

Central Queensland Hospital and Health Service Clinical Trial Unit

Local Services Offered:

Clinical trials site; 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.

<u>Facility Details:</u>	
What is your Facility ID? (Queensland Health only)	141
Please provide your Facility Website.	https://www.cq.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
Is your Facility affiliated with a government agency or part of a government funded health service?	Yes
Other Affiliated Research Sites	Royal Brisbane and Women's Hospital
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
Please provide other areas of expertise for your Facility.	Telehealth; Community services; Outpatient Clinics; Bloodborne Viruses and Sexual Health Hepatitis (A; B; C) Herpes Simplex Herpes Zoster HIV – AIDS HMT1 Human Papilloma Virus
Provide the list of Sub-Therapeutic Areas for your Facility.	Stroke; Kidney disease
Has your Clinical Trial Site been accredited?	No
Does your Clinical Trial site undertake any patient recruitment?	Yes
<u>IRB/ERB/Ethics Committee:</u>	
HREC Committee Name	Central Queensland
Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions?	No

Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions?	No
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	Two meetings per week in NMA
Does the HREC Committee require payment prior to the release of final approval documents?	Yes
<u>Consent:</u>	
Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	Yes
<u>Training:</u>	
Does your Facility have a training program for the research staff?	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 in- patient admissions for research studies?	No
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?	No

Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	No
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Yes
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
Storage Room Backup Power	Yes
Storage area securely constructed	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 your Facility have computers that are dedicated to research studies?	No
What browser does your facility use?	Internet Explorer
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

<u>Lab:</u>	
Is your Facility using a local pathology lab?	Yes
Please provide Local Lab Name.	Pathology Queensland-Rockhampton
<u>IP Storage Details:</u>	
IP Recipient Name	Rockhampton Hospital Pharmacy
Is the Investigational Product Storage Room secured with controlled access?	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
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Yes
<u>Source Documents:</u>	
Does your Facility have patient record archiving on-site?	Yes
Provide Location name and address of any offsite archives.	Yes
What Electronic Data Capture (EDC) systems has your staff used for clinical trials?	None
<u>Electronic Medical Records (EMR) /Electronic Health Records (EHR):</u>	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes