

Sunshine Coast University Hospital - Gastroenterology and Hepatology

Location:

-26.746786 - 153.113756

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

Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions?	No
Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	Yes
Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions?	No
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	Yes
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Does your Facility have computers that are dedicated to research studies?	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
Is your Facility capable of administering infusions?	Yes
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
Does your Facility have the ability to manage on-site or off-site destruction of the Investigational Product?	Yes
Does your Facility have patient record archiving on-site?	No
Secure Storage Records	Yes
Can your Facility support in-patient admissions for research studies?	Yes
Does your Facility have the ability to collect and store PK/PD specimens?	Yes
Facility written sop during transportation to satellite site	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
Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	Yes
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
Can your Facility support patient visits on weekends?	No
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Yes

Other Meeting Frequency	2 per week with NMA
Does the course content include GCP?	Yes
Lab Name	Pathology Queensland-SCUH
Local Lab Usage	Yes
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	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
Please provide program course/s name	Caledonian; ARCS; Syneos online
IP Recipient Name	Sunshine Coast University Hospital Pharmacy
Does the HREC Committee require payment prior to the release of final approval documents?	Yes
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study-specific instruction)?	No
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Yes
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
Does your Facility have a training program for the research staff?	Yes
Training program for the research staff	Yes
Storage Room Backup Power	Yes
Is the Investigational Product Storage Room secured with controlled access?	Yes
IP Storage Location Name	Sunshine Coast University Hospital

Storage area securely constructed	Yes
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
Other areas of expertise	Hepatology; GERD
Sub-Therapeutic areas	Gastroenterology; Diverticulitis; Hypochlorhydria; Irritable Bowel Syndrome; NASH; Pancreatitis; Ulcerative Colitis; Upper GI Disorders; Volvulus
Additional equipment	Ultrasounds
Please indicate all equipment that will be available to Monitors	Phone; Copy Machines; Internet Access
Does your Clinical Trial site undertake any patient recruitment?	Yes
Location of Monitor	Main facility Only
Medical access limitations	Cerner ieMR Solution in use at site; includes PowerTrials; monitors require login profile to access
EMR/EHR systems	In-house system
Does the HREC require contract/budget approval prior to release of final approval documents?	Yes