CANCER CLINICAL TRIALS UNIT

Lyell McEwin Hospital and Modbury Hospital

Government of South Australia

Health
Northern Adelaide
Local Health Network

NORTHERN ADELAIDE LOCAL HEALTH NETWORK

EVERYONE HAS A STORY. MATTERS. CONTRIBUTES. GROWS.

ACKNOWLEDGEMENT OF COUNTRY

Northern Adelaide Local Health Networkrlu tampinthi Kaurna miyurna yaitya yarta-mathanya Kaurna yartarna-arra ngadlu warpulayinthi.

Ngadlu tampinthi purkarna pukinangku, yalaka, tarrkarritya.

Ngadlu tampinthi yaitya mathanya kuma parnaku tuwila yartangka.

Northern Adelaide Local Health Network acknowledges the Kaurna people as the traditional custodians of the land where we proudly work and deliver health and wellbeing services.

We also honour Kaurna Elders past, present and emerging.

We recognise Aboriginal cultural authority, and their ongoing spiritual connection to Country.

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 420,000 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 four 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. Today, we see around 800 new cancer patients each year. 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 2005 with extensive experience in Phase I to IV studies, attracting patients from all around the state, including private referrals.

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

Gynaecological

Breast

Head and Neck

Melanoma

Brain

Sarcoma

Neuroendocrine

PLEASE CONTACT THE CANCER CLINICAL TRIALS UNIT FOR FURTHER INFORMATION

Andy Phay, Clinical Research Manager
andy.phay@sa.gov.au or
Health.NALHNCancerResearch@sa.gov.au
(08) 7117 7265
Lyell McEwin Hospital
Northern Adelaide Cancer Centre
Haydown Road
Elizabeth Vale SA 5112

NALHN PROVIDES MULTIDISCIPLINARY CARE FOR OVER

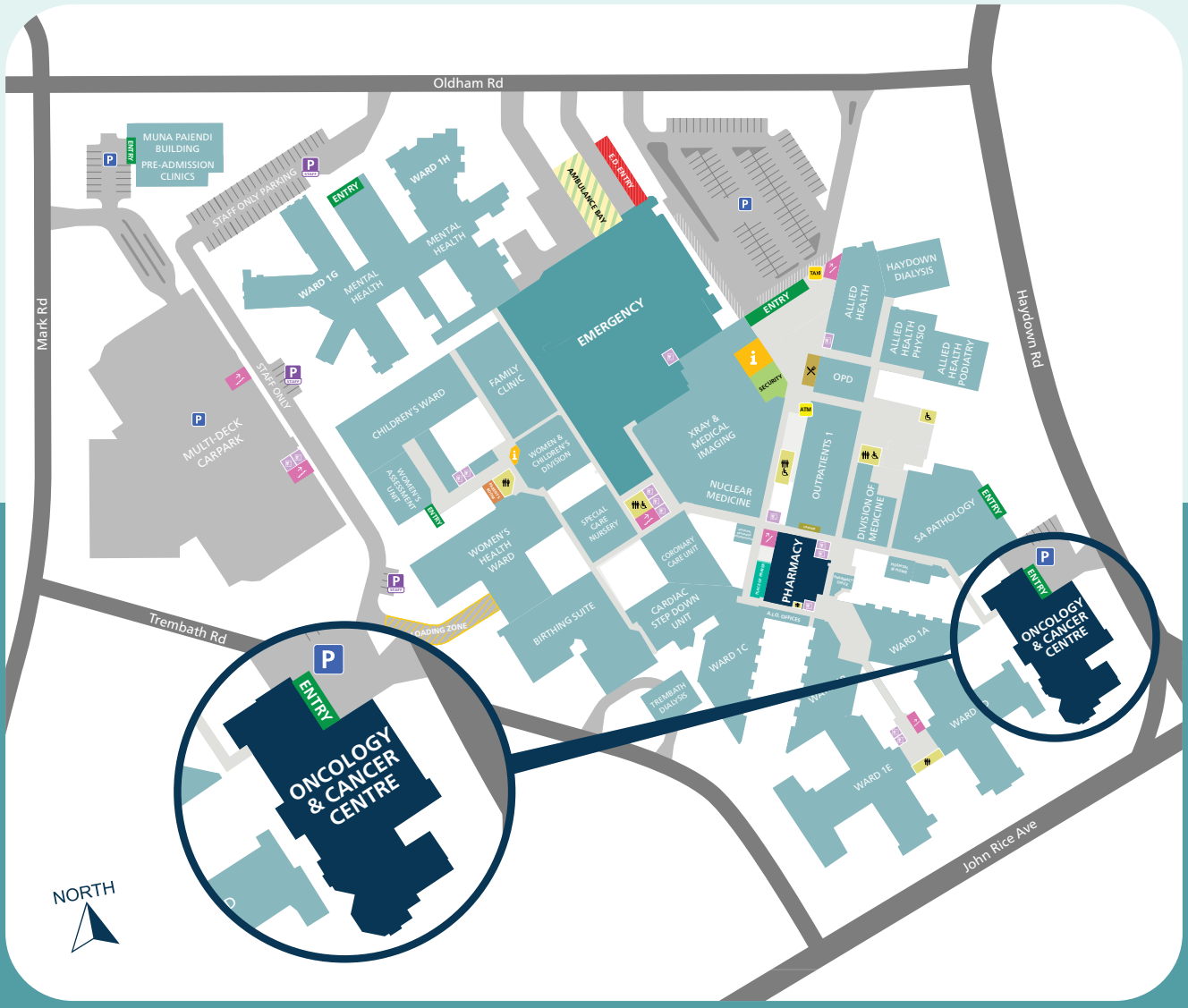
420,000

PEOPLE ACROSS ADELAIDE'S NORTH AND NORTH-EASTERN SUBURBS

RESEARCH UNIT LOCATION AND FACILITIES

LYELL MCEWIN HOSPITAL

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.



OFFICE HOURS

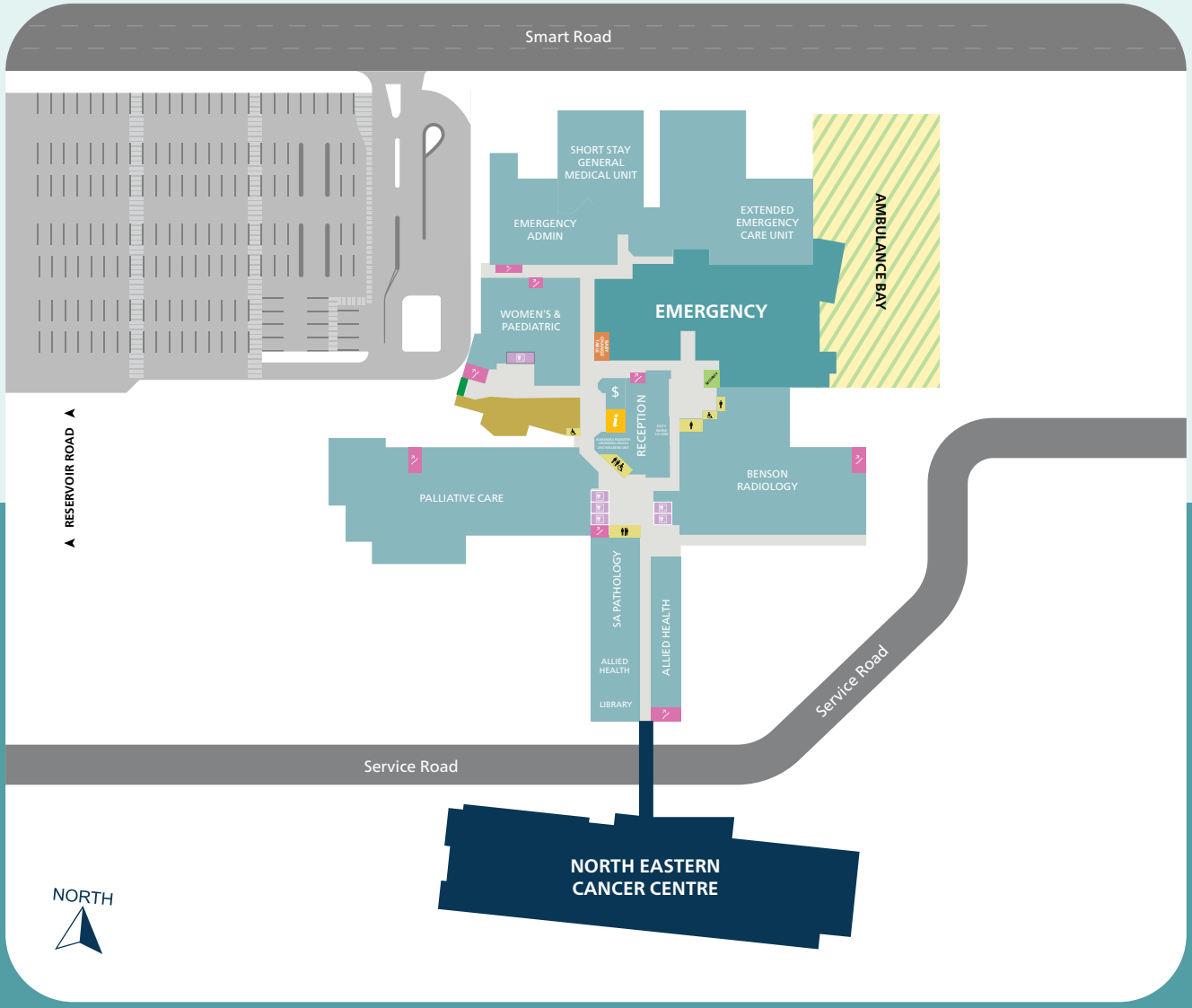
Variable between 8am–8pm (Monday to Saturday)

FACILITIES

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

MODBURY HOSPITAL

In February 2026, NALHN Cancer Services expanded into Modbury Hospital to bolster community access to cancer care within the network. The brand-new North Eastern Cancer Centre features 12 chemotherapy chairs, 6 consultation rooms and several treatment and interview rooms.



OFFICE HOURS

Variable between 8am–5pm (Monday to Friday)

FACILITIES

- Reception / Waiting area
- Secure Storage Rooms
- Conference Room
- Interview Rooms
- Clinic Rooms
- Kitchenette
- 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 Head of Medical Oncology, NALHN Director of Cancer Research and Clinical Trials	> 10 years	I – IV
A/Prof Rohit Joshi	Medical Oncology Consultant	> 10 years	I – IV
Dr Dainik Patel	Medical Oncology Consultant	> 10 years	I – IV
Dr Nimit Singhal	Medical Oncology Consultant	> 10 years	I – IV
Dr Hooi Wen Hong	Medical Oncology Consultant	> 10 years	I – IV
Dr Mark McGregor	Medical Oncology Consultant	> 5 years	I – IV
Dr Vineet Kwatra	Medical Oncology Consultant	> 10 years	I – IV
Dr Li Chia Chong	Medical Oncology Consultant	> 5 years	I – IV
Dr Annabel Smith	Medical Oncology Consultant	> 5 years	I – IV
Dr Anas Alawawdeh	Medical Oncology Consultant	> 5 years	I – IV
Dr Joanne Tang	Medical Oncology Consultant	> 5 years	I – IV
Dr Eryn Dow	Medical Oncology Consultant	> 5 years	I – IV
Dr Chen Yong	Medical Oncology Consultant	> 5 years	I – IV
Dr Alexius John	Medical Oncology Consultant	> 5 years	I – IV

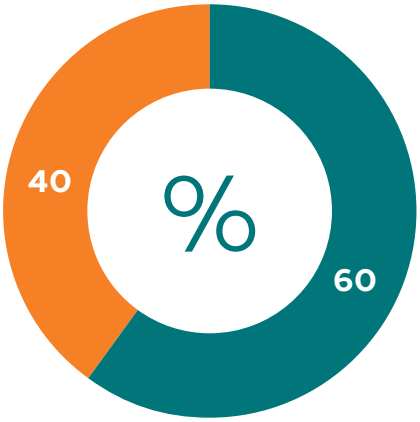
CANCER CLINICAL TRIALS UNIT STAFF

Name	Position	Phase
Andy Phay andy.phay@sa.gov.au	Clinical Research Manager	I – IV
Dr Michelle Forgione michelle.forgione@sa.gov.au	Oncology Clinical Trials Coordinator	I – IV
May Siew may.siew@sa.gov.au	Oncology Clinical Trials Coordinator	I – IV
Claire Ackroyd claire.ackroyd@sa.gov.au	Oncology Clinical Trials Coordinator	I – IV
Ayro Jones ayro.jones@sa.gov.au	Oncology Clinical Trials Coordinator	I – IV
Jessica Petticrew jessica.petticrew@sa.gov.au	Oncology Clinical Trials Coordinator	I – IV
Sarah Holden sarah.holden@sa.gov.au	Clinical Trials Administrative Coordinator	

