Queensland Children's Hospital - Paediatric Intensive Care Unit

Local Services Offered:
Clinical trials site;Investigator Initiated Trials;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://www.childrens.health.qld.gov.au/
What Department is your Trial Site? (**Queensland Health HHS**- *See List of Services and Levels-Clinical Services Capability Framework*).	Medical Services
Does your Clinical Trial site undertake any patient recruitment?	Yes
Please provide other areas of expertise for your Facility.	Burns; Dermatology and Sepsis
Provide the list of Sub-Therapeutic Areas for your Facility.	Congenital; Hereditary; and Neonatal Diseases and Abnormalities; Skin and connective tissue diseases; Hereditary; Neonatal Diseases; Abnormalities;Skin and connective tissue diseases; Critical care
What percentage of Clinical trials undertaken on your site do you meet or exceed the recruitment target?	80-90% dependent on study
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.	Children’s Health Queensland Hospital and Health Services Human Research Ethics Committee
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	Six weekly meetings. NHMRC Accredited committee for NMA

Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?	Yes
Does the HREC Committee require payment prior to the 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?	No
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study-specific instruction)?	Yes
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
Can your Facility support patient visits on weekends?	No

Is your Facility capable of administering infusions?	Yes
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.	CT Scan Computerized Tomography Scan, MRI Magnetic Resonance Imaging, PET and MIBG X-Ray, Ultrasound, EEG, Gait analysis, Gene Therapy PC2 Facility
IT Capabilities:	
Does your Facility have computers that are dedicated to research studies?	Yes
What type of computer operating system(s) does your institution use to support studies?	Windows 11

What browser does your facility use?	EDGE
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)?	All access to external portals in considered on a case by case review
Please indicate all equipment that will be available to Monitors	Phone, Copy Machine, Internet Access
Labs:	
Is your Facility using a local pathology lab?	Yes
Please provide the Local Lab Name.	Pathology Queensland-Children's Hospital
IP Storage Details:	
IP Recipient Name	Queensland Children's 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 controlled substances when appropriate?	Yes
Does the Facility have the ability to handle radio-labelled Investigational Products?	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 a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	Yes

Source Documents:	
Does your Facility have patient record archiving on-site?	Hospital uses an electronic medical record, historical paper charts are stored off site in a certified facility
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 do you use?	In-house system (Metavision, ieMR)