Lyell McEwin Hospital

Site Selection Pack

Level 2
Clinical Trials Unit
Introduction

Thank you for taking the time to consider the Lyell McEwin Hospital as a site to conduct your study. The following information is provided to assist you in your site assessment.

The Lyell McEwin Hospital (LMH) is part of the Northern Adelaide Local Health Network (NALHN). As well as The Lyell McEwin Hospital, NALHN incorporates Modbury Hospital, GP Plus Health Care Centres and Super Clinics, mental health services and provides care for approximately 350,000 people living in the northern metropolitan area of Adelaide.

LMH has extensive experience in the conduct of Clinical Trials (Phase I to IV) and a dedicated Research Team with experience in the following disciplines:

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

Our purpose built Clinical Trials Unit offers facilities for participants including a waiting area, lounge room and kitchen. Separate coordinator offices, dedicated treatment rooms, blood collection and laboratory, monitoring rooms and a meeting room.

Please contact the Clinical Trial Unit for further information.

Clinical Research Manager

Email: Health.LMHClinicalTrialsUnit@sa.gov.au
Phone: +61(08) 8282 0219
Address:
Lyell McEwin Hospital
Level 2, Clinical Trials Unit
Haydown Road
ELIZABETH VALE  SA  5112
Research Unit

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

Office Hours
Variable between 8 am – 6 pm (Monday to Friday)

Facilities
Reception / Waiting area
Meeting Room
Clinic & Treatment Rooms
Secure Storage Rooms
Laboratory
Monitoring Rooms
Kitchen
Sitting Room
Equipment & Maintenance

Laboratory Equipment

-70°C Freezer
-20°C Freezer
Refrigerator

Dry Ice
The Clinical Trial unit is unable to supply or source dry ice for shipping central laboratory samples. Please ensure the courier selected to send frozen samples is able to provide dry ice on collection (World Courier, Marken etc.)

Centrifuge
Make: Allegra X-22R 953606
Model: ALD07C045
Make HERAEUS BIOFUGE
Model: Primo R Centrifuge

Clinic Equipment

ECG
Make: Philips
Model: Page Writer Trim III, 860286

Fibroscan
Make: Echosens
Model: 402

Blood Pressure Monitor
Make: Welch Allyn
Model: UA-767
Make: Welch Allyn
Model: 420 Series

Ophthalmoscope
Make: Welch Allyn
Model: 767

Weight Scales
Make: Health Weight Rice Lake Weighing Systems
Model: 140-10-7N

Thermometer
Make: Covidien
Model: Genius 2

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. Special requests for calibration and maintenance may be made.
Clinical Trial Staff

All Staff have GCP certification and operate to SA Health Policy, Procedures and Guidelines. Our trial staff are experienced in the use of Electronic Data Capture (EDC), electronic capture Patient Reported Outcomes (PROs), conducting ECGs, venepuncture and processing/shipping central laboratory samples. Current certificates for GCP, EDC and IATA are available on request.

Medical Staff

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Experience in Research (years)</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/Prof Peak Mann Mah</td>
<td>Endocrinology Consultant</td>
<td>&gt; 10</td>
<td>II – IV</td>
</tr>
<tr>
<td>Dr Parind Vora</td>
<td>Endocrinology Consultant</td>
<td>&gt; 5</td>
<td>II – IV</td>
</tr>
<tr>
<td>A/Prof Dennis Liu</td>
<td>Senior Consultant Psychiatrist</td>
<td>&gt;10</td>
<td>II – IV</td>
</tr>
<tr>
<td>Prof Cherrie Galletly</td>
<td>Consultant Psychiatrist</td>
<td>&gt;10</td>
<td>II – IV</td>
</tr>
<tr>
<td>A/Prof Margaret Arstall</td>
<td>Cardiology Consultant</td>
<td>&gt;10</td>
<td>II – IV</td>
</tr>
<tr>
<td>A/Prof Chris Zeitz</td>
<td>Cardiology Consultant</td>
<td>&gt;10</td>
<td>II – IV</td>
</tr>
<tr>
<td>Dr Sharmalar Rajendran</td>
<td>Cardiology Consultant</td>
<td>&gt; 5</td>
<td>II – IV</td>
</tr>
<tr>
<td>Dr Alicia Chan</td>
<td>Cardiology Consultant</td>
<td>&gt; 5</td>
<td>III – IV</td>
</tr>
<tr>
<td>Dr Rajiv Mahajan</td>
<td>Cardiology Consultant</td>
<td>&gt; 5</td>
<td>III – IV</td>
</tr>
<tr>
<td>Dr Damian Harding</td>
<td>Gastroenterology Consultant</td>
<td>&gt; 5</td>
<td>II – IV</td>
</tr>
<tr>
<td>Dr Asif Chinnaratha</td>
<td>Gastroenterology Consultant</td>
<td>&gt; 5</td>
<td>II – IV</td>
</tr>
<tr>
<td>Dr Derrick Tee</td>
<td>Gastroenterology Consultant</td>
<td>&gt; 10</td>
<td>II – IV</td>
</tr>
<tr>
<td>Dr Hamish Philpott</td>
<td>Gastroenterology Consultant</td>
<td>&gt; 5</td>
<td>II – IV</td>
</tr>
<tr>
<td>Prof Rajvinder Sing</td>
<td>Gastroenterology</td>
<td>➔ 5</td>
<td>II - IV</td>
</tr>
<tr>
<td>Dr James Geake</td>
<td>Respiratory Consultant</td>
<td>&gt; 5</td>
<td>II – IV</td>
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Trial Staff

