

Gold Coast University Hospital (GCUH) - Haematology and Oncology

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

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| <u>Facility Details:</u> | |
| Please provide your Facility Website. | www.goldcoast.health.qld.gov.au/hospitals-and-centres/gold-coast-university-hospital |
| What Department is your Trial Site? (Queensland Health HHS- See List of Services and Levels-Clinical Services Capability Framework) | Medicine |
| 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 |
| 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> | N/A |
| Other facility details | N/A |
| Provide the list of Sub-Therapeutic Areas for your Facility. | Gynaecology and Obstetrics; Cystitis; Endometriosis; Fertility; Overactive Bladder |
| Does your Clinical Trial site undertake any patient recruitment? | Yes |
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| <u>IRB/ERB/Ethics Committee:</u> | |
| Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions? | Yes |

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| Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions? | No |
| Types of HREC (IRB/ERB/ETHICS) Committee that are used | Local;Central Acting as Local |
| What is the meeting frequency of your Local IRB/ERB/Ethics Committee? | Monthly, 2 per week with NMA |
| 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. | No |
| Does the HREC Committee require payment prior to the release of final approval documents? | Yes |
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| 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? | Yes |
| 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 |
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| 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. | IQVIA |

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| Do you have a process or program in place to retrain research staff when a protocol is amended? | Yes |
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| <u>Facility And Equipment:</u> | |
| <u>Facility Capabilities:</u> | |
| Is your Facility capable of administering infusions? | Yes |
| Can your Facility support in- patient admissions for research studies? | Yes |
| Can your Facility support patient visits on weekends? | 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 |
| 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 |
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| <u>Equipment:</u> | |
| 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. | Ultrasounds, PSMA-PET, FET PET |
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| <u>IT Capabilities:</u> | |
| Does your Facility have computers that are dedicated to research studies? | Yes |
| What type of computer operating system(s) does your institution use to support studies? | Windows (Windows XP; Windows 7; Windows 10; etc) |
| What browser does your facility use? | 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, CRA have read-only access |
| Please indicate all equipment that will be available to Monitors | Phone; Copy Machines; Internet Access |
| <u>Labs:</u> | |
| Does your Facility use a local lab? | Yes |
| Please provide the local lab details. | Pathology Queensland-Gold Coast |
| Does your Facility use a private lab service? | Yes |
| Please provide the private lab details. | SNP, QML |
| <u>IP Storage Details:</u> | |
| IP Recipient Name | Gold Coast University Hospital Pharmacy |
| Is the Investigational Product Storage Room secured with controlled access? | Yes |
| Does the Investigational Product Storage Room have Backup Power? | Yes |
| Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product? | Yes |
| Does the Facility have the ability to handle radio-labelled Investigational Products? | Yes |

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| Does your Facility have the ability to manage on-site or off- site destruction of controlled substances when appropriate? | 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)? | N/A |
| <u>Source Documents:</u> | |
| Does your Facility have patient record archiving on-site? | Yes |
| Provide Location name and address of any offsite archives. | Grace |
| What Electronic Data Capture (EDC) systems has your Facility used for clinical trials? | Oracle Inform;Medidata Rave;Oracle Remote Data Capture (RDC); Auslab |
| Please provide other EDC Systems. | iMedidata; RedCap; IVRS/IWRS |
| <u>Electronic Medical Records (EMR) /Electronic Health Records (EHR):</u> | |
| Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)? | Yes |