LYELL MCEWIN HOSPITAL CLINICAL TRIALS UNIT

SITE INFORMATION GUIDE

2023

Government of South Australia

Health
Northern Adelaide
Local Health Network

CONTENTS

Thank you for considering the Lyell McEwin Hospital's (LMH) Clinical Trials Unit (CTU) as a study site for your research. This guide contains information about our research facility and capacity, which should assist you with site assessment.

To discuss how the LMH CTU facility and Northern Adelaide Local Health Network (NALHN) expertise can be tailored to suit your research requirements, please contact:

Clinical Research Manager

Email: Health.LMHClinicalTrialsUnit@sa.gov.au

Phone: +61 (8) 8282 0219

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

ABOUT US

The Lyell McEwin Hospital (LMH) is one of four tertiary public hospitals in South Australia. We are part of the Northern Adelaide Local Health Network (NALHN), which provides care to more than 440,000 people living in the northern metropolitan area of Adelaide and people in regional areas. The LMH is a teaching hospital affiliated with the University of South Australia, Flinders University and The University of Adelaide. Our institution is accredited in compliance with the 10 National Safety and Quality Health Services Standards.

Various health disciplines at the LMH have successfully conducted clinical trials for more than 20 years. As the hospital capacity and demand in clinical trials have grown, the LMH CTU was formally established in 2016.

The CTU is a dedicated, purpose-built area within the hospital that 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 facilitate the practice of the highest standards in clinical research. The unit has an extensive portfolio of over 40 active trials in a range of different therapeutic areas, including:

- Cardiology
- Endocrinology
- Gastroenterology & Hepatology
- Psychiatry
- Renal medicine
- Infectious Diseases

LOCATION & HOURS OF OPERATION

The LMH CTU is a self-contained and purpose-built facility located on the second floor of the Lyell McEwin Hospital on Haydown Road in Elizabeth Vale (approximately 30-minute drive north of the Adelaide CBD). We provide high-quality care to patients between 8am to 5pm, Monday to Friday.