<table>
<thead>
<tr>
<th>Name</th>
<th>Contact Details</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pam Cooper</td>
<td>+61 8 8282 0219</td>
<td>I - IV</td>
</tr>
<tr>
<td>Jane Rose</td>
<td>+61 8 8282 0655</td>
<td>II – IV</td>
</tr>
<tr>
<td>Bernie Hoffmann</td>
<td>+61 8 8182 9000</td>
<td>II – IV</td>
</tr>
<tr>
<td>Jan Parkinson</td>
<td>+61 8 8182 9475</td>
<td>II – IV</td>
</tr>
<tr>
<td>Brenda Trezona</td>
<td>+61 8 8282 0666</td>
<td>II – IV</td>
</tr>
<tr>
<td>Beverley Hisee</td>
<td>+61 8 8182 9554</td>
<td>II – IV</td>
</tr>
</tbody>
</table>
CDA & Site Feasibility

Confidentially Agreements should be forwarded to the Research Governance Officer for execution through executive before release of the protocol.

Confidentiality Disclosure Agreement

CDAs are executed by the institution. The Department endorses mutual CDAs for the protection of privacy of both parties. A CDA template approved by the Crown Solicitors Office for the SA Department for Health and Aging is available on request.

Agreements are executed by the Executive Director of Medical Services on behalf of the institution and all staff/investigators. The agreement must be made out to the institution not an individual, 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”.

Feasibility / Site Selection

Feasibility visits can be scheduled with the Clinical Trial Coordinator or Manager.

Recruitment potential is available and will be estimated based on hospital data or past recruitment.

Schedule:

> Principal Investigator meeting – 30 minutes
> Clinical Trial Manager/Co-ordinator meeting and tour of the facilities – 60 to 90 minutes
> Pharmacy visit, 15 minutes
> Investigator CVs, medical certificates, GCP certificates, laboratory reference ranges and Medicare and NATA certificates are available at this visit.

CTRA

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

Amendments to Schedule 7 or Schedule 4 require SEBS approval.

Site Details for inclusion in the template:

Name of Institution: Northern Adelaide Local Health Network Incorporated, operating as Lyell McEwin Hospital
Address: Haydown Road, Elizabeth Vale, South Australia 5112
ABN: 46 371 200 573
Schedule 2

Payee Details:

All payments listed in this schedule will be made by the Sponsor to the Institution upon receipt of a tax invoice by direct credit.

Bank: Commonwealth Bank of Australia
Branch: 96 King William St, Adelaide
BSB: 065 266 Account Number: 10020646
Account Name: NALHN Oracle Operating
ABN: 46 371 200 573
Swift Code: CTBAAU2S

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

CTN

For sponsors submitting eCTNs 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: Roy Sneddon
Position: Research Governance Officer
Contact Phone: +61 8 8182 9346
Contact 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.
### Research Fees

#### Clinical Trial Unit Fees

<table>
<thead>
<tr>
<th>Service</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start Up Fee</td>
<td>$4000</td>
</tr>
<tr>
<td>Ongoing Monthly Administration Fee</td>
<td>$160/month (Invoiced quarterly from Site Initiation)</td>
</tr>
<tr>
<td>or Monthly Administration Fee (if Lead Site)</td>
<td>$320/month (Invoiced quarterly from SIV)</td>
</tr>
</tbody>
</table>

