

Cairns Hospital - Teletrials

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: In addition to the information contained within csv generated by this website, this PDF provides additional site information.

<u>Facility Details:</u>	
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?	Townsville University Hospital
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
Please provide other areas of expertise for your Facility.	Cardiology; Renal; CNS; Devices; Endocrinology; Gastroenterology; Hepatology; Infection; Respiratory and Sleep
Provide the list of Sub-Therapeutic Areas for your Facility.	Teletrials
Has your Clinical Trial Site been accredited?	Yes
If your Clinical Trial Site has been accredited, please provide the type of accreditation.	Internal
Does your Clinical Trial site undertake any patient recruitment?	Yes
<u>IRB/ERB/Ethics Committee:</u>	
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
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	Two meetings per week in NMA
Does your Facility have other review boards that need to approve the study prior to 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?	Yes
Is your Facility able to initiate study activities prior to HREC (IRB/ERB/ETHICS) Committee protocol approval?	Yes
<u>Consent:</u>	
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?	Yes
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)?	Yes
<u>Training:</u>	
Does your Facility have a training program for the research staff?	Yes
Does your facility training course content include GCP?	Yes
If your facility uses external program course/s. Please provide the program course/s name.	Caledonian; ARCS; Syneos online

Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
<u>Facility And Equipment:</u>	
<u>Facility Capabilities:</u>	
Can your Facility support patient visits on weekends?	Yes
Can your Facility support in- patient admissions for research studies?	Yes
Is your Facility capable of administering infusions?	Yes
Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product?	No
Does your Facility have the ability to collect and store PK/PD specimens?	No
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?	No
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 manage on-site or off-site destruction of controlled substances when appropriate?	Yes
<u>Equipment:</u>	
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

<u>IT Capabilities:</u>	
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
What browser does your facility use?	Internet Explorer
Does your Facility have computers that are dedicated to research studies?	No
Please indicate all equipment that will be available to Monitors	Phone;Copy Machines;Internet Access
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
Storage Room Backup Power	Yes
<u>Lab:</u>	
Is your Facility using a local pathology lab?	Yes
Please provide Local Lab Name	Pathology Queensland- Cairns Hospital
<u>IP Storage Details:</u>	
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 your Facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	Yes
<u>Source Documents:</u>	
Does your Facility have patient record archiving on-site?	Yes
If your Facility stores patient records offsite. Please provide the location name and address of any offsite archives.	Yes
<u>Electronic Medical Records (EMR) /Electronic Health Records (EHR):</u>	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes