UQ Centre for Clinical Trials (UQCCR)

Local Services Offered:
Clinical trials site, Pre-clinical, Phase 1 unit
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://clinical-research.centre.uq.edu.au/
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	Yes
Is your Facility affiliated with a government agency or part of a government funded health service?	No
Provide the list of Sub-Therapeutic Areas for your Facility.	Brain, Neurology, and Mental Health:: Language neuroscience; Translational neuroscience and drug repurposing, Queensland drug repurposing initiative; The genomic and epigenomic landscapes of epilepsy; The perinatal brain (the newborn brain injury and repair); Neuro-immunology; Neuro-mental health & dementia research; N of -1 trials and sleep research. Infectious diseases: Antibiotic resistance research; Antimicrobial optimisation; Microbial diagnostic and characterisation; Ear, Nose and Throat research; CRE in redefining antimicrobial use to reduce resistance; Burns trauma and critical care research centre. See attached document. Fertility: Human oocyte research; Epigenetics and oogenesis; Sirtuin-mediated regulation of female fertility; DNA damage and ovarian follicular reserve; Meiotic cell- cycle regulation and chromosome segregation Cancer: Molecular breast pathology; Queensland centre for gynaecological cancer; Exosome biology laboratory

Do you have Affiliated Research Sites or Satellite Sites/Clinics? *A Satellite Site is a secondary location where the investigator sees clinical trial subjects. Usually this is the same investigator who sees subjects at the primary site location.*	No
Does your Clinical Trial site or Service undertake any recruitment?	Yes
Has your Clinical Trial Site or Service been accredited?	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
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?	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 others	Yes
Details of other steps for HREC (IRB/ERB/Ethics)Committee review and submission	Scientific and Radiation Safety Committees. UQ IBC (Institutional Biosafey Committee). UQ Radiation
HREC Committee Name	MNHHS HREC
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?	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
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?	No
Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product?	Yes
Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	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

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
Please list any additional equipment that your Facility uses for Clinical Trials.	EEG Suite, Patient Scales (Stand-up digital and chair), Digital Sphygmomanometer, hoist, small bench top
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), 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, Other
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	Phone, Fax, Copy Machines, Internet Access, video conferencing facilities
IP Storage Details:	
IP Recipient Name	UQCCR
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?	Yes
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	No
Does your Facility have the ability to manage on-site or off- site destruction of controlled substances when appropriate?	No
Does the Facility have the ability to handle radio-labelled Investigational Products?	No
Source Documents:	
Does your Facility have secure storage for patient records?	Yes
Provide Location name and address of any offsite archives.	Grace Storage: 420 Sherbrooke Road, Willawong Qld
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
Medical access limitations	ieMR access - restricted access can be provided to monitor(s) under supervision and with approval from
What Electronic Data Capture (EDC) systems has your staff used for clinical trials?	Medidate Rave REDCap