#### Governance and Ethics Preparation Fees

- Major Amendment Submission: $230 per submission
- Minor Amendment Submission: $115 per submission

<table>
<thead>
<tr>
<th>Service</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Initial Ethics Preparation Fee</td>
<td>$2600 (base fee)</td>
</tr>
<tr>
<td>Each additional site listed in original submission</td>
<td>$300 (per site inclusion fee)</td>
</tr>
<tr>
<td>Each additional site after approval</td>
<td>$600 (site addition fee)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Service</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAE Reporting</td>
<td>$250 per SAE</td>
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<tr>
<td>Participant Re-Consent Fee</td>
<td>$113</td>
</tr>
<tr>
<td>Re-Consent Fee (if outside a regular scheduled visit)</td>
<td>$226</td>
</tr>
<tr>
<td>Remote Monitoring Fee</td>
<td>$230 (per instance)</td>
</tr>
<tr>
<td>Audit Fee</td>
<td>$1000</td>
</tr>
<tr>
<td>Close-Out Fee</td>
<td>$600</td>
</tr>
<tr>
<td>Remote Close-Out Fee</td>
<td>$1200</td>
</tr>
<tr>
<td>Archiving Storage Fee</td>
<td>$1500</td>
</tr>
<tr>
<td>Participant travel and meals</td>
<td>TBA</td>
</tr>
</tbody>
</table>

**Study Start-Up Fee** includes activities relating to feasibility assessment, protocol review, discussions with other required staff & departments, feasibility determination and completion of pre-study questionnaire and site selection visit, investigator meeting attendance, budget/contract negotiation & contract review, SSA application preparation. Department set up and Start up meeting.

**Monthly Administration Fee** incorporates the cost of all study related activities after activation including but not limited to: liaison 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. Preparing annual reports for ethics and governance submission. Review and submission of safety reports. Maintaining and providing pre-screening/screening logs and temperature logs. Monitoring visit preparation and follow up. Trial specific equipment set up and maintenance. Consumables including internet, fax, print and copy related costs, teleconference fees, supplies for exam rooms, 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 (administrative changes etc) or major amendments (IB, protocol etc requiring changes to the PICF).

**Witholding:** The Clinical Trial Unit operates on cost recovery model and cannot accept any fee withholding.

**Overhead:** NALHN requires 25%OH to be applied to per participant fees (not site fees) for operating expenses of running/maintaining the Clinical Trial Unit.
SA Pharmacy Department

Investigational Drugs Pharmacist
Jacinta Nagle

Location
Lyell McEwin Hospital
Haydown Road, Elizabeth Vale  SA 5112
Phone: 08 8282 1674
Fax: 08 8282 9046
Email: Health.LMHClinicalTrialsPharmacy@sa.gov.au

Fees
Please email pharmacy for a list of current fees/trial specific fees:
SA Medical Imaging Department

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)
- Fluoroscopy
- Ultrasound
- Mammography
- Angiography
- Digital Imaging (PACS)
- Nuclear Medicine

Fees

<table>
<thead>
<tr>
<th>Description</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setup fee</td>
<td>$500</td>
</tr>
<tr>
<td>Setup fee (MRI trials)</td>
<td>$1000</td>
</tr>
<tr>
<td>Copies of images on CD or hard drive (per scan)</td>
<td>$70</td>
</tr>
<tr>
<td>Hard copy Film (+$2 per sheet)</td>
<td>$50</td>
</tr>
</tbody>
</table>

The imaging required for a research study can be classified as either ‘additional to standard of care’ or as ‘standard of care’. Imaging that is additional to standard of care will be 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).

Equipment

Computed Tomography

**Scanner 1**
- **Hardware:** Toshiba– Helical, multislice (320 slice)
- **Software:** Aquilion ONE version 4.63
- Slice thicknesses available 0.5, 1, 2, 4, 5, 7, 8, 10mm
- Contrast power injector Medrad Stellant

**Scanner 2**
- **Hardware:** Toshiba– Helical, multislice (64 slice)
- **Software:** Aquilion 64 V3.5 ER 004
- Slice thicknesses available 0.5, 1, 2, 4, 5, 7, 8, 10mm
- Contrast power injector Medrad Stellant

Magnetic resonance imaging (MRI)

Philips Intera 1.5 Tesla

Ultrasound

6 x GE Voluson E8 and E9
**General X-Ray**
Siemens Ysio System  
Carestream Evolution  
Philips Optimus (x 2)

**Fluoroscopy**
Siemens Artis Zee MP

**Angiography**
Toshiba Infinix (Cardiology Cath Lab)

**Mammography**
Philips Mammo Diagnost

**Duel-energy X-ray Absorptiometry (DXA) Scanner**
Prodigy Bone Densitometer  
GE Lunar Prodigy Pro
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. Biopsy tissue is provided on slides (stained or unstained) as required.

NATA

![NATA Logo](image)

**National Association of Testing Authorities, Australia**

**SCOPE OF ACCREDITATION**

**SA Pathology**

**LYELL MCEWIN HOSPITAL SITE**

| Accreditation Number: 2348 | Site Number: 2739 |

**Address Details:**
120 - 130 Haydon Road
ELIZABETH, SA 5112
AUSTRALIA

**Website:** [www.sapathology.sa.gov.au](http://www.sapathology.sa.gov.au)

**Contact Details:**
Mr Jason Graefling
+61(08) 62231377
jason.graefling@health.sa.gov.au

**Availability:** Services available to external clients

**Supervision:** B (Branch)

**Note:** Not all of the columns of the scope of accreditation displayed include data. The only data displayed is that deemed relevant and necessary for the clear description of the activities and services covered by the scope of accreditation.

