Griffith University Clinical Trial Unit

Local Services Offered:
Clinical trials site; Complementary medicines clinical trials; Clinical trials site; Pre-clinical; GP trials Bench research; Investigator Initiated Trials; 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.	www.griffith.edu.au
Is your Facility affiliated with a government agency or part of a government funded health service?	Yes
Do you have Affiliated Research Sites or Satellite Sites/Clinics?	No
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	Yes
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?	80-90%
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
Please provide the HREC Committee Name.	GU HREC
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	Monthly
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, University Biosafety Committee
Details of other steps for HREC	Bellberry

Does the HREC Committee require payment prior to the release of final approval documents?	Yes
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 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
Training:	
Does your Facility have a training program for the research staff?	Yes
Does your Facility training course content include GCP?	Yes
Does your Facility training course content include GCP?	Transcelerate
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?	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 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 the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	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
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
What browser does your facility use?	Chrome, Firefox, Internet Explorer
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

Please indicate all equipment that will be available to Monitors.	Copy Machines; Internet Access
Labs:	
Is your Facility using a local pathology lab?	Yes
Please provide the Local Lab Name.	Pathology Queensland-Gold Coast
Does your Facility use private laboratory services?	Yes
Please provide the details of the private laboratory services used by your Facility.	SNP
IP Storage Details:	
IP Recipient Name	Griffith University Clinical Trial Unit
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Yes
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 to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	Not Applicable
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Not Applicable
Does the Investigational Product storage room have backup power	Yes
Is the Investigational Product Storage Room secured with controlled access?	Yes
Source Documents:	
Does your Facility have secure storage for patient records?	Yes
Does your Facility have patient record archiving on-site?	No
Provide Location name and address of any offsite archives.	ZircoData

What Electronic Data Capture (EDC) systems has your staff used for clinical trials?	Oracle Inform; Medidate Rave; Oracle Remote Data Capture (RDC), RedCap, Viedoc
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	No