Cholesterol Care Australia

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://cholesterolcare.com.au/
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
Is your Facility affiliated with a government agency or part of a government funded health service?	No
Please provide other areas of expertise for your Facility.	Lipidology
Does your Clinical Trial site or Service undertake any recruitment?	Yes
What percentage of Clinical trials undertaken on your site do you meet or exceed the recruitment target?	99%
Has your Clinical Trial Site or Service been accredited?	Not applicable
IRB/ERB/Ethics Committee:	
HREC Committee Name	Bellberry Limited
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?	Yes
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
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?	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 Other vulnerable populations?	No
Does your Facility have a written SOP/Policy/Procedure for Minor Assent for paediatric 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
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
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
Facility And Equipment:	
Facility Capabilities:	
Does your Clinical Trial Site have the capacity to conduct Clinical Trials involving GMOs?	No
Can your Facility support patient visits on weekends?	Yes
Can your Facility support in-patient admissions for research studies?	Not Applicable
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
Is your Facility capable of administering infusions?	No
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Not Applicable
Equipment:	
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 any additional equipment relevant to Clinical Trials?	Ultrasound
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?	Internet Explorer
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
Please list any access limitations/requirements for the Electronic Medical Records	N/A
Please indicate all equipment that will be available to Monitors	Phone, Fax, Copy Machines, Internet Access
Lab:	
Local Lab Usage	No
Does your Facility use private laboratory services?	Yes

IP Storage Details:	
IP Recipient Name	Cholesterol Care (onsite)
Is the Investigational Product Storage Room secured with controlled access?	Yes
Do you have the ability to generate a temperature monitoring log for this Investigational Product Storage Room?	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
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Not Applicable
Source Documents:	
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	No