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>SERVICE</td>
<td>PRODUCT</td>
<td>DETERMINANT</td>
<td>TECHNIQUE</td>
</tr>
<tr>
<td>Chemical pathology - Analysis of drugs for toxicological (non-legal) purposes and ingested or absorbed toxic chemicals</td>
<td>Blood; Snake bite site; Swabs; Urine</td>
<td>Snake venom detection</td>
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</tr>
<tr>
<td>Chemical pathology - Detection and/or quantitation of drugs for therapeutic monitoring</td>
<td>Plasma; Serum</td>
<td>Digoxin</td>
<td></td>
</tr>
<tr>
<td>Chemical pathology - Determination of hormones and hormone binding proteins (other than thyroid function tests)</td>
<td>Plasma; Serum</td>
<td>PTH</td>
<td></td>
</tr>
<tr>
<td>Test Category</td>
<td>Test Details</td>
<td></td>
<td></td>
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<tr>
<td>------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
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</tr>
<tr>
<td>Chemical pathology - Further investigation of cardiac function</td>
<td>Plasma; Serum; NT-pro B-type natriuretic peptide (BNP); Troponin;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemical pathology - Further investigation of lipid profiles for diagnosis of types III and IV hypoplasma</td>
<td>Plasma; Serum; HDL - Quantitation</td>
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<td></td>
</tr>
<tr>
<td>Chemical pathology - Investigation and determination of hepatic, cardiac, bone, lipid, renal, skeletal muscle and other profiles and metabolic studies</td>
<td>Plasma; Serum; V- Glutamin-transferase; Alanine aminotransferase; Albumin; Alkaline phosphatase; Ammonia; Amylase; Aspartate aminotransferase; Bicarbonate; Bilirubin - Any fractions; Bilirubin - Total; C-reactive protein (CRP); Calcium - Total; Chioride; Creatine kinase; Creatinine; Glucose; Lactate dehydrogenase (LDH); Lipase; Magnesium; Phosphate; Potassium; Sodium; Total cholesterol; Total protein; Triglycerides; Urate; Urea;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cerebrospinal fluid (CSF)</td>
<td>Plasma; Serum; Urine; Osmolarity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine</td>
<td>Cerebrospinal fluid (CSF) Glucose; Total protein;</td>
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</tr>
<tr>
<td>Chemical pathology - Quantitation of blood gases and other measurements (performed on the same specimen)</td>
<td>Urine Albumin; Chioride; Creatine; Potassium; Sodium; Total protein;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood</td>
<td>Blood; Chloride; Ionised calcium; Lactate; pCO₂; pH; pO₂; Potassium; Sodium;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cytocathology - Non-gynaecological cytological investigations on samples obtained via fine needle aspiration biopsy</td>
<td>FNAB samples from body sites Cytological examination; Review and reporting of fine needle aspiration samples;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haematology - Examination of blood films by special staining</td>
<td>Blood; Malaria</td>
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<tr>
<td>Haematology - Full blood examination</td>
<td>Blood; Reticulocytes</td>
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<tr>
<td>Laboratory Test</td>
<td>Type</td>
<td>Description</td>
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<tr>
<td>--------------------------------------------------------------------------------</td>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Haematology - Haemostasis related analysis (including special coagulation testing and platelet function tests)</td>
<td>Blood</td>
<td>APTT, D-dimer, Fibrinogen, INR, PT, TT;</td>
<td></td>
</tr>
<tr>
<td>Haematology - Limited blood examination</td>
<td>Blood</td>
<td>Erythrocyte sedimentation rate (ESR)</td>
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</tr>
<tr>
<td>Immunoa haematology - Blood group antibody detection</td>
<td>Blood</td>
<td>Other blood group systems, Rh phenotypes;</td>
<td></td>
</tr>
<tr>
<td>Immunoa haematology - Blood grouping</td>
<td>Blood</td>
<td>ABC, RhD;</td>
<td></td>
</tr>
<tr>
<td>Immunoa haematology - Determination of compatibility of blood donor units</td>
<td>Blood</td>
<td>Direct antiglobulin test (DAT), indirect Coombs test; Examination for blood group antibodies; Group checks of patient and donor; Identification of detected antibodies;</td>
<td></td>
</tr>
<tr>
<td>Immunoa haematology - Identification and quantification of blood group antibodies</td>
<td>Blood</td>
<td>Antibody elution</td>
<td></td>
</tr>
<tr>
<td>Immunoa haematology - Investigation of blood transfusion reactions</td>
<td>Blood products</td>
<td>Antibodies</td>
<td></td>
</tr>
<tr>
<td>Immunoa haematology - Issue and release of blood and blood product for transfusion</td>
<td>Blood</td>
<td>Issue and release of blood and blood products for transfusion</td>
<td></td>
</tr>
<tr>
<td>Infertility and pregnancy tests including assisted reproductive technology - Diagnosis of pregnancy</td>
<td>Plasma; Serum</td>
<td>Detection of human chorionic gonadotropin (hCG)</td>
<td></td>
</tr>
<tr>
<td>Infertility and pregnancy tests including assisted reproductive technology - Diagnosis of threatened abortion and/or diagnosis of ectopic pregnancy</td>
<td>Plasma; Serum</td>
<td>Quantitation of human chorionic gonadotropin (hCG)</td>
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<tr>
<td>Service</td>
<td>Product</td>
<td>Determinant</td>
<td>Technique</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
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<td>--------------------------------------</td>
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</tr>
<tr>
<td>In Vitro Fertilisation tests</td>
<td>Semen</td>
<td>Motility; Sperm number; Volume;</td>
<td></td>
</tr>
<tr>
<td>Parasitology - Detection of ova, cysts and parasites</td>
<td>Blood</td>
<td>Malaria</td>
<td></td>
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<tr>
<td>Serology of infection - Microbial antibody and/or antigen detection and quantification</td>
<td>Blood</td>
<td>Infectious mononucleosis</td>
<td></td>
</tr>
<tr>
<td>Tissue pathology - Examination of biopsy material</td>
<td>Formalin fixed tissue, Fresh tissue;</td>
<td>Review and reporting of biopsy material to identify or exclude morphological abnormalities</td>
<td></td>
</tr>
<tr>
<td>Tissue pathology - Immediate frozen section diagnosis</td>
<td>Fresh tissue</td>
<td>Intra-operative consultation and examination of biopsy material</td>
<td></td>
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<tr>
<td>Tissue pathology - Immunohistochemical (immunofluorescence) investigation</td>
<td>Fixed cytological smears</td>
<td>Detection of antigenic targets - Various</td>
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</tr>
</tbody>
</table>

**10**
- ISO 15189 (2012)

<table>
<thead>
<tr>
<th>Service</th>
<th>Product</th>
<th>Determinant</th>
<th>Technique</th>
<th>Procedure</th>
<th>Limitation/Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical pathology - Quantitation of blood gases and other measurements (performed on the same specimen)</td>
<td>Blood</td>
<td>Creatinine; Glucose; pO2; pH; Potassium; Chloride; Urea nitrogen; Haemoglobin; Sodium; Lactate; Haematocrit; pCO2;</td>
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**Cardiology Wards**
- ISO 15189 (2012)

