Gold Coast University Hospital - Trauma

Location:
-27.958375 - 153.38178
Local Services Offered:
Clinical trials site;Investigator Initiated Trials;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

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
Other Affiliated Research Sites	N/A
Does the Facility have the ability to handle radio-labelled Investigational Products?	Yes

Is your Facility capable of administering infusions?	Edge
What browser does your facility use?	Yes
Does the Facility have access to local IT support?	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?	No
Provide Location name and address of any offsite archives.	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

Other Meeting Frequency	Two meetings per week in NMA
Does the course content include GCP?	Yes
Lab Name	Pathology Queensland-GCUH
Local Lab Usage	Yes
Committee street name and number	1 Hospital Boulevard
Committee City	Southport
Committee Country	Australia
HREC Committee Name	Gold Coast HHS
Registration No.	EC00160
Committee State/Province/Region	Queensland
Committee Zipcode	4215
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
Program course name	IQVIA
IP Recipient Name	Gold Coast University Hospital Pharmacy
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)?	No
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	Yes

Storage Room Backup Power	Yes
Is the Investigational Product Storage Room secured with controlled access?	Yes
Storage area securely constructed	Yes
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
Therapeutic area	Wounds and Injuries
Sub-Therapeutic areas	Trauma
Location Information	Grace
EDC Systems Description	iMedidata; RedCap; IVRS/IWRS
EDC Systems	Oracle Inform;Medidate Rave;Oracle Remote Data Capture (RDC);Others
Additional equipment	Ultrasounds
Please indicate all equipment that will be available to Monitors	Phone;Copy Machines;Internet Access
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%
Additional General information	Recent opening of the Day Medical and Clinical Trials Unit. Dedicated clinical space - infusion chairs; inpatient beds and consultation rooms.
Medical access limitations	Cerner ieMR Solution in use at site; includes PowerTrials; monitors require login profile to access the system. Onboarding of Clinical Informatics Specialis(Research) from October 2019.