# Gold Coast University Hospital (GCUH) – Maternal Fetal Medicine

Location:
-27.9584,153.3818
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

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| LSQ Member | No |
| Facility Department | Women's and Family |
| Sub-Therapeutic areas | Pregnancy Complications, Prediction of pregnancy complications, Prevention of pregnancy complications, Fetal Malformations, Maternal Fetal Medicine, Placenta Dysfunction, First Trimester Screening, big data and digital transformation |
| Does your Clinical Trial Site have the capacity to conduct Clinical Trials involving GMOs? | No |
| Other Affiliated Research Sites | No |
| Is your Facility affiliated with a government agency or part of a government funded health service? | Yes |
| Are there any notable factors relating to your Patient Population (e | All Pregnant women |
| Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions? | Yes |
| Does your Clinical Trial site or Service undertake any recruitment? | Yes |
| What percentage of Clinical trials undertaken on your site do you meet or exceed the recruitment target? | 80-90% |
| Which is your Local HREC (IRB/ERB/Ethics) Committee? | Gold Coast HHS |
| Other Meeting Frequency | 2 weekly for NMA |
| Does the HREC Committee require payment prior to the release of final approval documents? | No |

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| Does your Facility have other review boards that need to approve the study prior to HREC (IRB/ERB/Ethics) Committee submission? | No |
| Does the HREC require contract/budget approval prior to release of final approval documents? | Yes |
| 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 |
| Local Lab Usage | Yes |
| Lab Name | University Hospital |
| Does your Facility use private laboratory services? | Yes |
| If you selected 'Yes' on the previous question, please specify here which services | SNP, QML |
| 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)? | No |
| Does your Facility have a training program for the research staff? | Yes |
| Include GCP | Yes |
| Training program for the research staff | IQVIA |
| Do you have a process or program in place to retrain research staff when a protocol is amended? | Yes |

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| 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 |
| Can your Facility support patient visits on weekends? | Yes |
| Can your Facility support in-patient admissions for research studies? | 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 PK/PD samples beyond normal business hours? | Yes |
| Does your Facility have the ability to collect and store PK/PD specimens? | Yes |
| Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes? | Yes |
| Additional equipment | GE Ultrasound Machine, Samsung W10 Ultrasound Machine, Griffith Pregnancy |
| 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 necessary equipment to treat medical emergencies (for example crash/code cart)? | Yes |
| Computers for Research | Yes |
| What type of computer operating system(s) does your institution use to support studies? | Windows (Windows XP, Windows 7, Windows 10, etc) |
| Internet Browser | Edge |
| Does the Facility have access to local IT support? | Yes |
| IP Recipient Name | Gold Coast University Hospital |
| Is the Investigational Product Storage Room secured with controlled access? | Yes |
| Storage Room Backup Power | Yes |

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| Does your Facility have the ability to manage on-site or off-site destruction of the Investigational Product? | Yes |
| Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate? | 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 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 |
| Provide Location name and address of any offsite archives. | Grace |
| Does your Facility have patient record archiving on-site? | Yes |
| Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)? | Yes |
| Please list any access limitations/requirements for the Electronic Medical Records | Yes, CRA has read-only access |
| Monitor Equipment | Printer, photocopies |
| EDC Systems | iMedidata; RedCap; IVRS/IWRS, |