

# Coral Sea Clinical Research Institute

Location:

-21.1276,149.1658

Local Services Offered:

Clinical trials site, Investigator Initiated Trials, 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

Life Sciences Queensland (LSQ) Member	Yes
Facility Department	Medicine
Other areas of expertise	Gastroenterology; Immune; Nutrition;
Does your Clinical Trial Site have the capacity to conduct Clinical Trials involving GMOs?	No
Other Affiliated Research Sites	N/A
Is your Facility affiliated with a government agency or part of a government funded health service?	No
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
Any Additional Process	No
Does your Clinical Trial site or Service undertake any recruitment?	Yes
Audit	No
Has your Clinical Trial Site or Service been accredited?	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
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
Is your Facility using a local pathology lab?	Yes

Lab Name	Mackay
Does your Facility use private laboratory services?	No
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
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
Can your Facility support patient visits on weekends?	No
Can your Facility support in-patient admissions for research studies?	No
Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product?	No
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 Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	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 necessary equipment to treat medical emergencies (for example crash/code cart)?	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)
Internet Upload Speed	7.25 Mbps
Internet Download Speed	52.3 Mbps
What browser does your facility use?	Chrome
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
Does the Facility have access to local IT support?	Yes
IP Recipient Name	Elizabeth Gibson
IP Recipient   Street Name and Number	76 Willetts Road
Phone Number	1800692727
If you selected 'Other' for the IP Storage Location Name, please fill in the information here	Mackay Discount Drug Store
Location of Investigational Product storage   Street name and number	93 Willetts Road
Location of Investigational Product storage   Country	Australia
Location of Investigational Product storage   State / Territory	Queensland
Location of Investigational Product storage   Postcode	4740
Location of Investigational Product storage   Phone number	(07) 4842 0555
Location of Investigational Product storage   email address	<a href="mailto:disp@northsidechemist.com.au">disp@northsidechemist.com.au</a>
Is the Investigational Product Storage Room secured with controlled access?	Yes
Storage Room Backup 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
Is your Facility capable of administering infusions?	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
Provide Location name and address of any offsite archives.	N/A
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	No
Please indicate all equipment that will be available to Monitors	Copy Machines, Internet Access