QIMR Berghofer

Local Services Offered:
Early Phase, Pre-clinical, Bench research, Investigator Initiated Trials
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://www.qimrb.edu.au/
Is your Facility affiliated with a government agency or part of a government funded health service?	No
Does your Clinical Trial site or Service undertake any recruitment?	No
Has your Clinical Trial Site or Service been accredited?	Not Applicable
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
HREC Committee Name.	QMIR HREC
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	9 times per year
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.	Yes
If other review boards, please provide details of the process.	Human scientific subcommittee and Clinical trial protocol committee. Safety/Biosafety committee meets monthly
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?	Yes

Details of other steps for HREC (IRB/ERB/Ethics)Committee review and submission?	Details of other steps for HREC (IRB/ERB/Ethics) Committee review and submission: HREC review includes a staged review, first scientific review (clinical trial protocol committee or human scientific sub-committee) and then ethics review
Does the HREC require contract/budget approval prior to release of final approval documents?	No
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Consent:	
Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	No
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?	No
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
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
Is your Facility capable of administering infusions?	No
Can your Facility support patient visits on weekends?	No
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 typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Equipment:	
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	No
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:	
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP, Windows 7, Windows 10, etc), Apple/Mac (OS X Snow Leopard, Mountain Lion, El Captain, etc), Unix/Linux (Solaris, Ubuntu, Redhat, etc)
What browser does your facility use?	Internet Explorer, Safari, Firefox, 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)?	No

Labs:	
Is your Facility using a local pathology lab?	No
Does your Facility use private laboratory services?	Yes
If you selected 'Yes' on the previous question, please specify here which services	Q-Gen Cell Therapeutics - Microbiological, Immunological
IP Storage Details:	
IP Recipient Name	QIMR Berghofer Medical Research Institute
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 Product?	No
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Not Applicable
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Not Applicable
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
Source Documents:	
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	No