Cairns Hospital - Clinical Research Unit

Local Services Offered:
Clinical trials site, Satellite Site, 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:	
What is your Facility ID (**Queensland Health only**)	214
Please provide your Facility Website	https://www.cairns-hinterland.health.qld.gov.au/hospitals-and-health-centres/cairns-hospital
What Department is your Trial Site? (**Queensland Health HHS**- *See List of Services and Levels-Clinical Services Capability Framework)*	Medical Services
Is your Facility affiliated with a government agency or part of a government funded health service?	Yes
Do you have Affiliated Research Sites or Satellite Sites/Clinics? A Satellite Site is a secondary location where the investigator sees clinical trial subjects. Usually this is the same investigator who sees subjects at the primary site location.	Yes
Please provide other Facility details.	We are part of the Northern Cluster for teletrials and can be the lead or satellite site.
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	Yes
Does your Clinical Trial Site have the capacity to conduct Clinical Trials involving GMOs?	No
Has your Clinical Trial Site or Service been accredited?	Yes
If your Clinical Trial Site or Service has been accredited, please provide the type of accreditation.	NATA
Does your Clinical Trial site or Service undertake any recruitment?	Yes
What percentage of Clinical trials undertaken on your site do you meet or exceed the recruitment target?	90%
Are there any notable factors relating to your Patient Population?	ATSI population
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?	No
Does your facility have other steps/additional process/s for HREC (IRB/ERB/Ethics)Committee review and submission?	Central HREC driven by Sponsor
Does your Facility have other review boards that need to approve the study prior to HREC (IRB/ERB/Ethics) Committee submission? For example, scientific, radiation safety committees, or others	No
Does the HREC Committee require payment prior to the release of final approval documents?	No
Does the HREC require contract/budget approval prior to release of final approval documents?	No
Consent:	
Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	Yes- National Standards Operations Procedures for Clinical Trials including Teletrials, in Australia
Does your Facility have a written SOP/Policy/Procedure for Other vulnerable 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 the 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 your Facility have a training program for the research staff?	No
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 patient visits on weekends?	No
Can your Facility support in-patient admissions for research studies?	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 the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	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
Equipment:	
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
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	Yes
Computers Capabilities:	
Does your Facility have computers that are dedicated to research studies?	Yes
Does the Facility have access to local IT support?	Yes
What type of computer operating system(s) does your institution use to support studies?	Windows 11
Which internet browser does your facility use?	Internet Explorer, Firefox, Chrome, Edge
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)?	No

Please indicate all equipment that will be available to Monitors	Multifunctional Device
Lab Name:	
Is your Facility using a local pathology lab?	Yes
Please provide Local Lab Name.	Pathology Queensland- Cairns
Does your Facility use private laboratory services?	Yes
Please provide the name of the private lab service/s that your facility use.	Sullivan and Nicolaides and QML
IP Storage Details:	
Please provide the IP Recipient Name.	Cairns Hospital Pharmacy
Is the Investigational Product Storage Room secured with controlled access?	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
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Yes
Does the Facility have the ability to handle radio-labelled Investigational Products?	No
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Yes
Source Documents:	
Does your Facility have patient record archiving on-site?	No
If your Facility stores patient records offsite. Please provide the location name and address of any offsite archives.	Grace Management, Toohey Street, Portsmith, Cairns Queensland 4870 Australia
Please list any access limitations/requirements for the Electronic Medical Records	Read only
For Facilities with satellite sites, where is the monitor required to access source documents?	Can monitor at primary and satellite sites
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Does your Facility have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
Please provide the EMR/EHR systems used by your Facility.	Other

What Electronic Data Capture (EDC) systems does your Facility use for clinical trials?	Staff proficient in most Sponsor provided EDC systems