Sunshine Coast University Private Hospital - Clinical Trials Unit

Local Services Offered:
Clinical trials site;Trial Patient Recruitment;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:	
Please provide your Facility Website.	https://www.sunshinecoastuniversityprivate.com.au/
Is your Facility affiliated with a government agency or part of a government funded health service?	No
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.	Ramsay Healthcare
Has your Clinical Trial Site been accredited?	No
Does your Clinical Trial site undertake any patient recruitment?	Yes
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
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?	Yes

Details of other steps for HREC (IRB/ERB/Ethics)Committee review and submission.	SSA and approval by dedicated Advisory Committee
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?	Yes
Consent:	
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?	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 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.	The Global Health Network Online; IQVIA
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes

Facility And Equipment:	
Facility Capabilities:	
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?	Yes
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	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

Please list any additional equipment that your Facility uses for Clinical Trials.	Ultrasound
IT Capabilities:	
Does your Facility have computers that are dedicated to research studies?	Yes
What type of computer operating system(s) does your institution use to support studies?	Phone;Copy Machines;Internet Access
What browser does your facility use?	Internet Explorer
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
IP Storage Details:	
IP Recipient Name	Sunshine Coast University Private Hospital
Does the Investigational Product Storage Room have back-up power?	Yes
Is the Investigational Product Storage Room secured with controlled access?	Yes
Is the Investigational Product Storage Area securely constructed?	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?	No
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	Not Applicable
Source Documents:	
Does your Facility have patient record archiving on-site?	No
Does your Facility have secure storage for patient records?	Yes
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes