Translational Research Institute

Local Services Offered:
Pre-clinical device design, Early Phase, Complementary medicines clinical trials, Clinical trials site, Pre- clinical, GP trials, Phase 1 unit, Bench research, Investigator Initiated Trials, Satellite Site, Trial Patient Recruitment, Treatment of patients, Completion of study documentation as per ICH GCP and contract
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.tri.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?	Yes
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.*	Yes
Please provide other facility details.	Brisbane and interstate
Please provide other areas of expertise for your Facility.	N/A
Provide the list of Sub-Therapeutic Areas for your Facility.	N/A
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%
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?	Yes

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	No
Details of other steps for HREC (IRB/ERB/Ethics)Committee review and submission	Parallel ethics and research governance submissions. HREC meets monthly.
HREC Committee Name.	Metro South HHS HREC
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	N/A
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?	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.	The Global Health Network ICH Good Clinical
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?	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 and store PK/PD specimens?	Yes
Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	No
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
Please specify which other types of GMOs	Live attenuated bacteria and viral agents.
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.	N/A
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)
What browser does your facility use?	Internet Explorer, Safari, Firefox, Chrome
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
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
Labs:	
Is your Facility using a local pathology lab?	Yes
Please provide the Local Lab Name.	Pathology Queensland- Princess Alexandra
Does your Facility use private laboratory services?	Yes
Please provide the details of the private laboratory services used by your Facility.	SNP, QML
IP Storage Details:	
IP Storage Location Name	Princess Alexandra Hospital Pharmacy
Is the Investigational Product Storage Room secured with controlled access?	Yes
Is your Facility capable of administering infusions?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of the 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
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Yes
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Yes
Source Documents:	
Provide Location name and address of any offsite archives.	Yes
Does your Facility have secure storage for patient records?	N/A
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
What EMR/EHR system does your Facility use?	Other
What Electronic Data Capture (EDC) systems has your staff used for clinical trials?	Sponsor specific.
Medical access limitations	Annual access fee per monitor per study.