LYELL MCEWIN HOSPITAL

CANCER CLINICAL TRIALS UNIT

Site Information Document

Government of South Australia
Health
Northern Adelaide
Local Health Network

CONTENTS

INTRODUCTION

Thank you for expressing an interest in conducting your study at the Lyell McEwin Hospital. 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). Together with the Lyell McEwin Hospital, NALHN incorporates Modbury Hospital, GP Plus Health Care Centres, mental health services and provides multidisciplinary care for over 400,000 people living in the north and north eastern areas of Adelaide, as well as people in regional areas.

The Lyell McEwin Hospital is one of three tertiary hospitals in South Australia and is currently servicing the area of highest population growth in the state.

The cancer unit was initially established in 2000 but quickly outgrew its capacity and a purpose built cancer centre was opened in 2014 to accommodate for the increased demand of cancer care in the north. Together with a rapidly growing medical oncology service; haematology and also on-site radiotherapy have facilitated local care for patients without the need to travel across the city.

The Lyell McEwin Hospital has been conducting clinical research in Oncology since the year 2000 with extensive experience in Phase I to IV studies. We have a dedicated Research Team with experience in cancers of the:

- Genitourinary system
  - Prostate
  - Urothelial
  - Renal cell carcinoma
- Respiratory
  - Non-small cell lung cancer
  - Small cell lung cancer
  - Mesothelioma
- Gastrointestinal system
  - Gastric
  - Hepatic
  - Oesophageal
  - Pancreatic
  - Colorectal
- Breast
- Head and Neck
- Melanoma
- Brain
- Sarcoma
- Neuroendocrine

Please contact the Cancer Clinical Trials unit for further information.

Andy Phay
Clinical Research Manager
Email: Andy.Phay@sa.gov.au or Health.NALHNCancerResearch@sa.gov.au
Phone: +61 8 8282 0833
Address:
Lyell McEwin Hospital
Northern Adelaide Cancer Centre
Haydown Road
ELIZABETH VALE SA 5112

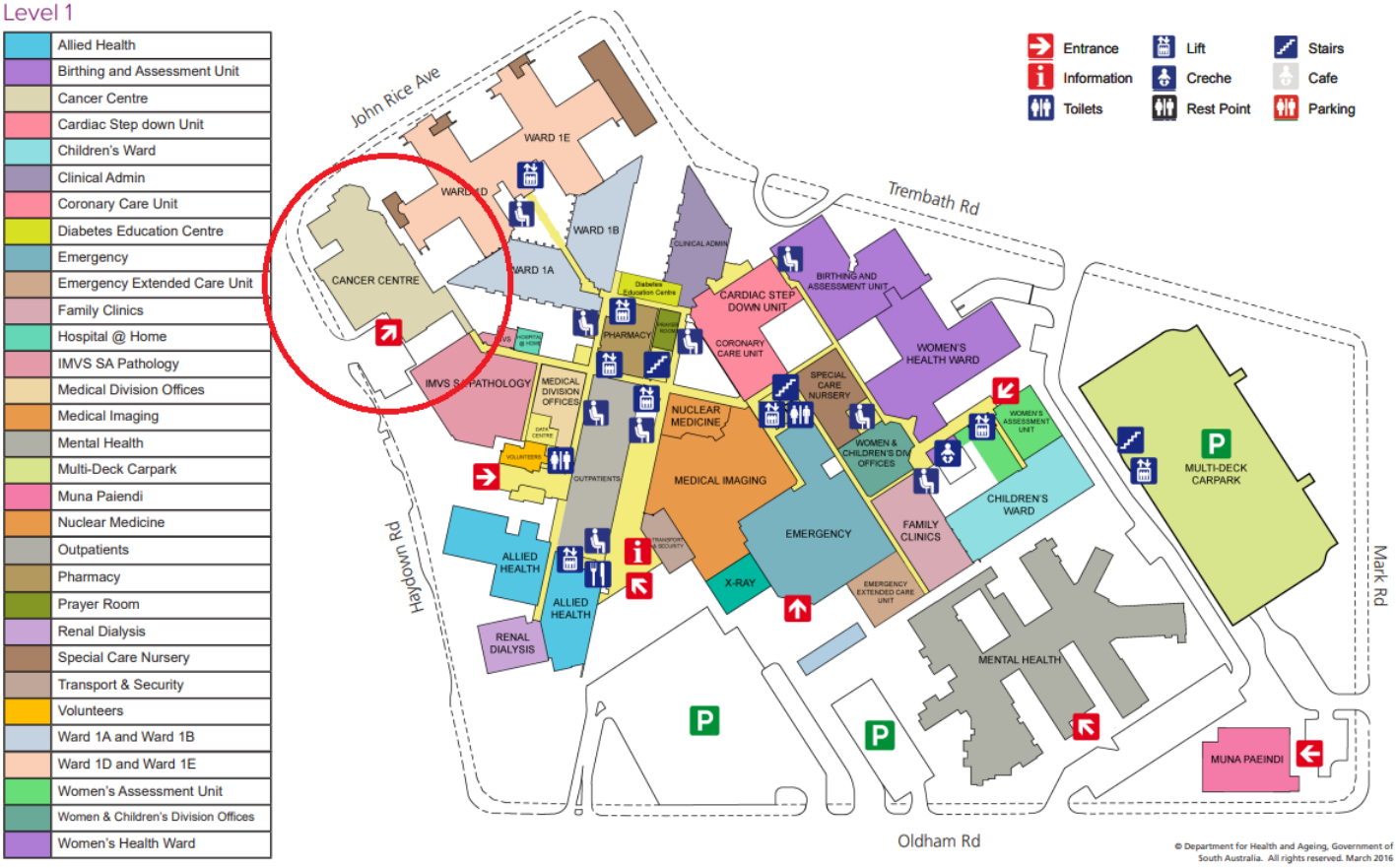
RESEARCH UNIT LOCATION AND FACILITIES

Northern Adelaide Local Health Network

Lyell McEwin Hospital

Government of South Australia | Health Northern Adelaide Local Health Network

Level 1



OFFICE HOURS

Variable between 8 am – 8 pm (Monday to Friday)

Approximately 30 minutes north of the CBD, the Cancer Clinical Trials office is located within the Northern Adelaide Cancer Centre at the Lyell McEwin Hospital. The chemotherapy day suite is a 12 chair facility where cancer therapies are administered to patients. This unit is staffed by a nursing team who are experienced in the treatment and strict requirements of clinical trial patients.

FACILITIES

Reception / Waiting area	Monitoring Rooms
Conference Room	Interview Rooms
Clinic Rooms	Kitchenette
Secure Storage Rooms	Laboratory

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 Patient Reported Outcomes (ePROs), conducting ECGs, venepuncture, processing and shipping of biological samples. Current certificates for GCP, EDC and IATA are available on request.

MEDICAL STAFF

Name	Position	Experience in Research	Phase
Dr Christopher Hocking	Medical Oncology Consultant Director of Cancer Services, NALHN Director of Cancer Research and Clinical Trials	> 5 years	I – IV
Dr Rohit Joshi	Medical Oncology Consultant	> 10 years	I – IV
Dr Jacqueline Adams	Medical Oncology Consultant	> 10 years	I – IV
Dr Dainik Patel	Medical Oncology Consultant	> 5 years	I – IV
Prof Timothy Price	Medical Oncology Consultant	> 10 years	I – IV
Dr Nimit Singhal	Medical Oncology Consultant	> 10 years	I – IV
Dr Hooi Hong	Medical Oncology Consultant	> 5 years	I – IV
Dr Mark McGregor	Medical Oncology Consultant	> 5 years	I – IV
Dr Vineet Kwatra	Medical Oncology Consultant	> 5 years	I – IV
Dr Louisa Lo	Medical Oncology Consultant	> 5 years	I – IV
Dr Li Chia Chong	Medical Oncology Consultant	> 5 years	I - IV

CANCER CLINICAL TRIALS UNIT STAFF

Name	Position	Phase
Andy Phay E: Andy.Phay@sa.gov.au	Clinical Research Manager	I – IV
Rebbecca Cato E: Rebbecca.Cato@sa.gov.au	Oncology Clinical Trials Coordinator	II – III
Jessica Petticrew E: Jessica.Petticrew@sa.gov.au	Oncology Clinical Trials Coordinator	II – III
Sarah Holden E: Sarah.Holden@sa.gov.au	Clinical Trials Administrative Coordinator	

CONFIDENTIALITY DISCLOSURE AGREEGMENT (CDA) AND SITE FEASIBILITY

Confidentiality Agreements should be forwarded to the Clinical Research Manager for execution through executive before release of the protocol and exchange of confidential information.

CONFIDENTIALITY DISCLOSURE AGREEMENT

CDAs are executed by the institution. The Department of Health 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 assessments should be sent to the Clinical Research Manager who will distribute to the appropriate investigators who specialise in the indication to be investigated. Alternatively, feasibility surveys may be sent through the Shared Investigator Platform.

SHARED INVESTIGATOR PLATFORM

Site selection visits should be scheduled with the clinical research manager. Recruitment potential is available and will be estimated based on hospital data or past recruitment.

SCHEDULE:

- Principal Investigator Meeting
- Clinical Research Manager meeting and tour of facilities
- On-site Pharmacy visit
- Investigator CVs, Medical licenses, GCP certificates and laboratory reference ranges are available at this visit.

CLINICAL TRIALS RESEARCH AGREEMENT (CTRA)

Medicines Australia Standard CTRA templates are endorse 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 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
Contact for Notices:	Clinical Research Manager
Fax for Notices:	-
Phone Number:	+61 8 8282 0833

SCHEDULE 2

Payee Details:

All payments listed in this schedule will be made by the Sponsor to the Institution 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

CLINICAL TRIALS NOTIFICATION (CTN)

For Sponsors submitting eCTNs for clinical trials being conducted at the 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	Dr John Maddison
Position	Executive Director of Medical Services, Northern Adelaide Local Health Network
Phone Contact	+61 8 8182 9346
Email Contact	HealthNALHNRGO@sa.gov.au

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

RESEARCH FEES
CANCER CLINICAL TRIALS UNIT FEES

Study Start-up Fee	$5000
Ongoing Monthly Administration Fee	$160/month (invoiced quarterly from SIV)
or Monthly Administration Fee (if Lead Site)	$320/month (Invoiced quarterly from SIV)
Governance and Ethics Preparation Fees	
• Major Amendment submission	$230 per submission
• Minor Amendment submission	$115 per submission
Initial Ethics Preparation Fee	$3000 (base fee)
• Each additional site listed in original submission	$300 (per site inclusion fee)
• Each additional site after approval	$600 (site addition fee)
SAE Reporting	$250 per SAE
Participant Re-Consent Fee	$113
Re-Consent Fee (if outside a regular scheduled visit)	$226
Remote Monitoring Fee	$230 (per instance)
Audit Fee	$1000
Close-Out Fee	$600
Remote Close-Out Fee	$1200
Archiving Storage Fee	$1500
Participant expenses	TBA

Study Start-up Fee includes activities relating to feasibility assessment, protocol review, discussions with other required staff & departments, completion of pre-study questionnaire and site selection visit, budget/contract negotiation and contract review, SSA application for RGO submission, department setup and site initiation visit.

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. Preparation of annual progress reports for ethics and governance submission. 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 including internet, fax, print and copy related costs, teleconference fees, 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).

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

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

SA PHARMACY DEPARTMENT

The Lyell McEwin Hospital Pharmacy has a dedicated Investigational drugs pharmacy that is able to accommodate and manage investigational products of a variety of dosage forms. In recent years, the service has been expanded to include onsite investigational drugs 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 product is in place. Additional cold-chain requirements should be discussed at the time of site selection visit.