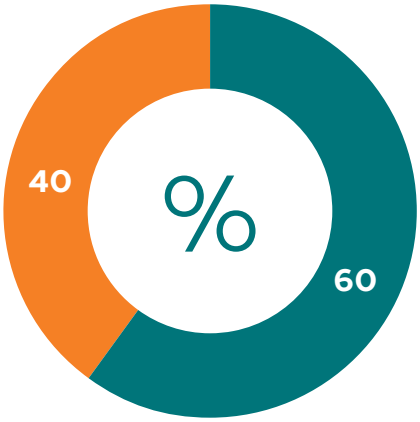
PATIENTS REPORT HIGH LEVEL OF SATISFACTION WITH THE CLINICAL TRIALS COORDINATOR AT THE NORTHERN ADELAIDE CANCER CENTRE

What our participants told us

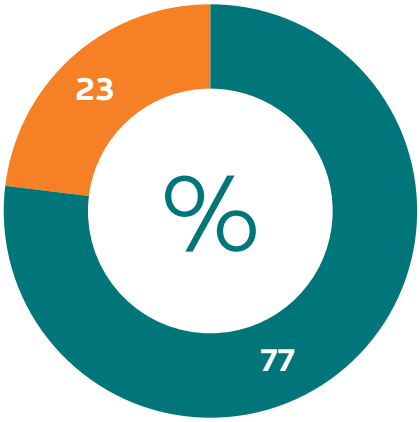
Clearly explained clinical trial procedures to me



