

# Princess Alexandra Hospital - Sleep; Narcolepsy and Cataplexy

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 |

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| 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 |
| 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 |

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| Lab Name  | Pathology Queensland-PAH               |
| Local Lab Usage   | Yes                                    |
| 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                                    |

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| What type of computer operating system(s) does your institution use to support studies?                  | Windows (Windows XP; Windows 7; Windows 10; etc) |
| Sub-Therapeutic areas  | Sleep;Narcolepsy;Cataplexy                       |
| 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   |