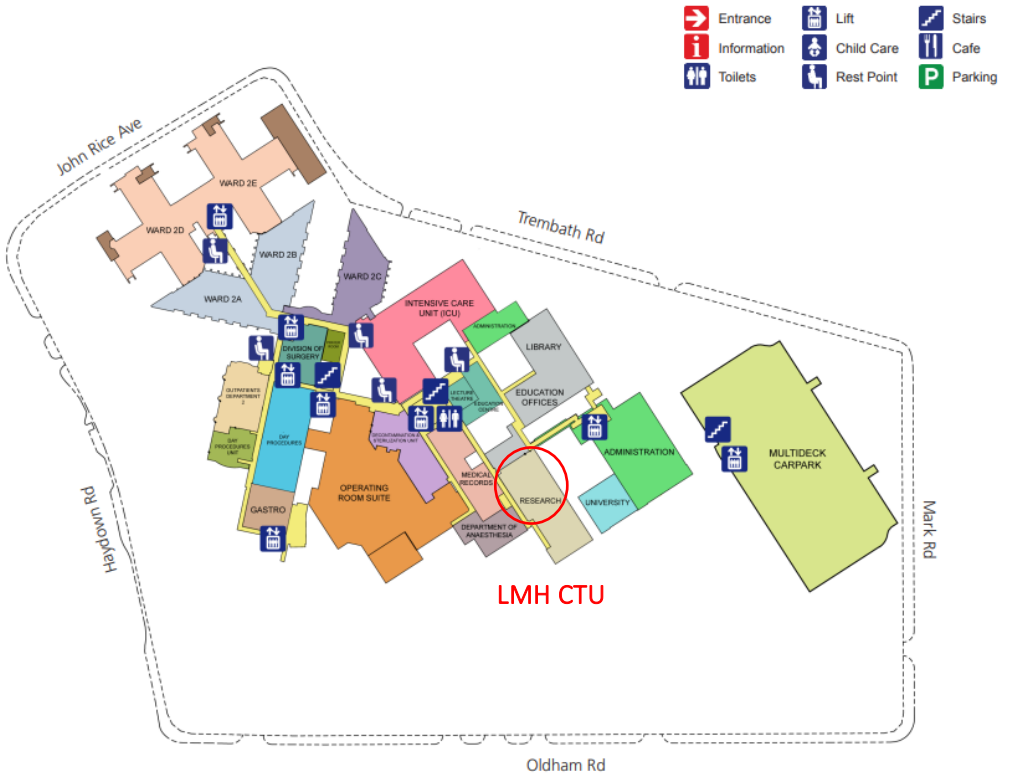
Northern Adelaide Local Health Network

Lyell McEwin Hospital

Government of South Australia
SA Health

Level 2

Administration
Day Procedures Unit
Day Procedures
Decontamination & Sterilization Unit
Department Of Anaesthesia
Division of Surgery
Education Offices
Education Centre
Gastro
Intensive Care Unit (ICU)
Lecture Theatre
Library
Medical Records
Multi-Deck Carpark
Operating Room Suite
Outpatients Department 2
Prayer Room
Research
University
Ward 2A
Ward 2B
Ward 2C
Ward 2D
Ward 2E



LMH CTU STAFF

The CTU is staffed by specialty nursing and research staff with a diverse range of clinical and academic qualifications and experience. All staff have ICH-GCP certification and adhere to all SA Health policies, procedures and guidelines.

DEDICATED RESEARCH STAFF

Name	Position	Phase
Paul Knudsen E: Paul.Knudsen@sa.gov.au	Clinical Trials Unit Manager Clinical Research Manager	II-IV
Brenda Trezona E: brenda.trezona@sa.gov.au	Senior Clinical Research Coordinator	II-IV
Rity Wong E: rity.wong@sa.gov.au	Senior Clinical Research Coordinator	II-IV
Janki Patel E: janki.patel@sa.gov.au	Senior Clinical Research Coordinator	II-IV
Deb Hobbs E: deb.hobbs@sa.gov.au	MH Clinical Trials Coordinator	II-IV
Lauran Hinter E: lauran.hinter@sa.gov.au	Clinical Trials Support Officer	II-IV

MEDICAL STAFF

Name	Position	Experience
CARDIOLOGY		
A/Prof Margaret Arstall	Director of Cardiology	A/Professor Arstall has over 20 years of research experience, including 10 years running Phase II-IV clinical trials. Researcher profile.
A/Prof Rajiv Mahajan	Senior Consultant Cardiologist & Electrophysiologist	A/ Professor Mahajan has over 28 years of research experience, including 10 years running Phase II-IV clinical trials. Researcher profile.
Dr Purendra Pati	Senior Consultant Cardiologist/ Interventionalist	Dr. Pati has over 20 years of research experience, including 16 years running Phase II-IV clinical trials. Researcher profile.
Dr Dimitrios Lypourlis	Senior Consultant Cardiologist/ Interventionalist	Dr. Lypourlis has over 15 years of research experience, including 6 years running Phase II-IV clinical trials.
Dr Luan Huynh	Senior Consultant Cardiologist	Dr. Huynh has over 17 years of research experience, including 15 years running Phase II-IV clinical trials.
Dr Eng Lee, Ooi	Senior Consultant Cardiologist	Dr. Ooi has over 17 years of research experience, including 9 years running Phase II-IV clinical trials.
Dr Andien Munawar	Senior Consultant Cardiologist	Dr. Munawar has over 5 years of research experience.
Dr York Yann Chow	Senior Consultant Cardiologist	Dr. Chow has over 5 years of research experience.
ENDOCRINOLOGY		
A/Prof Peak Mann Mah	Senior Endocrinologist	A/Professor Mah has over 14 years of research experience, including 12 years running Phase II-IV clinical trials.
Dr Parind Vora	Senior Endocrinologist	Dr. Vora has over 10 years of research experience, including 10 years running Phase II-IV clinical trials.

Dr Jessica Stranks	Endocrinologist	Dr. Stranks has over 5 years of research experience, including 5 years running Phase II-IV clinical trials.
Dr Ryan Jalleh	Endocrinologist	Dr. Jalleh has over 5 years of research experience.
Dr Ana McCarthy	Endocrinologist	Dr. McCarthy has over 7 years of research experience.
Dr Linda Watson	Endocrinologist	Dr. Watson has over 9 years of research experience.
Dr Anjana Radhakutty	Endocrinologist	Dr. Radhakutty has over 11 years of research experience, including 4 years running Phase II-IV clinical trials.
GASTROENTEROLOGY		
Professor Rajvinder Singh	Director of Gastroenterology	Professor Singh has over 20 years of research experience, including 15 years running Phase II-IV clinical trials. Researcher profile.
A/Prof Hamish Philpott	Senior Gastroenterologist	A/Professor Philpott has over 18 years of research experience, including 10 years running Phase II-IV clinical trials. Researcher profile.
Dr Damian Harding	Gastroenterologist/ Hepatologist	Dr. Damian Harding has over 8 years of research experience, including 6 years running Phase II-IV clinical trials. Researcher profile.
Dr Derrick Tee	Senior Gastroenterologist	Dr. Tee has over 13 years of research experience, including 8 years running Phase II-IV clinical trials. Researcher profile.
Dr Asif Chinnaratha	Senior Gastroenterologist/ Hepatologist	Dr. Asif Chinnaratha is a consultant Gastroenterologist/ hepatologist at the Lyell McEwin Hospital. He has a special interest in Hepatology; in particular, hepatocellular carcinoma and viral hepatitis. Researcher profile.
Dr Jin Tan	Gastroenterologist Fellow	Dr. Tan has 5 years of research experience and is currently a PhD candidate at the University of Adelaide, supervised by Prof Rajvinder Singh. His research interests are in Artificial Intelligence, Early gastrointestinal cancer detection, Health Economics and Indigenous Health. Researcher profile.

PSYCHIATRY		
A/Prof Dennis Liu	Consultant Psychiatrist	A/Professor Liu has over 30 years of research experience, including 15 years running Phase II-IV clinical trials.
A/Prof Oliver Schubert	Consultant Psychiatrist	A/Professor Schubert has over 15 years of research experience, including 10 years running Phase II-IV clinical trials. Researcher profile.
Dr Anna Nowak	Resident Medical Officer and Sub investigator	Dr. Nowak has 7 year of Clinical Trials experience and has a special interest in trials of Ketamine for Major Depressive Disorder.
INFECTIOUS DISIEASES		
Professor Mark Boyd	Infectious Diseases Physician	Professor Boyd has over 23 years of research experience, including 23 years running Phase II-IV clinical trials. Researcher profile.
RENAL		
Dr Nitesh Rao	Director of Nephrology	Dr. Rao has over 11 years of research experience, including 10 years running Phase II-IV clinical trials.
Dr Jola Kapojos	Renal Consultant	Dr. Kapojos has over 4 years of research experience.

THE CTU FACILITY

The CTU operates independently as a purpose-built facility contained within the LMH. Our space consists of the following areas:

- Reception/ waiting room.
- Kitchen.
- Conference room.
- Accessible bathrooms (staff and patient).
- Fully equipped, private clinic and interview rooms (single rooms).
- Secure storage rooms.
- Monitoring rooms.
- Laboratories (including a sample processing room [primary use] and access to an adjacent, larger laboratory containing a walk-in 4°C fridge, and -20°C and -80°C freezers (The University of Adelaide, Robinson Research Institute).

- Clinic rooms and offices are equipped with SA Health computers, tablet devices and telephones.
- WiFi capability available for patient use.
- Additional areas (e.g., operating theatres, clinical consulting rooms, trials pharmacy) located in respective departments are accessed by CTU staff as required.

