Princess Alexandra Hospital- Rheumatology Inflammation

Local Services Offered:
Clinical trials site;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.metrosouth.health.qld.gov.au/hospital-and-health-centres/princess-alexandra-hospital
What Department is your Trial Site? (**Queensland Health HHS**- *See List of Services and Levels-Clinical Services Capability Framework*).	Medical Services
Is your Facility affiliated with a government agency or part of a government funded health service?	Yes
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
Provide the list of Sub-Therapeutic Areas for your Facility.	Rheumatology;Inflammation
Has your Clinical Trial Site been accredited?	Not Applicable
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?	No

HREC Committee Name.	Metro South HHS HREC
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?	No
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?	Yes
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?	Yes
Does your Facility have a written SOP/Policy/Procedure for Other vulnerable 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
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?	Yes
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 (Windows XP; Windows 7; Windows 10; etc)
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
Please indicate all equipment that will be available to Monitors	Phone;Copy Machines;Internet Access
Labs:	
Does your Facility use Local Lab Services?	Yes
Please provide Local Lab Name	Pathology Queensland-PAH
IP Storage Details:	
IP Recipient Name	PA Clinical Trials Pharmacy Department
Does the Investigational Product Storage Room have back-up power?	Yes
Is the Investigational Product Storage Room secured with controlled access?	Yes
Is the Investigational Product Storage Area securely constructed?	Yes
Does the Facility have the ability to handle radio-labelled Investigational Products?	Yes
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 for the destruction of Investigational Product?	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 to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	Yes
Source Documents:	
Does your Facility have secure storage for patient records?	Yes
Does your Facility have patient record archiving on-site?	Yes
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
What EMR/EHR system do you use?	In-house system