# Royal Brisbane and Women's Hospital - Women's and Newborn

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:** | |
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| 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 |
| Please provide other areas of expertise for your Facility. | Gynaecology |
| Provide the list of Sub-Therapeutic Areas for your Facility. | Female Urogenital Diseases and Pregnancy Complications; Neonatal obstetrics and; Obstetric medicine; Endometriosis; Fertility; Cystitis |
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| **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 |
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| **Consent:** | |

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| 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 |
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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. | 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 |
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| **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 |

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| 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 |
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| **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 |
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| **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 |
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| **Labs:** | |
| Is your Facility using a local pathology lab? | Yes |

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| Please provide the Local Lab Name. | Pathology Queensland- RBWH |
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| **IP Storage Details:** | |
| IP Recipient Name | Royal Brisbane and Women's Hospital Pharmacy<br>Clinical Trials Pharmacy<br>Level 1 Ned Hanlon Building<br>Royal Brisbane and Women's Hospital<br>Butterfield St<br>Herston QLD 4029 |
| 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 |
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| **Source Documents:** | |
| Does your Facility have patient record archiving on-site? | Yes |
| Does your Facility have secure storage for patient records? | Yes |
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| **Electronic Medical Records (EMR) /Electronic Health Records (EHR):** | |

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|---|---|
| Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)? | Yes |