EQUIPMENT

We have a variety of equipment available on-site for clinical trials (with the option of accessing external equipment and services required for more complex trial protocols):

- Basic diagnostic equipment, including blood pressure monitors (including BP+ Uscom), thermometers, pulse oximeters, scales, stadiometers, Glucometer etc.
- ECG machine, exercise ECG testing, Ambulatory ECG and BP monitoring, transthoracic, transoesophageal and stress echocardiography suite. Fibroscan, Intestinal ultrasound, ultrasound of liver/abdomen, pH study and manometry
- Endoscopy includes single balloon enteroscopy, spiral enteroscopy, endoscopic ultrasound (EUS), endoscopic retrograde cholangiopancreatography (ERCP) + spyglass, capsule endoscopy, colonoscopy, advanced endoscopic imaging, and artificial intelligence.
- Sample processing facility (including 4°C fridge and -20°C freezer).
- Temperature-controlled centrifuges.
- Laboratory incubators.
- Fully equipped coronary intervention and electrophysiology suite.
- Access to a larger laboratory, including additional equipment such as fume hoods, biosafety cabinets and -80°C freezer available upon request.

Equipment maintenance and calibration

To ensure that CTU delivers safe patient care and reliable data to our Sponsors, biomedical equipment is scheduled for annual servicing and calibration certificates. NALHN Biomedical Engineering is responsible for monitoring and compliance with this schedule in close partnership with CTU. Special request to review our maintenance schedule and calibration certificates is welcomed at any time.

OTHER LEGAL CONTRACTS AND AGREEMENTS

The NALHN Executive Director of Medical Service / or nominated delegate is the only person authorised to sign contracts on behalf of NALHN. Do not edit the body of the standard agreement. Any non-standard agreements (not on an approved template) will need to be reviewed by a legal representative prior to signing.

As of SA Health Office for Research, based on advice from the Crown Solicitor's Office (CSO) on June 2022, SA Health employees should not enter into any agreements personally with third parties. Only SA Health delegates (which included Northern Adelaide Local Health Network)- NALHN delegates) should enter into a relevant agreement with a third part. Under the terms of the agreement, SA Health will accept liability for the actions of its employees which cause any breach of the terms of the agreement. Please note the SA Health Website here noting the required SA Health directive.

The directive is based on advice from the CSO following review of FDA1572 Form, examples of FDA1572 -like forms and other investigator Agreements, and the Medicines Australia Clinical Trial Research Agreement (CTRA), Medical Technology Association of Australia Clinical Investigation Research Agreement (CIRA) templates. Signature pages for protocols, investigator brochures are investigator agreements containing commitments a Principal Investigator (PI) must agree to abide by.

The CSO advice was clear:

- A PI employed by SA Health (which includes NALHN employees) should not be required to agree to terms and conditions with a third party which are covered by an existing agreement between the sponsor and PI's employer.
- A PI becomes personally liable when signing these documents.

It is essential that any third-party agreements be negotiated and presented for signing at the same time as the researcher lodges the SSA.

These commonly include:

- Collaboration agreements with Universities/Medical Research Institutes/Hospitals
- Funding agreements
- Mutual Confidentiality Agreements
- Material Transfer Agreements (MTAs)
- Multi-Institution Agreements (MIAs)
- Intellectual Property Deeds
- Moral Rights declarations
- Service agreements
- Import/Export permits
- Student scholarship agreements
- Sanctioned Country clearances

Researchers should be aware that contract negotiations may take months, so these should be discussed with the NALHN Research Office at the earliest opportunity.

CONFIDENTIAL DISCLOSURE AGREEMENTS

The Confidential 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 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. The agreement must be addressed to the Institution and not to any individuals 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 Crown has approved the following statement 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".