<table>
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<tr>
<th>Service</th>
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<th>Procedure</th>
<th>Limitation/Range</th>
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</thead>
<tbody>
<tr>
<td>Chemical pathology - Further investigation of cardiac function</td>
<td>Troponin</td>
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**Mobile/Field PoCT**
<table>
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<tr>
<th>SERVICE</th>
<th>PRODUCT</th>
<th>DETERMINANT</th>
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<th>PROCEDURE</th>
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<td>Haematology - Haemostasis related analysis (including special coagulation testing and platelet function tests)</td>
<td>Blood</td>
<td>INR</td>
<td></td>
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<td>Hospital in the Home</td>
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</tbody>
</table>

Accreditation Number: 2348 | Site Number: 2739 | Printed on: 15-Aug-2018

------------------------ END OF SCOPE ------------------------
Ethics

Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) EC00192

Research applications involving the use of human participants to be conducted at the Lyell McEwin Hospital are submitted to the Central Adelaide Local Health Network Human Research Ethics Committee.


2015: Median HREC approval time for studies approved at LMH was 28 days

Fees

Please refer to the CALHN HREC website for the current fee schedule

For more information:
Mr Ian Tindall
CALHN HREC Chair

Contact Details
Email: Health.CALHNResearchEthics@sa.gov.au
Phone: +61 8 8222 4139
Level 3, Roma Mitchell House
136 North Terrace, ADELAIDE SA 5000
SA Single Ethical Review Model

The SA Health HREC operates as part of the SA Health Single Ethical Review Model. The Model promotes greater efficiency in ethical review across the public health system. The model allows a single (once only) ethical and scientific review for all research taking place over multiple sites within the SA public health system.

In the single model, one of the four SA public health system HRECs will undertake the ethical and scientific review of the research proposal as the ‘lead’ HREC.

All other SA Health sites participating in the research will accept the outcomes of the review of the lead HREC without further ethical or scientific consideration.

Applications submitted under this model must be completed online (HREA) via the Online Forms website.

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, a NHMRC certified HREC provides the single ethical and scientific review of a multi-centre clinical trial application. Once a decision to approve the ethics protocol is made, this decision is then accepted by all participating jurisdictions without the requirement for 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 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 and Torres Strait Islander participants will also need to be reviewed by the Aboriginal Human Research Ethics Committee (AHREC) in addition to a Certified HREC.
Governance

A Governance Application (Site Specific Assessment) must be submitted to the NALHN Research Governance Office (RGO):

**Roy Sneddon**  
Research Governance Officer  
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

2015: Median number of days from HREC Approval at LMH to the date of Governance authorisation was 12 days

**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 is available for download from the following website:  
Monitoring

For privacy and confidentiality the Clinical Trials Unit has available 2 separate monitoring rooms and a meeting room. To book a room, please contact the Clinical Trial Coordinator and specify if you wish to meet with the Principal Investigator.

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 Coordinator at least 1 week prior to your visit. The Coordinator can order the medical records and ensure they are available for your visit. Please note that case notes may be unavailable at any given time during your visit if the patient presents for an appointment/accident & emergency.

After the visit the Study Coordinator will return all medical records.

If a visit with pharmacy is required please inform the clinical trial pharmacist to schedule an appointment.

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

Please note that Internet access is not provided.

Monitoring rooms are available from 9 am to 5 pm (unless otherwise arranged with your Study Coordinator).

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 $150 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

Confidential material is disposed of in locked containers which are collected for shredding by SUEZ. Secure documents collected by SUEZ are monitored from the point of collection through to arriving and processing at their secure facility where documents are screened for contaminants, before being shredded.

Archiving

The Clinical Trials Unit stores all complete and inactive files off site at Iron Mountain. Iron Mountain is an offsite storage provider located at 160 Churchill Road North, Cavan SA 5094.

Iron Mountain provides (where required) the following records management services:

> transition; > transfer of Official Records; > retrieval and delivery of Official Records; > destruction of Official Records; > online services (Recall System); > training; and > ancillary services.
For more information

Clinical Trials Unit
Division of Medicine
Lyell McEwin Hospital
Level 2 Clinical Trial Unit
Telephone: 8282 0219