

# Princess Alexandra Hospital- Stroke Unit

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.

|  |   |
|--|---|
| <b><u>Facility Details:</u></b>  |   |
| Please provide your Facility Website.  | <a href="https://www.metrosouth.health.qld.gov.au/hospital-and-health-centres/princess-alexandra-hospital">https://www.metrosouth.health.qld.gov.au/hospital-and-health-centres/princess-alexandra-hospital</a> |
| What Department is your Trial Site?<br>( <b>Queensland Health HHS- See List of Services and Levels-Clinical Services Capability Framework</b> ). | 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.   | Stroke; Ischaemia; Haemorrhagic Stroke; Endovascular clot retrieval   |
| Has your Clinical Trial Site been accredited?  | HASU is an accredited Comprehensive Stroke Unit   |
| 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%  |
|  |   |
| <b><u>IRB/ERB/Ethics Committee:</u></b>  |   |
| 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 |
|  |     |
| <b><u>Consent:</u></b>   |     |
| 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 |
|  |     |
| <b><u>Training:</u></b>  |     |
| 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 |
|  |     |
| <b><u>Facility And Equipment:</u></b>  |     |
| <b><u>Facility Capabilities:</u></b>   |     |

|   |  |
|---|--|
| 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  |
|   |  |
| <b><u>Equipment:</u></b>  |  |
| 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  |
|   |  |
| <b><u>IT Capabilities:</u></b>  |  |
| 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    |
|  |  |
| <b><u>Labs:</u></b>  |  |
| Does your Facility use Local Lab Services?   | Yes                                    |
| Please provide Local Lab Name  | Pathology Queensland-PAH               |
|  |  |
| <b><u>IP Storage Details:</u></b>  |  |
| 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             |
|   |                 |
| <b><u>Source Documents:</u></b>   |                 |
| Does your Facility have secure storage for patient records?   | Yes             |
| Does your Facility have patient record archiving on-site?   | Yes             |
|   |                 |
| <b><u>Electronic Medical Records (EMR) /Electronic Health Records (EHR):</u></b>  |                 |
| Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?  | Yes             |
| What EMR/EHR system do you use?   | In-house system |