ASSESSING SITE FEASIBILITY

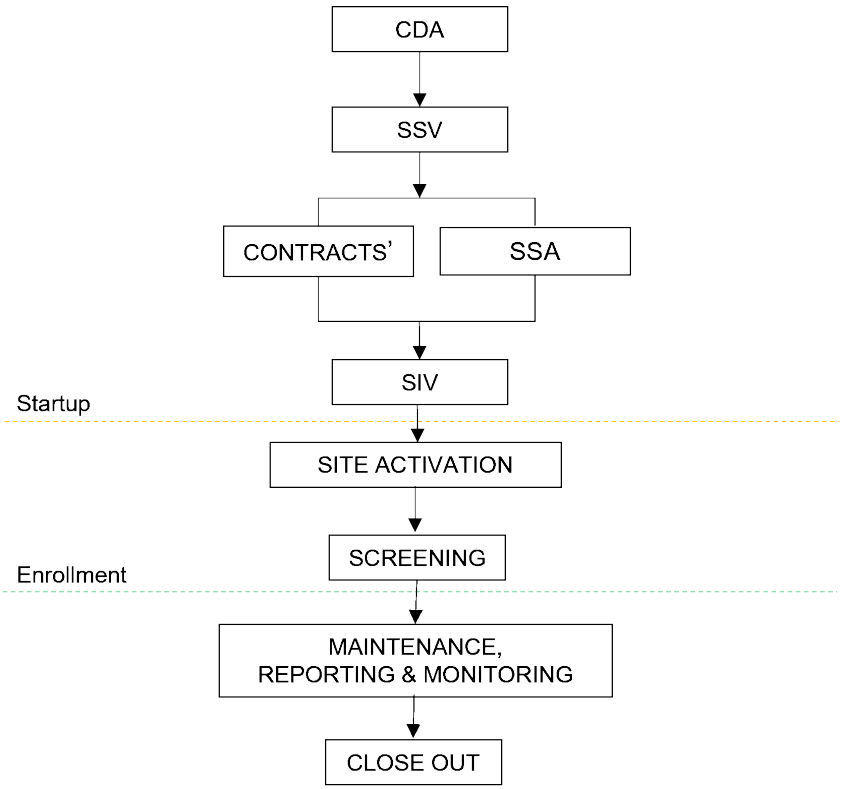
Feasibility assessments should be sent to the Clinical Research Manager via email (Health.LMHClinicalTrialsUnit@sa.gov.au), who will distribute them to the appropriate investigators who specialise in the indication to be investigated.

Subsequent to this, sponsors may schedule meetings with the Principal Investigator and Clinical Research Manager for a tour of the CTU facility and Clinical Trials Pharmacy.

Investigator CVs, medical licenses, GCP certificates and laboratory reference ranges can be made available for review at this visit.

SETTING UP YOUR TRIAL

Once our site has been selected, we can commence contract negotiations including budgetary review. A draft CTRA and Indemnity will require pre-review by the Clinical Research Manager, followed by NALHN's Research Governance Office.



CLINICAL TRIALS RESEARCH AGREEMENT (CTRA)

Medicines Australia Standard CTRA templates are endorsed by SA Health and should be used wherever possible to avoid the need for additional legal review.

Amendments to Schedule 7 or Schedule 4 of the CTRA require South-eastern Border States (SEBS) approval.

Site specific details should be included as follows:

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 AUSTRALIA
ABN	46 371 200 573
Contact for Notices	Clinical Trials Unit Manager
Email	Health.LMHClinicalTrialsUnit@sa.gov.au
Phone Number	+61 8 8282 0219

Schedule 2- Payee Details:

Bank	Commonwealth Bank of Australia
Branch	96 King William St, Adelaide SA 5000
BSB	065 266
Account Number	10020646
Account Name	NALHN Oracle Operating
ABN	46 371 200 573
Swift Code	CTBAAU2S
Contact	Clinical Trials Research Manager, Health.LMHClinicalTrialsUnit@sa.gov.au

Parties to the agreement: The Sponsor is responsible for study payments and must be the party listed in Schedule 2 for NALHN to Invoice.

After a mutually acceptable budget is negotiated, the draft version of the CTRA will be submitted to the NALHN RGO for their final review and approval.

Our institutional Delegate is the Executive Director of Medical Services for NALHN. All Signatures are managed via the Research Governance Office when final support is undertaken.

Fully executed copies of the CTRA and Indemnity will be provided as electronic copies to the study sponsor upon receipt of SSA from the RGO by the Clinical Trial Manager.

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
Approving Authority Contact Officer	Research Governance Officer
Position	Research Governance Officer, Northern Adelaide Local Health Network
Phone Contact	+61 8 8182 9346
Email Contact	HealthNALHNRGO@sa.gov.au

ETHICS AND GOVERNANCE

The LMH CTU has extensive experience as a lead site, including submitting human research ethics applications to different national HRECs. The NALHN RGO accepts approvals from all National Mutual Accepted (NMA) accredited Australian HRECs. South Australian HRECs commonly used include Bellberry and Central Adelaide Local Health Network (CALHN), Southern Adelaide Local Health Network (SALHN), and Women's and Children's Health Network (WCHN) HREC, with further information provided below.

NATIONAL MUTUAL ACCEPTANCE

SA Health is a signatory to the national system of streamlined ethical review of clinical trials across participating public health organisations (National Mutual Acceptance).

Under this system, an NHMRC-certified HREC provides the single ethical and scientific review of a multi-centre clinical trial application. Once a decision to approve the ethics of a project is made, this decision is then accepted by all participating jurisdictions without the requirement of further ethical and scientific review.

In South Australia, Phase 0 and Phase I clinical trials (exploratory and first time in human studies) are currently exempt from a single ethical review within the South Australian public health system and will require ethical and scientific review by each participating SA public health organisation through their associated HREC.

Clinical trials involving South Australian Aboriginal or Torres Strait Islander participants will also need to be reviewed by the Aboriginal Human Research Ethics Committee (AHREC) in addition to a certified HREC.

BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE (A – L)

The Lyell McEwin Hospital is uniquely placed to now accept ethical approvals from Bellberry.
Bellberry has 12 NHMRC registered and certified ethics committees that run up to 3 weekly meetings. This allows Bellberry to ensure timely application review, significantly shortening study start-up timelines.
As an NHMRC-certified ethics committee, Bellberry can also provide multi-centre ethical review and approve applications in line with the National Approach to Single Ethics Review of Multi-Centre Research.
For further information about fees and submission guidelines, please visit the Bellberry.

CENTRAL ADELAIDE LOCAL HEALTH NETWORK HUMAN RESEARCH ETHICS COMMITTEE (CALHN HREC) EC00192

The Lyell McEwin Hospital is affiliated with the CALHN HREC, where submissions require review by a public health institution. Please visit the Royal Adelaide Hospital Research Fund for further information about fees and submission guidelines.

GOVERNANCE: NALHN RGO

The NALHN RGO provides Site Specific Approvals via Research GEMS. This must be undertaken before the commencement/activation of any research project at the NALHN.

Research Governance Office

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

The RGO charges schedules of fees as listed here, which should be contained in Schedule 2 of the CTRA.

RESEARCH FEES (excluding GST)

The clinical research manager negotiates budgets for sponsored clinical trials and must include the standard fees listed below. Please note these fees may be increased if work required by the sponsor is deemed in excess of the standard amounts listed below.

Collective research groups (CRGs) and Low to negligible-risk applications may also be considered by the CTU. Please contact us directly for further information about these fee structures.

FEES FOR SPONSORED CLINICAL TRIALS (excluding GST)

The table below outlines the standard fees applied for sponsored clinical trials. Some conditions and brief descriptions of these fees are provided below.

