Sunshine Coast University Hospital - Endocrinology

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.

Facility Details:	
Please provide your Facility Website.	https://www.sunshinecoast.health.qld.gov.au/hospitals-and-health-centres/sunshine-coast-university-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/organisation a Life Sciences Queensland (LSQ) Member?	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.	Other SC HHS sites: Coloundra, Gympie, Nambour
Sub-Therapeutic areas	Endocrine; Endocrinology; Diabetes; Insulin; Thyroid
Does your Clinical Trial site undertake any patient recruitment?	Yes
IRB/ERB/Ethics Committee:	
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
HREC Committee Name.	All NMA approved HREC
Other Meeting Frequency	2 per week with NMA

Does the HREC Committee require payment prior to the release of final approval documents?	Yes
Does the HREC require contract/budget approval prior to 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?	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)?	No
Training:	
Does the course content include GCP?	Yes
Please provide 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
Does your Facility have a training program for the research staff?	Yes
Training program for the research staff	Yes
Facility And Equipment:	
Facility Capabilities:	
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Is your Facility capable of administering infusions?	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
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
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
Additional equipment	Ultrasounds, Hybrid Theatre
IT Capabilities:	
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 computers that are dedicated to research studies?	Yes

What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
Please indicate all equipment that will be available to Monitors	Phone;Copy Machines;Internet Access
Labs:	
Lab Name	Pathology Queensland-SCUH
Local Lab Usage	Yes
IP Storage Details:	
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
Facility written sop during transportation to satellite site	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
IP Recipient Name	Sunshine Coast University Hospital Pharmacy
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	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
Source Documents:	
Does your Facility have patient record archiving on-site?	No
Secure Storage Records	Yes
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	

Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
EMR/EHR systems	In-house system
Medical access limitations	Cerner ieMR Solution in use at site; includes PowerTrials; monitors require login profile to access