

Asia-Pacific Centre for Neuromodulation

Local Services Offered: Clinical trials site

Details: This PDF complements the information found in the CSV generated by this website with additional site information.

<u>Facility Details:</u>	
Is your Facility affiliated with a government agency or part of a government funded health service?	N/A
Do you have Affiliated Research Sites or Satellite Sites/Clinics? <i>A Satellite Site is a secondary location where the investigator sees clinical trial subjects. Usually this is the same investigator who sees subjects at the primary site location.</i>	Yes
Please provide other Affiliated Research Sites or Satellite Sites/Clinics facility details.	Royal Brisbane and Women's Hospital
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
Please provide other areas of expertise for your Facility.	Movement Disorders Touretts,
Provide the list of Sub-Therapeutic Areas for your Facility.	Parkinsons; Touretts; Neurological
Has your Clinical Trial Site or Service been accredited?	N/A
If your Clinical Trial Site has been accredited, please provide the type of accreditation.	N/A
Are there any notable factors relating to your Patient Population?	No
Does your Clinical Trial site or Service undertake any patients recruitment?	Yes
<u>IRB/ERB/Ethics Committee</u>	
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
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	N/A

Does your Facility have other review boards that need to approve the study prior to IRB/ERB/Ethics Committee submission? For example, scientific, radiation safety committees, or others.	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
<u>Consent</u>	
Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	Yes
Does your Facility have a written SOP/Policy/Procedure for Other vulnerable populations?	No
Does your Facility have a written SOP/Policy/Procedure for Minor Assent for paediatric populations?	No
Does your Facility provide language translations for consents?	No
<u>Training</u>	
Does your Facility have a training program for the research staff?	No
Does your facility training course content include GCP?	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
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
<u>Facility And Equipment</u>	
Facility Capabilities:	
Can your Facility support patient visits on weekends?	Yes
Can your Facility support in-patient admissions for research studies?	Yes

Is your Facility capable of administering infusions?	No
Does your Facility have the ability to collect and store PK/PD specimens?	No
Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	No
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	No
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
Does your Clinical Trial Site have the capacity to conduct Clinical Trials involving GMOs?	No
Equipment:	
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	No
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.?	No
Describe any additional equipment available at your Facility to ensure clinical program / trial feasibility?	MRI Magnetic Resonance Imaging
IT Capabilities:	
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP, Windows 7, Windows 10, etc), Apple/Mac (OS X Snow Leopard, Mountain Lion, El Captain, etc)
Which internet browser does your facility use?	Safari, 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)?	No
Please indicate all equipment that will be available to Monitors	Phone, Copy Machines, Internet Access

<u>Lab:</u>	
Does your Facility use private laboratory services?	Yes
<u>IP Storage Details:</u>	
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Yes
Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product?	Yes
Does your Facility have the ability to manage on-site or off- site destruction of controlled substances when appropriate?	Not Applicable
Does the Facility have the ability to handle radio-labelled Investigational Products?	No
<u>Source Documents:</u>	
If your Facility stores patient records offsite. Please provide the location name and address of any offsite archives.	Yes
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Does your Facility have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	No
Which EMR/EHR system does your facility use?	In-house

