

Caloundra Hospital

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.

<u>Facility Details</u>	
What is your Facility ID (Queensland Health only)	43
Please provide your Facility Website	https://www.sunshinecoast.health.qld.gov.au/services/locations/caloundra-health-service
What Department is your Trial Site? (Queensland Health HHS- See List of Services and Levels-Clinical Services Capability Framework)	Medical Services
Do you have Affiliated Research Sites or Satellite Sites/Clinics? <i>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.</i>	Sunshine Coast University Hospital
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
Provide the list of Therapeutic Areas for your Facility	See Facility website
Please provide other areas of expertise for your Facility	Palliative Care; Renal
Provide the list of Sub-Therapeutic Areas for your Facility	Renal
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?	No
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	2 meetings per week in NMA
Does the HREC Committee require payment prior to the release of final approval documents?	Yes
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
<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
<u>Training</u>	
Does your Facility have a training program for the research staff?	Yes
Does your facility training course content include GCP?	Yes
Please provide program course/s name	Caledonian; ARCS and Syneos
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
<u>Facility And Equipment</u>	
Facility Capabilities:	
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
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?	No
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 access to translators and translation support for study conduct (e.g. consent, study- specific instruction)?	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
Describe any additional equipment available at your Facility to ensure clinical program / trial feasibility?	Specialised Imaging at SCUH
IT Capabilities:	
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
Which internet browser does your facility use?	Internet Explorer
Does the Facility have access to local IT support?	Yes
Does your Facility have computers that are dedicated to research studies?	No
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 lab?	Yes
Please provide Local Lab Name	Pathology Queensland- Caloundra Hospital
<u>IP Storage Details:</u>	
Please provide the IP Recipient Name.	Caloundra Hospital Pharmacy
If your facility stores IP at another location, please provide the Location Name	Sunshine Coast University Hospital
Is the Investigational Product Storage Room secured with controlled access?	Yes
Does the Investigational Product Storage Room have back-up power?	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 the Investigational Product?	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 controlled substances when appropriate?	Yes
Does your Facility have a written SOP/Policy/Procedure to ensure that the 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>	
Does your Facility have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	No

What Electronic Data Capture (EDC) systems does your Facility use for clinical trials?	None
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