CDH Research Institute

Local Services Offered: Clinical trials site
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://cdhresearch.com.au/
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
Provide the list of Therapeutic Areas for your Facility.	Digestive System Diseases
Please provide other areas of expertise for your Facility.	IBS; Paediatric gastroenterology; Hepatology; Colon cancer screening;
Provide the list of Sub-Therapeutic Areas for your Facility.	Inflammatory Bowel diseases; Gastroenterology ;Hiatus Hernia; Crohn's Disease; Diverticulitis; GERD; Hypochlorhydria; Irritable Bowel Syndrome; NASH; Pancreatitis; Ulcerative
Has your Clinical Trial Site been accredited?	Not Applicable
Does your Clinical Trial site undertake any patient recruitment?	Yes
What percentage of Clinical trials undertaken on your site do you meet or exceed the recruitment target?	90%
IRB/ERB/Ethics Committee:	
HREC Committee Name	Bellberry Ltd
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
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	8 per month
Does your Facility have other review boards that need to approve the study prior to HREC (IRB/ERB/Ethics) Committee submission?	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?	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 your Facility have a training program for the research staff?	Yes
Does your facility training course content 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
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	No

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?	No
Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	No
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
Facility written sop during transportation to satellite site	Not Applicable
Is your Facility storage area securely constructed?	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 provide any additional diagnostic equipment available at or near the Facility to support research studies?	Ultrasounds; Echocardiogram
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
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

Please indicate all equipment that will be available to Monitors.	Phone;Copy Machines;Internet Access
Lab:	
Is your Facility using a local pathology lab?	No
Does your Facility use private laboratory services?	Yes
If your Facility use private laboratory services. Please provide the name of the private laboratory.	Sullivan & Nicolaides Pathology
IP Storage Details:	
Please provide the IP Recipient Name.	Coastal Digestive Health
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?	No
Does your Facility have a written SOP/Policy/Procedure to ensure that the Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	Not Applicable
Source Documents:	
Does your Facility have patient record archiving on-site?	Yes
Provide Location name and address of any offsite archives.	Yes
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes