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

| Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions? Does your Facility have a written SOP/Policy/Procedure for Informed Consent? Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions? Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)? Is your Facility affiliated with a government agency or part of a government funded health service? Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes? Does your Facility have the ability to manage on-site or off- site destruction of controlled substances when appropriate? Does the Facility have the appropriate? Does the Facility have the appropriate? Does wour Facility have the ability to manage on-site or off- site destruction of controlled substances when appropriate? Does the Facility have the appropriate? Does your Facility have the ability to manage on-site or off- site destruction of controlled substances when appropriate? Does the Facility have the appropriate? Does your Facility have the appropriate? Does your Facility have the appropriate? Does your Facility have the appropriate? Does the Facility have approprime app | - | l |
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| use? Does the Facility have access to Yes | administering infusions? | |
| Does the Facility have access to Yes | What browser does your facility | Chrome |
| 5 | use? | |
| local IT support? | Does the Facility have access to | Yes |
| <u> </u> | local IT support? | |

| | × - |
|-----------------------------------|--------------------------|
| Does your Facility limit or | Yes |
| 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)? | |
| Does your Facility have the | Yes |
| ability to manage on-site or off- | |
| site destruction of the | |
| Investigational Product? | |
| Does your Facility have patient | Yes |
| record archiving on-site? | |
| | Yes |
| Secure Storage Records | |
| Can your Facility support in- | Yes |
| patient admissions for research | |
| studies? | × 7 |
| Does your Facility have the | Yes |
| ability to collect and store | |
| PK/PD specimens? | |
| Facility written sop during | Yes |
| transportation to satellite site | |
| Does your Facility have an SOP | Yes |
| or process that ensures routine | |
| calibration and maintenance of | |
| general equipment? Examples of | |
| general equipment include: scale, | |
| pulse oximeter, stadiometer, | |
| sphygmomanometer, etc.? | |
| | |
| Does your Facility have the | Yes |
| ability to collect PK/PD samples | |
| beyond normal business hours? | |
| Is your Facility adequately | Yes |
| 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.)? | × 7 |
| Can your Facility support patient | Yes |
| visits on weekends? | |
| Does your facility have a written | Yes |
| SOP/Policy/Procedure for the | |
| destruction of Investigational | |
| Product? | |
| Lab Name | Pathology Queensland-PAH |
| Local Lab Usage | Yes |
| н <u> </u> | • |

| Committee Country | Australia |
|--|--|
| Do you have Electronic Health | Yes |
| | i es |
| Records (EHR)/ Electronic | |
| Medical Records (EMR)? | |
| Life Sciences Queensland (LSQ) | No |
| Member | |
| Does your Facility have a written | Yes |
| SOP/Policy/Procedure for Minor | |
| Assent for paediatric | |
| populations? | |
| Does your Facility have a written | Yes |
| SOP/Policy/Procedure for Other | |
| vulnerable populations? | |
| | |
| IP Recipient Name | PA Clinical Trials Pharmacy Department |
| Does the HREC Committee | Yes |
| require payment prior to the | |
| release of final approval | |
| documents? | |
| Does your Facility have access to | Ves |
| translators and translation | |
| support for study conduct (e.g. | |
| | |
| consent, study-specific | |
| instruction)? | X 7 |
| Do you provide your Satellite | Yes |
| Site(s) with a dedicated | |
| inventory of Investigational | |
| Product? | |
| Do you have a process or | Yes |
| program in place to retrain | |
| research staff when a protocol is | |
| amended? | |
| Does your Facility have a | Yes |
| training program for the research | |
| staff? | |
| Training program for the | Caledonian; ARCS; Syneos online |
| research staff | |
| Storage Room Backup Power | Yes |
| Is the Investigational Product | Yes |
| - | 100 |
| Storage Room secured with controlled access? | |
| | V |
| Storage area securely constructed | res |
| What type of computer operating | Windows (Windows XP; Windows 7; |
| system(s) does your institution | Windows 10; etc) |
| use to support studies? | |
| | |
| Other areas of expertise | Chronic kidney disease |
| | |

| Sub-Therapeutic areas | Renal transplantation and Chronic kidney |
|------------------------------------|--|
| | disease;Antibody Injury;Renal |
| | transplantation;Complication of |
| | immunosuppression;Hypotension;Diabetic |
| | kidney disease;Glomeralonephritis |
| Please indicate all equipment | Phone;Copy Machines;Internet Access |
| that will be available to Monitors | |
| | |
| Has your Clinical Trial Site been | Not Applicable |
| accredited? | |
| Has your Clinical Trial site been | Not Applicable |
| audited? | 11 |
| If your Clinical Trial Site has | Other |
| been audited, please select all | |
| relevant types. | |
| Does your Clinical Trial site | Yes |
| undertake any patient | |
| recruitment? | |
| What percentage of Clinical | 80-90% |
| trials undertaken on your site do | |
| you meet or exceed the | |
| recruitment target? | |
| EMR/EHR systems | In-house system |
| Does the HREC require | Yes |
| contract/budget approval prior to | |
| release of final approval | |
| documents? | |
| Any Additional Process | No |