Coral Sea Clinical Research Institute

Local Services Offered:
Clinical trials site, Investigator Initiated Trials, Completion of study documentation as per ICH GCP a contract
Details: This PDF complements the information found in the CSV generated by this website with additional site information.

Facility Details:	
Facility Department	Medicine
Please provide your Facility Website.	
Is your Facility affiliated with a government agency or part of a government funded health service?	No
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	Yes
Please provide other areas of expertise for your Facility.	Gastroenterology; Immune; Nutrition;
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.*	N/A
Has your Clinical Trial Site or Service been accredited?	No
Does your Clinical Trial site or Service undertake any 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
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?	No
Does the HREC require contract/budget approval prior to release of final approval documents?	No
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)?	No
Training:	
Does your Facility have a training program for the research staff?	Yes
Include GCP	Yes
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
Does the study staff that prepares or transports dangerous goods have training that meets the IATA International Air Transport Association (US) or other countries hazardous training requirements for shipping dangerous goods?	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 the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	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 Clinical Trial Site have the capacity to conduct Clinical Trials involving GMOs?	No
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes

Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	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
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?	Windows (Windows XP, Windows 7, Windows 10, etc)
What browser does your facility use?	Chrome
Does the Facility have access to local IT support?	Yes
Please indicate all equipment that will be available to Monitors	Copy Machines, Internet Access
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)?	No
Lab:	
Is your Facility using a local pathology lab?	No
Please provide Local Lab Name.	N/A
Does your Facility use private laboratory services?	Yes
Please provide Local Lab Name.	Sullivan Nicolaides
IP Storage Details:	
IP Recipient Name	Louisa Poon
Please provide other IP Storage Location Name,.	Mackay Discount Drug Store
Is the Investigational Product Storage Room secured with controlled access?	Yes
Does the Investigational Product Storage Room have back-up power?	No
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 the Facility have the ability to handle radio-labelled Investigational Products?	No
Source Documents:	
Provide Location name and address of any offsite archives.	N/A
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	No

ınd