice for shipping of frozen laboratory samples. It is the sponsors' responsibility to select a courier service that is able to provide dry ice on a day of sample collection

Equipment Maintenance and Calibration

As part of a state-wide policy, each piece of equipment is risk-assessed by the Biomedical Engineering (BME) Department based on their use and potential for malfunction. In 2018, South Australian BME developed a process aligned with Australian standards to meet legislative requirements. Maintenance and calibration is based on a formal risk assessment analysis according to the Australian Standard 3551 and therefore, no calibration certificates are provided. Each piece of CTU equipment is labelled with a yellow sticker stating "This device is NOT scheduled for maintenance".

Special requests for calibration and maintenance may be made.

Confidentiality Disclosure Agreement

Confidentially Disclosure Agreement (CDA) is a mutual document between a sponsor and the CTU that protects any confidential information to be disclosed to a third party by either side .The mechanism to protect the confidential information is the execution of the CDA by both parties.

A CDA template approved by the Crown Solicitors Office for the SA Department for Health and Aging must be used and is available on request. Initial CDA should be forwarded to the Clinical Trials Unit Manager for execution through the Institution, prior to disclosing any trial related confidential material.

At the LMH, a CDA is executed by the Executive Director of Medical Services on behalf of the Institution and other staff / Investigators. The agreement must be addressed to the Institution and not to any Individual/s as follows:

"Northern Adelaide Local Health Network Incorporated operating as Lyell McEwin Hospital (ABN 46 371 200 573) of Haydown Rd Elizabeth Vale South Australia 5112, Australia"

The institution will not be held accountable to the laws of other jurisdictions. The following statement has been approved by the Crown for inclusion in the CDA:

GOVERNING LAW
"This Agreement shall be governed and construed in accordance with the laws and regulatory requirements of the State of South Australia and the Parties agree to submit to the exclusive jurisdiction of the courts of that State and the courts of appeal from them".

Site Feasibility Assessment

A site feasibility questionnaire should be emailed to the potential Principal Investigator and Clinical Trials Unit Manager. Please email to Health.LMHClinicalTrialsUnit@sa.gov.au

Site Selection Visit

Site Selection visits should be scheduled with the Clinical Trials Unit Manager in advance.

At the visit, you will be meeting with the following staff:

- Principal Investigator
- Clinical Trials Unit Manager
- Study Coordinator
- Onsite Pharmacy (if required)

If the sponsor is new to the CTU, a tour of our facility can be arranged on request.

Indemnity

SA Health has standard insurance and indemnity arrangements that apply to the whole of the Government sector, including public hospitals. SA Health has adopted the Medicines Australia indemnity position set out in the Standard Medicines Australia Indemnities. As this position has long been accepted as the appropriate standard by both Government and industry, clauses that seek to alter or re-state this indemnity position will not be agreed to.

Standard Indemnity template is available on request.

Clinical Trials Research Agreement

The Standard Clinical Trails Research Agreement (CTRA) reflects a fair and reasonable commercial agreement between the contracting parties. The purpose of the Standard CTRA is not to delete or to modify essential clauses that have been subject of long negotiation with Medicines Australia and, through them, the pharmaceutical industry. Accordingly clauses that seek to substantially alter the core provisions of the agreement will not be agreed to. This includes and not limited to the following clauses: the publication, the confidentiality, the intellectual property and termination provisions.

Standard CTRA template is available on request.

Site specific details must be included as follows:

Site Details

Name of Institution	Northern Adelaide Local Health Network Incorporated, operating as Lyell McEwin Hospital
Address	Clinical Trials Unit, Level 2 Haydown Road, Elizabeth Vale, South Australia 5112
ABN	46 371 200 573
Contact for Notices	Clinical Trials Unit Manager
Phone Number	+61 8 8282 0219

Schedule 2 - Payee Details

Bank	Commonwealth Bank of Australia
Branch	96 King William St, Adelaide 5000
BSB	065 266
Account Name	NALHN Oracle Operating
Account Number	1002 0646
ABN	46 371 200 573
Swift Code	CTBAAU2S

Amendments to Schedule 7 or Schedule 4 of the CTRA require SEBS approval.

After negotiation of a mutually acceptable budget has been reached, the draft version of the CTRA will be submitted to the NALHN LMH RGO for their final review and approval. The sponsor should provide three wet ink signed copies to the site for the final execution.

Clinical Trials Notification

For sponsors submitting electronic Clinical Trials Notification (eCTN) for clinical trials being conducted at Lyell McEwin Hospital the approving authority information is below:

Name of Approving Authority	Northern Adelaide Local Health Network Incorporated operating as Lyell McEwin Hospital
Contact Name	Roy Sneddon and / or Lorraine Cichon
Position	Research Governance Officers
Phone	+61 8 8182 9346
Email	HealthNALHNRgo@sa.gov.au

The CTN can be submitted prior to governance authorisation and a copy of the TGA acknowledgement provided with the governance application or post authorisation.

Clinical Trials Unit Fees

DESCRIPTION	FEES
*CTU Start Up Fee	$5000 (one off fee to be invoiced upon CTRA execution)
**Monthly Administration Fee	$200 (monthly until the close out visit, to be invoiced quarterly after Site Initiation Visit)
Participant Re-Consent Fee	$160 (if occurs at next scheduled visit)
Participant Re-Consent Fee	$300 (if outside a regular scheduled visit)
Initial RGO Submission	$2000 (SSA form and initial submission)
#RGO Amendment Submission Fees	
• Major Amendment	$300 (per submission)
• Minor Amendment	$150 (per submission)
SAE Reporting	$250 (per occurrence)
Close-Out Fee	$600
Remote Close-Out Fee	$1200
Remote Monitoring Fee	$230 (per instance)
Archiving Preparation Fee (boxing etc)	$500
Archiving Storage Fee	$1800 (one off)
Audit Fee	$1000 (per day)
Participant travel and meals	To be negotiated
Advertising	If required
&Trial relating mandatory training	To be invoiced (per staff member/per hour)
Investigator Meeting attendance	To be negotiated
If CTU is a Lead Site (in addition to above)	
CTU Initial HREC Submission Fee	$2600
• additional site listed in original submission	$300 (per site inclusion fee)
• additional site listed after approval	$600 (site addition fee)
Ongoing Monthly Administration Fee	$320 (monthly until the close out visit, to be invoiced quarterly from Site Initiation Visit date)
#Additional HREC submissions	
• Major Amendment	$400 (per submission)
• Minor Amendment	$200 (per submission)
Low Negligible Risk Trial submission	Please contact the site for fees
Miscellaneous Fees	Will be added according to the protocol requirements
• Local Laboratory - trial set up	Refer to page 12
• Imaging Department - trial set up	Refer to page 12

The CTU fees are based on the standard costs for conducting clinical trials in Australia.

***Study Start-Up Fee** includes activities relating to the following:

Site preliminary assessment including signing the confidentiality disclosure agreement, protocol review, feasibility determination, discussion and negotiations with external staff & relevant departments, accommodation of the Site Selection Visit and staff attendance (PI, SC and the Manager) , budget negotiation, CTRA execution, Site Initiation Visit (PI, Sub-I, SC, back-up SC and the Manager), equipment set up, source documents creation and pre-screening/recruitment activity.

****Monthly Administration Fee** incorporates the cost of daily study related activities after site activation including but not limited to:

- Ongoing liaison with Clinical Research Associate (CRA) and/or sponsor or their representatives
- Invoicing
- Maintaining study source documents, Investigator Site Files (ISF) and study supplies (e.g. central laboratory kits/storage/re-order and destruction) for the duration of the study.
- Review of safety reports and ongoing communication
- Maintaining temperature logs
- Accommodating CRA visit
- Trial specific equipment maintenance
- Consumables relating to the trial: use of computers, internet, fax and printer related costs
- Secure storage of ISF, source documents, study equipment and supplies for the duration of the study

[#]**Research Governance Office (RGO) / HREC preparation fees** incorporate the following:

- Minor amendment (submission of documents with administrative changes, annual reports, SAEs, SUSAR/USAED reports, sponsor notifications, close out report etc)
- Major amendment (submission of either new version of IB, protocol and / or Participant Information Sheet / Informed Consent Forms (PIS/ICF) and site specific versions of PIS/ICF).

[&]**Trial Related Mandatory Training Fee** relates the following but not limited to:

- GCP Online training / certification
- IWRS portal access / certification
- Trial specific technology use (e.g. tablet, smart phones, iPad)
- eCRF completion /certification
- IP administration / certification
- Webinar requests
- Teleconferences
- Protocol amendments
- Laboratory
- Licencensed questionnaire administration / certification
- Training for specific procedures
- Re-training

The site must be reimbursed for trial related training activities that occur outside the training provided at the Investigator Meeting, Site Initiation Visit or at any time after the site has been activated or throughout the trial.

Withholding Fee

The Clinical Trials Unit operates on cost recovery model and cannot accept fee withholding schedule.

Overhead Policy

NALHN requires a 25%OH to be applied to per participant fees (not site fees) for operating expenses of running / maintaining the Clinical Trials Unit.

SA Health Pharmacy LMH

Location:

Investigational Drugs Pharmacy
Lyell McEwin Hospital
Level 1, Haydown Road
Elizabeth Vale SA 5112

Contact:

Email: Health.LMHClinicalTrialsPharmacy@sa.gov.au

Fees

Fees are depending on the Investigational product constituent, preparation and dispensing instructions.

Human Research Ethics Committee

For clinical trials to be conducted at the Lyell McEwin Hospital, the affiliated central HREC is the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) – EC00192.

Please refer to the CALHN HREC website for all relevant details (submission dates, current fee schedule, documents, templates etc).
Website: https://www.rahresearchfund.com.au/rah-research-institute/for-researchers/human-researchethics/

For more information, please contact:
Ian Tindall
HREC Chairman
Email: Health.CALHNResearchEthics@sa.gov.au
Phone: +61 8 8222 4139

Research Governance Office

For clinical trials to be conducted at the Lyell McEwin Hospital, the affiliated Research Governance Office is the Northern Adelaide Local Health Network Research Governance Office (NALHN LMH RGO).

