

Proserpine Hospital

Local Services Offered:

Clinical trials site, Trial Patient Recruitment, Treatment of patients, Completion of study documentation as per ICH GCP

Details: This PDF complements the information found in the CSV generated by this website with additional site information.

<u>Facility Details:</u>	
Please provide your Facility Website.	https://www.mackay.health.qld.gov.au/your-hospitals/proserpine-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
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
Please provide other areas of expertise for your Facility.	Telehealth
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?	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

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 in-patient admissions for research studies?	No
Can your Facility support patient visits on weekends?	No
Is your Facility capable of administering infusions?	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?	No
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

<u>Equipment:</u>	
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 type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
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)?	Yes
Please indicate all equipment that will be available to Monitors	Phone; Copy Machines; Internet Access
<u>Labs:</u>	
Is your Facility using a local pathology lab?	Yes
Please provide the Local Lab Name.	Pathology Queensland-Mackay
<u>IP Storage Details:</u>	
IP Recipient Name	Proserpine Hospital Pharmacy
Does the Investigational Product Storage Room have back-up power?	Yes
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

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
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>	
<u>Electronic Medical Records (EMR) /Electronic Health Records (EHR):</u>	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes

