The Prince Charles Hospital - Lung Transplant

Local Services Offered:
Clinical trials site; Investigator Initiated Trials; Satellite Site; Trial Patient Recruitment; Treatment of patients; Completion of study documentation as per ICH GCP and contract
Details:This PDF complements the information found in the CSV generated by this website with additional site information.

Facility Details:	
Please provide your Facility Website.	https://metronorth.health.qld.gov.au/tpch
What Department is your Trial Site? (**Queensland Health HHS**- *See List of Services and Levels-Clinical Services Capability Framework*)	Medical Services
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
Is your Facility affiliated with a government agency or part of a government funded health service?	Yes
Provide the list of Sub-Therapeutic Areas for your Facility.	Lung Transplant; Transplant; Lung
Does your Clinical Trial site undertake any patient recruitment?	Yes
IRB/ERB/Ethics Committee:	
Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions?	Yes
Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions?	Yes
HREC Committee Name	Metro North HHS HREC
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	2 per week with NMA
Does the HREC Committee require payment prior to the release of final approval documents?	Yes
Does the HREC require contract/budget approval prior to release of final approval documents?	Yes
Consent:	

Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	Yes
Does your Facility have a written SOP/Policy/Procedure for Minor Assent for paediatric populations?	No
Does your Facility have a written SOP/Policy/Procedure for Other vulnerable populations?	Yes
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study-specific instruction)?	No
Training:	
Does your Facility have a training program for the research staff?	Yes
Does your Facility training course content include GCP?	Yes
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
Does the study staff that prepares or transports dangerous goods have training that meets the IATA International Air Transport Association (US) or other countries hazardous training requirements for shipping dangerous goods?	Yes
Facility And Equipment:	
Facility Capabilities:	
Can your Facility support in- patient admissions for research studies?	Yes
Is your Facility capable of administering infusions?	Yes
Can your Facility support patient visits on weekends?	No
Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product?	Yes
Does your Facility have the ability to collect and store PK/PD specimens?	Yes
Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	Yes

Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
Equipment:	
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	Yes
Does your Facility have an SOP or process that ensures routine calibration and maintenance of general equipment? Examples of general equipment include: scale, pulse oximeter, stadiometer, sphygmomanometer, etc.?	Yes
Please list any additional equipment that your Facility uses for Clinical Trials.	Ultrasound
IT Capabilities:	
Does your Facility have computers that are dedicated to research studies?	Yes
What browser does your facility use?	EDGE
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
Does the Facility have access to local IT support?	Yes
Does your Facility limit or prohibit access and use of external web- based tools or sites for clinical research (E.g. web portals to submit documents to sponsors or CROs)?	Yes
Please indicate all equipment that will be available to Monitors	Phone;Copy Machines;Internet Access
Labs:	
Is your Facility using a local pathology lab?	Yes
Please provide the Local Lab Name.	Pathology Queensland-TPCH
IP Storage Details:	
IP Recipient Name	The Prince Charles Hospital Pharmacy
Does the Investigational Product Storage Room have back-up power?	Yes
Is the Investigational Product Storage Room secured with controlled access?	Yes

Is the Investigational Product Storage Area securely constructed?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of the Investigational Product?	Yes
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Yes
Does the Facility have the ability to handle radio-labelled Investigational Products?	No
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Yes
Source Documents:	
Does your Facility have patient record archiving on-site?	Yes
Does your Facility have secure storage for patient records?	Yes
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
What EMR/EHR system does your Facility use?	In-house system