INVESTIGATIONAL DRUGS PHARMACY – LYELL MCEWIN HOSPITAL

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

INVESTIGATIONAL DRUGS PHARMACY – THE QUEEN ELIZABETH HOSPITAL

Investigational Drugs Pharmacy

Level 2, The Queen Elizabeth Hospital

28 Woodville Road,

Woodville South, SA, 5011

P: +61 8 8222 6651

E: TQEHClinTrials@health.sa.gov.au

FEES

Please contact the pharmacy for a list of their current fees and specifications. In some cases, a separate pharmacy Services Agreement may be required, separate from the CTRA.

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 addition charge. The imaging required for a research study can be classified as either 'additional to standard of care' or as 'standard of care' as determined by the Principal Investigator. Imaging in line with standard of care may be billed to Medicare. (Exceptions to this are if the imaging is unable to be billed to Medicare – e.g. Non-rebateable MRI scans).

Tumour assessments are performed by the investigator to ensure consistency and correlation with clinical presentation.

FEES

Radiology Setup Fee	$500
De-identification and digital image acquisition (CD or other electronic media) and image transfer	$120

RESEARCH INVOLVING IONISING RADIATION EXPOSURE

The protocol and applicable imaging manual will be required for 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.

A fee may be applicable dependant on the complexity of the imaging requirements.

PATHOLOGY

SA Pathology is an accredited state-wide pathology provider for the public health sector. SA Pathology offers a wide range of services and can also perform testing outside of routine care or tests not rebateable by Medicare.

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

ANATOMICAL PATHOLOGY

In accordance with SA Pathology practice, tissues blocks cannot be provided unless extra samples are explicitly requested at the time of biopsy. Tissue will be sectioned and provided on slides as per the central laboratory manual.

HUMAN RESEARCH ETHICS

The Cancer Clinical Trials team have extensive experience in producing high quality human research ethics submissions. Our team have taken on responsibility of Coordinating Principal Investigator and lead site for several multi-centre studies.

The Lyell McEwin Hospital may accept ethics approval from public health HRECs as well as Bellberry.

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 who run up to 3 meetings each week. This allows Bellberry to ensure timely review of applications which significantly shortens study start up timelines.

As a NHMRC certified ethics committee, Bellberry is also able to 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 website:
https://bellberry.com.au/

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 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 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.

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.

For further information about fees and submission guidelines, please visit the website:

https://www.rahresearchfund.com.au/rah-research-institute/for-researchers/human-research-ethics/

RESEARCH GOVERNANCE

A Governance Application (Site Specific Assessment) must be submitted to the NALHN Research Governance Office for institutional authorisation prior to commencement/activation of any research project.

Research Governance Officer

Clinical Trials Unit

Level 2, Lyell McEwin Hospital

Haydown Road,

Elizabeth Vale, SA, 5112

E: HealthNALHNRGO@sa.gov.au

P: +61 8 8182 9346

W: 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/

FEES

The schedule of fees and the RGO Fee form is available for download from their website:

https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/health+and+medical+research/research+ethics/research+ethics+and+governance+fees

PARALLEL SUBMISSION

NALHN supports dual submission of ethics and governance. This allows simultaneous submissions to be made in order to reduce timelines. In 2019, the average time from submission to authorisation was less than 1 week.

MONITORING

For privacy and confidentiality, 2 separate monitoring rooms are available in the Clinical Trials Unit on level 2 of the hospital. 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; however a review of the main monitoring issues can be discussed with the research manager at each visit.

MONITORING VISIT PREPARATION

All medical records and source documents at the Lyell McEwin Hospital 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. Please note that medical records may be unavailable at any given time during your visit if the patient is admitted as an inpatient, if the patient presents for an appointment or 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 is available in the unit for use but 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 (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 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 assist to retrieve 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 archived offsite at Iron Mountain.
Iron Mountain is a secure offsite archiving facility located at 25-55 Burma Rd, Pooraka, SA, 5095.

For more information

Cancer Clinical Trials Unit
Division of Medicine
Lyell McEwin Hospital
Haydown Road, Elizabeth Vale, SA 5112
(08) 8282 0833
sahealth.sa.gov.au/nalhn

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