# Queensland Children's Hospital - Respiratory

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

| **Facility Details:** | |
|---|---|
| Please provide your Facility Website. | https://www.childrens.health.qld.gov.au/ |
| What Department is your Trial Site? (**Queensland Health HHS**- *See List of Services and Levels-Clinical Services Capability Framework* ). | Medical Services |
| Does your Clinical Trial site undertake any patient recruitment? | Yes |
| Provide the list of Sub-Therapeutic Areas for your Facility. | Paediatric Respiratory; Allergic Rhinitis; Asthma; Chronic Bronchitis; Chronic Obstructive Pulmonary Disease; Cystic fibrosis; Emphysema; Idiopathic Pulmonary Fibrosis; Pneumonia; Pulmonary Arterial Hypertension; Pulmonary Embolism; Pulmonary Oedema; Sinusitis |
| What percentage of Clinical trials undertaken on your site do you meet or exceed the recruitment target? | 80-90% dependent on study |
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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. | CHQ HREC |
| What is the meeting frequency of your Local IRB/ERB/Ethics Committee? | Two meetings per week in NMA |
| Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission? | Yes |

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| 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? | 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 |
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## Training:

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| Does your Facility have a training program for the research staff? | 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 dangerous goods? | Yes |
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## Facility And Equipment:

### Facility Capabilities:

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| Can your Facility support in-patient admissions for research studies? | Yes |
| Can your Facility support patient visits on weekends? | No |
| Is your Facility capable of administering infusions? | Yes |

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| Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product? | Yes |
| Does your Facility have the ability to collect and store PK/PD specimens? | No |
| 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 |
| Please list any additional equipment that your Facility uses for Clinical Trials. | Ultrasound to all profiles, EEG, Gait analysis and body |
| | |
| **IT Capabilities:** | |
| 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 |

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| 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 |
| Please indicate all equipment that will be available to Monitors | Phone, Copy Machine, Internet Access |
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## Labs:

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| Is your Facility using a local pathology lab? | Yes |
| Please provide the Local Lab Name. | Pathology Queensland-Children's Hospital |
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## IP Storage Details:

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| IP Recipient Name | Queensland Children's Hospital Pharmacy |
| 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 controlled substances when appropriate? | Yes |
| Does the Facility have the ability to handle radio-labelled Investigational Products? | 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 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:

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| Does your Facility have patient record archiving on-site? | No |
| Does your Facility have secure storage for patient records? | Yes |
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| **Electronic Medical Records (EMR) /Electronic Health Records (EHR):** | |
| Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)? | Yes |
| What EMR/EHR system do you use? | In-house system |