

University of Sunshine Coast Clinical Trial Unit

Location:

-26.711328 - 153.064315

Local Services Offered:

Clinical trials site;GP trials;Trial Patient Recruitment;Completion of study documentation as per ICH GCP and contract

Details: In addition to the information contained within csv generated by this website, this PDF provides additional site information

Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions?	No
Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	Yes
Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions?	No
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	Yes
Is your Facility affiliated with a government agency or part of a government funded health service?	No
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Does your Facility have computers that are dedicated to research studies?	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?	No
Is your Facility capable of administering infusions?	Yes
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
Does your Facility have the ability to manage on-site or off-site destruction of the Investigational Product?	Yes
Other facility details	Yes
Other Affiliated Research Sites	Morayfield
Does your Facility have patient record archiving on-site?	No
Secure Storage Records	Yes
Can your Facility support in-patient admissions for research studies?	No
Does your Facility have the ability to collect and store PK/PD specimens?	Yes
Facility written sop during transportation to satellite site	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
Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	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
Can your Facility support patient visits on weekends?	Yes
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Yes
Does the course content include GCP?	Yes
Local Lab Usage	No

Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	No
Life Sciences Queensland (LSQ) Member	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
Please provide program course/s name	ARCS; Praxis
IP Recipient Name	USC Clincial Trials - Sippy Downs
Does the HREC Committee require payment prior to the release of final approval documents?	Yes
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study-specific instruction)?	No
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Not Applicable
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
Does your Facility have a training program for the research staff?	Yes
Training program for the research staff	Yes
Storage Room Backup Power	Yes
Is the Investigational Product Storage Room secured with controlled access?	Yes
Storage area securely constructed	Yes
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
Other areas of expertise	Vaccine Development
Provide Location name and address of any offsite archives.	Grace Archives
Other review boards	No
Does your Clinical Trial Site have the capacity to conduct Clinical Trials involving GMOs?	Yes
EDC Systems Description	Rave; Medidata

EDC Systems	Oracle Inform;Medidate Rave;Oracle
Additional equipment	ultrasound - off-site
Please indicate all equipment that will be available to Monitors	Phone;Copy Machines;Internet Access
Has your Clinical Trial Site been accredited?	No
Has your Clinical Trial site been audited?	Yes
If your Clinical Trial Site has been audited, please select all relevant types.	Other
Other Audit Type	Bellberry
Internet Download Speed	500mbps
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%
Location of Monitor	In office
Internet Upload Speed	500mbps
Does your Facility use private laboratory services?	Yes
If you selected 'Yes' on the previous question, please specify here which services.	QML; Sullivan Nicolaides
Please list any access limitations/requirements for the Electronic Medical Records	Permission required
Does the HREC require contract/budget approval prior to release of final approval documents?	No
Other IP Storage Location Name	USC Clinical Trials Centre