

Redcliffe Hospital - Intensive Care Unit (ICU)

Local Services Offered:

Clinical trials 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. | https://metronorth.health.qld.gov.au/redcliffe/ |
| What Department is your Trial Site? (Queensland Health HHS- See List of Services and Levels-Clinical Services) | Medical Services |
| Is your Facility affiliated with a government agency or part of a government funded health service? | Yes |
| 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 |
| Is your facility/organisation a Life Sciences Queensland (LSQ) Member? | No |
| Please provide other areas of expertise for your Facility. | Sepsis |
| Provide the list of Sub-Therapeutic Areas for your Facility. | Sedation; ICU |
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| <u>IRB/ERB/Ethics Committee:</u> | |
| Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions? | No |
| Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee | No |
| HREC Committee Name. | Metro North 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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| <u>Consent:</u> | |

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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. | Yes |
| | |
| <u>Training:</u> | |
| Does your Facility have a training program for | Yes |
| Does your Facility training course content include GCP? | Yes |
| 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 | Yes |
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| <u>Facility And Equipment:</u> | |
| <u>Facility Capabilities:</u> | |
| Can your Facility support in-patient admissions | Yes |
| Can your Facility support patient visits on weekends? | No |
| Is your Facility capable of administering infusions? | No |
| Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product? | No |
| 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 | Yes |
| Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples | Yes |

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| Does the Facility have storage space for Study- Related materials (e.g. Lab Kits, Patient | 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, | Yes |
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| <u>IT Capabilities:</u> | |
| 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 (Windows XP; Windows 7; Windows 10; etc) |
| Other Operating Systems Supporting Studies | JAVA |
| What browser does your facility use? | Internet Explorer |
| 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 | Yes |
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| <u>Labs:</u> | |
| Is your Facility using a local pathology lab? | Yes |
| Please provide the Local Lab Name. | Pathology Queensland-Redcliffe Hospital |
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| <u>IP Storage Details:</u> | |
| IP Recipient Name | Redcliffe Hospital; Research Hub |
| 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 |

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| Does your Facility have a written SOP/Policy/Procedure to ensure on-site or off-site destruction of the Investigational | Yes |
| Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate? | N/A |
| Does the Facility have the ability to handle radio-labelled Investigational Products? | N/A |
| Do you provide your Satellite Site(s) with a dedicated inventory of Investigational | Yes |
| Does your Facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite | Yes |
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| <u>Source Documents:</u> | |
| Does your Facility have secure storage for patient records? | Yes |
| Does your Facility have patient record archiving on-site? | Yes |
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| <u>Electronic Medical Records (EMR) /Electronic Health Records (EHR):</u> | |
| Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)? | Yes |