Treated me with respect and kindness

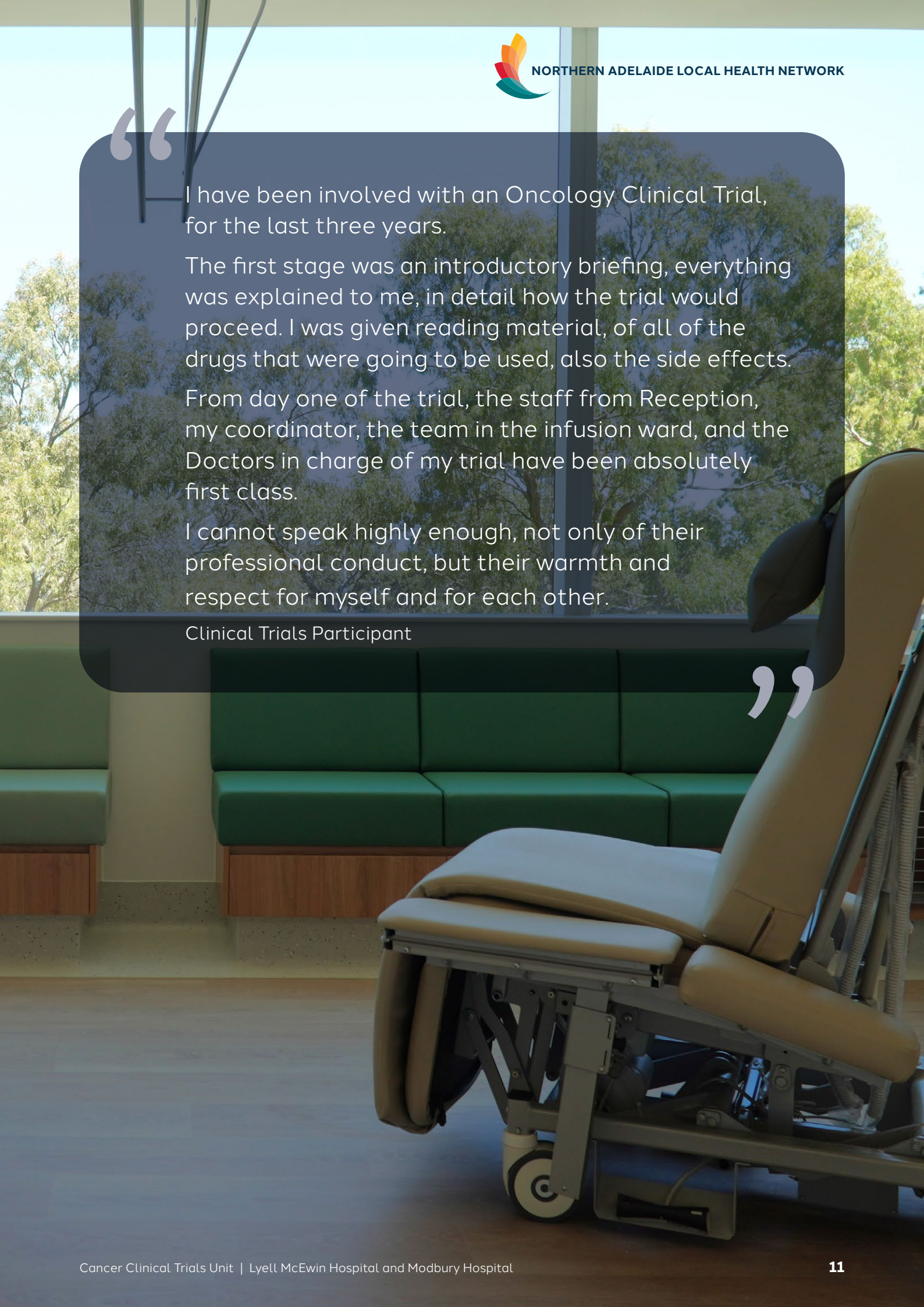


Listened carefully and took my concerns and symptoms seriously



Strongly agree
Agree

> I began the trial on the 19th June and have to date found the care and attention provided by May and her team to be exemplary. Even before the trial began, the discussions with the team regarding the trial were open and honest and realistic expectations were set regarding my participation in the trial.
>
> When administering the drug my level of comfort has always been a priority and any concerns I have or had have been addressed.
>
> I agreed to participate in this trial in the hope it might help me but also in the hope my participation will help others in the future.
>
> Clinical Trials Participant



I have been involved with an Oncology Clinical Trial, for the last three years.

The first stage was an introductory briefing, everything was explained to me, in detail how the trial would proceed. I was given reading material, of all of the drugs that were going to be used, also the side effects.

From day one of the trial, the staff from Reception, my coordinator, the team in the infusion ward, and the Doctors in charge of my trial have been absolutely first class.

I cannot speak highly enough, not only of their professional conduct, but their warmth and respect for myself and for each other.

Clinical Trials Participant

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.

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 7117 7265

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	ANZ
Branch	18/83 Pirie Street, Adelaide SA 5000
BSB	015 101
Account Number	838568636
Account Name	NALHN Oracle Operating
ABN	46 371 200 573
Swift Code	ANZBAU3MXXX

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 7117 8251
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

Study Start-up Fee	$6,000
Ongoing Monthly Administration Fee	$200/month (invoiced quarterly from SIV)
or Monthly Administration Fee (if Lead Site)	$350/month (Invoiced quarterly from SIV)
Governance and Ethics Preparation Fees	
• *Major Amendment submission* • *Minor Amendment submission*	*$250 per submission* *$125 per submission*
Initial Ethics Preparation Fee	$3,000 (base fee)
• *Each additional site listed in original submission* • *Each additional site after approval*	*$300 (per site inclusion fee)* *$600 (site addition fee)*
SAE Reporting	$250 per SAE
Participant Re-Consent Fee	$150
Re-Consent Fee (if outside a regular scheduled visit)	$300
Remote Monitoring Fee	$90 (per hour)
Audit Fee	$2000
Close-Out Fee	$600
Remote Close-Out Fee	$1,200
Archiving Storage Fee	$1,500
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. The monthly administration also includes the licensing fees of electronic management systems.

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 8182 9808
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	$1,000
De-identification and digital image acquisition (CD or other electronic media) and image transfer	$150

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 are not routinely 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: 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: 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
Level 3 South
Lionsgate Business Park
180 Phillip Highway,
Elizabeth South, SA, 5112
P: +61 8 7117 8251
E: HealthNALHNRGO@sa.gov.au
For more information vist: sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/northern+adelaide+local+health+network/research

FEES

The schedule of fees and the RGO Fee form is available for download from their website: sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/health+and+medical+research/ethics+and+governance+in+south+australia/ethics+and+governance+in+south+australia

PARALLEL SUBMISSION

NALHN supports dual submission of ethics and governance. This allows simultaneous submissions to be made in order to reduce timelines.

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

There is a hybrid model for the management of medical records and source documents at the Lyell McEwin Hospital. Clinical documentation and investigations will mostly be present within the ONC certified Sunrise™ Acute Care EMR. Study specific worksheets and other source documentation may be retained 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 and 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 68 East Avenue, Beverley SA 5009.

NOTES

FOR MORE INFORMATION

Cancer Clinical Trials Unit
Division of Medicine
Lyell McEwin Hospital
Haydown Road
Elizabeth Vale, SA 5112
(08) 7117 7265
sahealth.sa.gov.au/nalhn

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