The information about NALHN RGO is available at the following website:
https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/northern+adelaide+local+health+network/nalhn+research+secretariat/research+governance/research+governance+at+nalhn

For more information, please contact:
Roy Sneddon or Lorraine Cichon
Research Governance Officers
Email: healthnalhnrgo@sa.gov.au
Phone: +61 8 8182 9346

Address:
Lyell McEwin Hospital
Level 2, Clinical Trials Unit
Haydown Road
ELIZABETH VALE SA 5112

Dual Submission

NALHN supports dual submission of ethics and governance. Dual submission allows the governance and ethical review to occur in parallel.

Fees

The Schedule of Fees and the RGO Fee form are available for download from the following website: https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/northern+adelaide+local+health+network/nalhn+research+secretariat/research+governance

SA Medical Imaging

The Medical Imaging Department provides services for research across the Lyell McEwin Hospital.

Imaging modalities and services include:

- X-ray
- Computed Tomography (CT)
- Magnetic Resonance Imaging (MRI)
- Ultrasound
- Mammography
- Coronary Angiography
- Digital Imaging (PACS)
- Nuclear Medicine
- Bone densitometry
- Digital Imaging (PACS)
- PET – CT can be performed at other providers, if required.

Fees

Radiology Setup fee	$500
MRI Setup fee	$1000
MRI Image de-identification and digital transfer to any electronic device	$70
MRI Image transfer fee	$50
Medical Scientist Radiology Exposure report	$400
PET scan Set Up fees	TBC

The imaging required for a clinical trial will be classified as 'additional to standard of care' and billed to the Clinical Trial Unit. Exceptions to this are if the imaging is unable to be billed to Medicare – e.g. Non rebateable MRI scans.

SA Pathology

SA Pathology is the state-wide pathology provider for the public health sector.

Local laboratory results are ordered and reviewed electronically for clinical assessment copies of lab reports will be printed and certified by the Investigator retrospectively for source verification.

Anatomical Pathology

In accordance with SA Pathology regulations, tissue blocks cannot be provided. Sponsor to organise, if required. Biopsy tissue is provided on slides (stained or unstained) as required.

Fees

SA Pathology Trial Set up fee of $500 and lab test fee per item are applicable.
Lab test fee will be charged per nominated item and at 140% of the MBS prescribed fee.

Site Monitoring

For privacy and confidentiality the Clinical Trials Unit has available two separate monitoring rooms and a conference room. To book a monitoring visit, please contact the Clinical Trial Coordinator and arrange a mutually agreeable date and time for the visit. If you wish to meet with the Principal Investigator, please request it in advance.

Monitoring Visit Preparation

All source documents at the LMH are in paper format. Please request the medical records to be reviewed by providing a list to the Study Coordinator at least 1 week prior to your visit. The Study Coordinator will arrange for the medical records to be available for your visit. Please note that medical records may be unavailable at any given time during your visit due to preexisting appointments, accident & emergency attendance or inpatient admissions.

At the end of monitoring visit the trial monitor is responsible to hand over all medical records, Investigator Site Files and source documents in complete order to the Study Coordinator. The monitoring room should be left in clean state for the next user.

If a visit with pharmacy is required, it is trial monitor's responsibility to schedule an appointment with the clinical trial pharmacist. Please email Health.LMHClinicalTrialsPharmacy@sa.gov.au to arrange a mutually agreeable time.

A photocopier / scanner is available in the unit for use.

Please note that computer or Internet access is not provided due to hospital policies.

Remote Monitoring

Any work completed to support offsite monitoring activities etc. collation, de-identification and provision of source documents, collation and provision of essential documents or ISF reconciliation will be supported at a cost to the sponsor of $230 per instance.

Audits

Written notification to the institution is required prior to attendance and will include the agreed date of the audit, the auditor(s) attending and an agreed visit schedule.

Close Out Visit

Close out visits can be booked by contacting the Study Coordinator. The Study Coordinator will ensure required site staff are available and retrieve all study materials for the visit.

Document Destruction

The documents that require destruction must be handed over to the Study Coordinator for further action. Confidential material will be disposed of in locked container which is collected and shredded by a contracted company.

Archiving

Once a clinical trial has closed out and the necessary HREC and RGO notifications have been performed and acknowledged, study files will be archived offsite at Iron Mountain.

Iron Mountain is an offsite storage provider located at 160 Churchill Road North, Cavan SA 5094.

Clinical Trials Unit Location

Lyell McEwin Hospital
Level 2, Clinical Trials Unit
Haydown Road
ELIZABETH VALE SA 5112

The Clinical Trials Unit is located within the Lyell McEwin Hospital. If you plan to visit us, we highly recommend you to print a copy of the map below, as we want to make it as easy as possible for you to find us.

If you need guidance in finding us, please contact the CTU staff on 8282 0219.