Nucleus Network Pty Ltd

Local Services Offered:
Early Phase, Clinical trials site, Phase 1 unit, Trial Patient Recruitment, Completion of study documentation as per ICH GCP and contract. Studies in Healthy Volunteers
Details: This PDF complements the information found in the CSV generated by this website with additional site information.

Facility Details:	
Please provide your Facility Website.	https://www.nucleusnetwork.com/au/
Is your Facility affiliated with a government agency or part of a government funded health	No
Please provide other areas of expertise for your Facility.	Healthy Volunteers
Does your Clinical Trial site or Service undertake any recruitment?	Yes
Has your Clinical Trial Site or Service been accredited?	Yes
If your Clinical Trial Site or Service has been accredited, please select all relevant types	NATA
IRB/ERB/Ethics Committee:	
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?	Yes
Types of HREC (IRB/ERB/ETHICS) Committee that are used	Local
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	Monthly
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?	No
Does your Facility have other review boards that need to approve the study prior to HREC (IRB/ERB/Ethics) Committee submission? For example, scientific, radiation safety committees, or others.	Yes
Details of other steps for HREC (IRB/ERB/Ethics)Committee review and submission	Radiation Safety Committee/Officer for clinical trials needing radiology service and Independent Expert Reviewer for FTIH

Does the HREC require contract/budget approval prior to release of final approval documents?	No
Consent:	
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 have access to translators and translation support for study conduct (e.g. consent, study-specific instruction)?	No
Training:	
Does your Facility have a training program for the research staff?	Yes
Does the course content include GCP?	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
Facility And Equipment:	
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 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
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
Equipment:	
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
Please list any additional equipment that your Facility uses for Clinical Trials.	TTE, EEG, Spirometry