

Core Research Group Pty Ltd

Local Services Offered:

Early Phase, Complementary medicines clinical trials, Clinical trials site, Trial Patient Recruitment, Treatment of patients

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.	N/A
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	Cardiology, Lipids, Diabetes, Obesity, Chronic
Provide the list of Sub-Therapeutic Areas for your Facility.	Internal Medicine generally.
Has your Clinical Trial Site or Service been accredited?	Yes
If your Clinical Trial Site or Service has been accredited, please select all	Internal, NSQHS (National Safety and Quality
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?	90%
Are there any notable factors relating to your Patient Population? (e.g., First Nations people).	No
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?	Yes
Any Additional Process	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	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?	Yes
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)?	Yes
Training:	
Does your Facility have a training program for the research staff?	Yes
Does your facility training course content include GCP?	Yes
If your facility uses external program course/s. Please provide the program course/s name.	IQVIA GCP Training
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 patient visits on weekends?	Yes
Can your Facility support in-patient admissions for research studies?	Yes
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 Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Does your Clinical Trial Site have the capacity to conduct Clinical Trials involving GMOs?	Yes
If yes, which of the following? (chose all that apply)	GM products that do not contain live GMOs, Modified human somatic cells, DNA vaccines, Clinical trials
Additional equipment	Echocardiogram, Mercury Sphygmomanometers, Frozen
<u>Equipment:</u>	
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
<u>IT Capabilities:</u>	
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
Which internet browser does your facility use?	Internet Explorer, Firefox, Chrome
Does the Facility have access to local IT support?	Yes
Please indicate all equipment that will be available to Monitors	Phone, Fax, 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
<u>Lab:</u>	
Is your Facility using a local lab?	No
Does your Facility use private laboratory services?	Yes
Please provide the name of the private laboratory Service.	Sullivan Nicolaides
<u>IP Storage Details:</u>	
IP Recipient Name	A/Prof David Colquhoun

If you selected 'Other' for the IP Storage Location Name, please fill in the information here	Core Research Group Pty Ltd
Is the Investigational Product Storage Room secured with controlled access?	Yes
Does the Investigational Product Storage Room have back-up power?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of the Investigational	Yes
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
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	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?	Yes
Source Documents:	
Does your Facility have patient record archiving on-site?	Yes
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	No
Please provide the EMR/EHR systems used by your Facility.	Other