

Sunshine Coast University Hospital - Oncology

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.

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| Facility Details: | |
| Please provide your Facility Website. | https://www.sunshinecoast.health.qld.gov.au/hospitals-and-health-centres/sunshine-coast-university-hospital |
| What Department is your Trial Site? (Queensland Health HHS - See List of Services and Levels-Clinical Services Capability Framework). | Medical Services |
| Is your facility/organisation a Life Sciences Queensland (LSQ) Member? | No |
| Do you have Affiliated Research Sites or Satellite Sites/Clinics? 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. | Yes |
| Please provide other facility details. | Other SC HHS sites: Coloundra, Gympie, Nambour |
| Provide the list of Sub-Therapeutic Areas for your Facility. | Brain Cancer; Basal Cell Cancer; Breast Cancer; Cervical Cancer; Colorectal Cancer; CRPC; Follicular Lymphoma; Gastro Intestinal Solid Tumours; Head and Neck Cancer; Hepatocellular Carcinoma; Hereditary Angioedema; HR Prostate Cancer; Islet Cell Tumours; Lung Cancer; Lymphoma; Malignant Pleural Mesothelioma; Melanoma; Multiple Myeloma; Neuroma; Non- Hodgkin's Lymphoma; Non-Small Cell Lung Cancer; Ovarian Epithelial Carcinoma; Pancreatic Cancer; Prostate Cancer; Renal Cell Carcinoma; Sarcoma; Soft Tissues Sarcomas; Squamous & Non Squamous Sarcomas; Thyroid Cancer; Throat Cancer; Acquired Haemophilia; Acute Lymphoblastic Leukaemia; Acute Myelogenous Leukaemia; Chronic Lymphocytic Leukaemia; Chronic Myelogenous Leukaemia; Lymphocytic leukaemia; Mantle Cell Lymphoma; Myelodysplastic Syndrome |

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| Please provide other areas of expertise for your Facility. | Breast; Gastrology; Head and neck; Pancreatic; Lung; Prostate; Renal; Hepatic; Ovarian and Solid tumors.;Liver Cancer |
| 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? | No |
| Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions? | No |
| HREC Committee Name. | All NMA approved HREC |
| Other Meeting Frequency | 2 per week with NMA |
| Does the HREC Committee require payment prior to the release of final approval documents? | Yes |
| Does the HREC require contract/budget approval prior to release of final approval documents? | Yes |
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| <u>Consent:</u> | |
| 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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| <u>Training:</u> | |
| Does the course content include GCP? | Yes |
| Please provide program course/s name | Caledonian; ARCS; Syneos online |
| Do you have a process or program in place to retrain research staff when a protocol is amended? | Yes |

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| Does your Facility have a training program for the research staff? | Yes |
| Training program for the research staff | Yes |
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| <u>Facility And Equipment:</u> | |
| <u>Facility Capabilities:</u> | |
| Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes? | Yes |
| Is your Facility capable of administering infusions? | Yes |
| Can your Facility support in- patient admissions for research studies? | 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 |
| 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 |
| Can your Facility support patient visits on weekends? | No |
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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 |
| Additional equipment | Ultrasounds, Hybrid Theatre |
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| <u>IT Capabilities:</u> | |
| What browser does your facility use? | Internet Explorer |

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| 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 |
| 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) |
| Please indicate all equipment that will be available to Monitors | Phone;Copy Machines;Internet Access |
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| <u>Labs:</u> | |
| Lab Name | Pathology Queensland-SCUH |
| Local Lab Usage | Yes |
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| <u>IP Storage Details:</u> | |
| 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 |
| Facility written sop during transportation to satellite site | 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 |
| IP Recipient Name | Sunshine Coast University Hospital Pharmacy |
| Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product? | Yes |
| Storage Room Backup Power | Yes |
| Is the Investigational Product Storage Room secured with controlled access? | Yes |
| IP Storage Location Name | Sunshine Coast University Hospital |
| Storage area securely constructed | Yes |
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| <u>Source Documents:</u> | |

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| Does your Facility have patient record archiving on-site? | No |
| Secure Storage 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 |
| EMR/EHR systems | In-house system |
| Medical access limitations | Cerner ieMR Solution in use at site; includes PowerTrials; monitors require login profile to access |