Royal Brisbane and Women's Hospital - Nutrition and Dietetics

Local Services Offered:
Clinical trials site, Trial Patient Recruitment, Treatment of patients, Completion of study documentation as per ICH GCP.
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://metronorth.health.qld.gov.au/rbwh/
What Department is your Trial Site? (**Queensland Health HHS**- *See List of Services and Levels-Clinical Services Capability Framework*).	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.	Diabetes; Nutrition
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
HREC Committee Name.	Metro North HHS HREC
Other Meeting Frequency	Two meetings per week in NMA
Does the HREC Committee require payment prior to the release of final approval documents?	Yes
Consent:	
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?	No

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
Training:	
Does your Facility have a training program for the research staff?	Yes
Does your Facility training course content include GCP?	Yes
If your facility uses external program course/s. Please provide the program course/s name.	Caledonian; ARCS and Syneos online
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 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
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
IT Capabilities:	
Does your Facility have computers that are dedicated to research studies?	No
What type of computer operating system(s) does your institution use to support studies?	Windows
What browser does your facility use?	Microsoft Explorer 11, EDGE
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
Labs:	
Is your Facility using a local pathology lab?	Yes
Please provide the Local Lab Name.	Pathology Queensland- RBWH
IP Storage Details:	
IP Recipient Name	Royal Brisbane and Women's Hospital Pharmacy

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 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
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
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
Source Documents:	
Does your Facility have patient record archiving on-site?	Yes
Does your Facility have secure storage for patient records?	Yes
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes