

Princess Alexandra Hospital- Renal

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

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| Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions? | Yes |
| 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? | Yes |
| 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? | Yes |
| 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 |

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| 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 |
| Does your Facility have patient record archiving on-site? | Yes |
| Secure Storage Records | Yes |
| Can your Facility support in-patient admissions for research studies? | Yes |
| 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 |
| Lab Name | Pathology Queensland-PAH |
| Local Lab Usage | Yes |

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| Committee Country | Australia |
| Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)? | Yes |
| Life Sciences Queensland (LSQ) Member | No |
| 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 |
| IP Recipient Name | PA Clinical Trials Pharmacy Department |
| 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)? | Yes |
| Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product? | Yes |
| 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 | Caledonian; ARCS; Syneos online |
| 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 | Chronic kidney disease |

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| Sub-Therapeutic areas | Renal transplantation and Chronic kidney disease;Antibody Injury;Renal transplantation;Complication of immunosuppression;Hypotension;Diabetic kidney disease;Glomerulonephritis |
| Please indicate all equipment that will be available to Monitors | Phone;Copy Machines;Internet Access |
| Has your Clinical Trial Site been accredited? | Not Applicable |
| Has your Clinical Trial site been audited? | Not Applicable |
| If your Clinical Trial Site has been audited, please select all relevant types. | Other |
| 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% |
| EMR/EHR systems | In-house system |
| Does the HREC require contract/budget approval prior to release of final approval documents? | Yes |
| Any Additional Process | No |