DESCRIPTION	FEES
CTU Start-Up Fee	$5000 (one-off fee to be invoiced upon CTRA execution)
Monthly Administration Fee	$200 per month from SIV to COV dates.
Participant Re-Consent Fee	$160 (if occurs at the next scheduled visit)
	$300 (if outside a regularly scheduled visit)
Preparation of initial SSA Submission to RGO	$2000 (SSA form and initial submission)
Preparation and submission of RGO Amendments:	
Major amendments (e.g. protocol, ICFs, IB)	$300 per submission
Minor Amendment	$150 per submission
SAE Reporting	$250 per occurrence
Close-Out Fee (on site)	$600 once off
Remote Close-Out Fee*	$1200 capped at 6 hours
Remote Monitoring Fee*	$230 per instance capped at 2 hours, $110 per hour thereafter.
Archiving Preparation Fee	$500 once off
Archiving Storage Fee	$1800 once off
Audit Fee	$1000 (per day)
Participant travel and meals	Negotiable
Advertising	Negotiable
Trial relating to mandatory training	Time invoiced per staff member rate
Investigator Meeting attendance	Negotiable
Laboratory set up fee	Negotiable depending on the required equipment
Setting up external service agreements	$330 per contract
If CTU is a Lead Site, the following fees also apply:	
CTU Initial HREC Submission Fee	$2600 + $300 per site included
Amend additional sites listed in the original submission	$600 for each occasion
Other HREC submissions Major amendments (e.g. protocol, ICFs, IB) Minor amendment	 $400 $200
Ongoing Monthly Administration Fee (replaces above fee)	$320 per month from SIV to COV dates.

*Although the COVID-19 pandemic is not currently resulting in restrictions to monitors attending our public hospital, these fees must now be included in the CTRA. They should only be implemented under difficult circumstances where a site visit cannot occur and may be subject to approval by the sponsor's representatives.

The study start-up fee includes activities relating to preliminary assessments including CDA execution, 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.

The monthly administration fee incorporates the cost of all study related activities after activation including but not limited to: liaising with investigators and/or Sponsor, invoicing, maintaining study records, Investigator Site Files (ISF) and study supplies (e.g. central laboratory kits/storage/re-order and destruction) for the duration of the study until close out. Review and submission of safety reports performed as required by the NHMRC. Maintaining and providing pre-screening/screening logs. Monitoring visit preparation and follow-up. Trial-specific equipment set-up and maintenance. Consumables include internet, fax, print and copy-related costs, teleconference fees, and storage of study files and supplies for the duration of the study.

Governance and ethics preparation fees incorporate the cost of preparation for minor amendments (e.g. administrative changes, annual progress reports, SUSARs, etc.) or major amendments (e.g. IB, protocol, PICF).

Trial-relating mandatory training fees include new or renewed IWRS portal access/certification, trial-specific technology use (e.g. tablet, smartphones, iPad), eCRF completion /certification, IP administration/certification, training webinar requests, teleconferences, protocol amendments, laboratory processes or manuals, questionnaire administration/certification, and any training or re-training for specific procedures.

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

Withholding payments: The Clinical Trials Unit operates on a cost recovery model and cannot accept withheld payments.

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

Payment schedules: Study payment visit costs will be paid quarterly for all completed patient study visits entered into the electronic Case Report Form (eCRF) up to the quarterly payment cut-off date. To enable this, CTU will issue invoices every two months, with payments due within 30 days.

CLINICAL TRIALS PHARMACY- SA PHARMACY DEPARTMENT

The Lyell McEwin Hospital Pharmacy has a dedicated Investigational drugs pharmacy that can accommodate and manage investigational products. In recent years, the service has been expanded to include onsite investigational drug production to support the growth of clinical trials at NALHN. The convenience of a co-located pharmacy offers additional flexibility and close collaboration for optimal patient management.

For certain investigational products with a cytotoxic component, the pharmacy department of The Queen Elizabeth Hospital may be utilised. A well-established Standard Operating Procedure for the transfer of investigational products is in place. Additional cold-chain requirements should be discussed at the time of the site selection visit.

Contact:
Investigational Drugs Pharmacy
Level 1, Lyell McEwin Hospital
Haydown Road,
Elizabeth Vale, SA, 5112
P: +61 8 8282 1674

E: Health.LMHClinicalTrialsPharmacy@sa.gov.au

FEES

Please contact the pharmacy for a list of their current fees and specifications. These often depend on the IP constituency, preparation, storage and dispensation.

RADIOLOGY AND IMAGING

Outsourcing of medical imaging ensures same-day examination and reporting for our patients in most cases. Imaging modalities and services include:

- X-Ray
- Multi-slice Computed Tomography (CT)
- Magnetic Resonance Imaging (MRI)
- Ultrasound
- Mammography
- Nuclear medicine
- Bone Densitometry
- Digital Imaging (PACS)
- PSMA-PET, FDG-PET

All examinations may be de-identified and made available digitally on electronic media as required. Clinical trial staff are very experienced in image upload for the purpose of central imaging review.

All imaging will be reported as per routine standard practice. Any study-specific radiological reporting requested may attract an additional charge.

Research involving ionising radiation exposure- Bio Safety, Chemical and Radiation Safety
The protocol and applicable imaging manual will be required for the determination of research-related radiation exposure. The Principal Investigator will assess the modalities and frequency of imaging of the protocol. If deemed as not consistent with routine care, a Research Radiation Statement will be sought from a qualified Medical Physicist. Suggested wording for site-specific Patient Information Sheets will be provided for ethical review and approval.

Research involving radiation must be conducted in accordance to the Australian Protection and Nuclear Safety Agency (APRANSA) Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposed (2005).

The South Australian Environmental Protection Agency (EPA) must also be notified in writing of the research before the research commences using the EPA Notification of a Research Study involving Exposure of Humans to Ionising Radiation Form (Radiation management plan | EPA).

FEES *(excluding GST)*

Radiology Setup Fee	$610
De-identification and digital image acquisition (CD or other electronic media) and image transfer	$120

Fees for other services, including external service agreements, are advised dependent on the trial protocol and reporting requirements. The CTU's imaging provider can provide CT with contrast, MRIs including gadolinium, DXA scans, MUGA (GBPS), PET FDG/PSMA and some interventions (e.g., spinal injections, lumbar punctures).

LOCAL PATHOLOGY- 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 to external parties. Sponsors are able to organise the collection of additional tissues for shipment to central laboratories, as required.

FEES *(excluding GST)*

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.

MONITORING

For privacy and confidentiality, 3-4 separate monitoring rooms/ desks are available in the CTU. To arrange a monitoring room, please contact the Study Coordinator and specify if you wish to meet with the Principal Investigator. To meet with the PI, sufficient notice will be required. A review of the main monitoring issues can be discussed with the research manager at each visit.

PREPARATION

SA Health and NALHN uses the state-wide Electronic Medical Records system (Sunrise), whereas source documents in CTU is kept in paper format. Temporary access to the medical records of consented research participants can be provided electronically through SA Health's secure Share file system. These copies will be permanently erased seven days after being made available. Alternatively, paper copies can be prepared before each monitoring visit to enable source data verification. To enable this, please provide a list of required documents to the primary Clinical Research Coordinator at least one week before your visit.

Unless otherwise arranged with your Study Coordinator, monitoring rooms are available during standard opening hours.

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

If a visit with the pharmacy is required, please inform the clinical trial pharmacist to schedule an appointment. Please email Health.LMHClinicalTrialsPharmacy@sa.gov.au to arrange an agreeable time.

REMOTE MONITORING

Any work completed to support offsite monitoring activities (e.g. 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.

AUDITS

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

CLOSEOUT VISIT

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

ARCHIVING

Once a study has closed out and the necessary HREC and RGO notifications have been performed, study files will be kept on-site for 12 months and archived off-site at Iron Mountain.

Iron Mountain is a secure offsite archiving facility at 2 5-55 Burma Rd, Pooraka, SA, 5095.