Mackay Institute of Research and Innovation (MIRI)

Local Services Offered: Clinical trials site; Investigator Initiated Trials; Satellite 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.

Facility Details:	
Please provide your Facility Website.	https://www.mackay.health.qld.gov.au/research
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
Other Affiliated Research Sites	Royal Brisbane and Women's Hospital; Princess Alexandra Hospital; Rockhampton Hospital; Toowoomba Hospital; Townsville University Hospital, Cairns Hospital, James Cook University, Central Queensland University, Griffith University and Tropical Australian Academic Health Centre (TAAHC).
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
Does your Clinical Trial site undertake any patient recruitment?	Yes
Please provide other areas of expertise for your Facility.	Anaesthesiology, Cardiovascular, Oncology, Injuries and Accidents, Mental Health, Metabolic and Endocrine, Neurological, Oral and Gastrointestinal, Renal and Urogenital, Reproductive Health and Childbirth, Respiratory, Stroke, Orthopaedics, and General Surgery.

Provide the list of Sub-Therapeutic Areas for your Facility.	Acute Coronary Syndrome, Acute Kidney Disease, Acute Lymphoblastic Leukaemia, Acute Myelogenous Leukaemia, ADHD (Attention Deficit Hyperactivity Disorder), Adult Coronary Syndrome, Aged, Allergic Rhinitis, Allergy, Allied Health, Alzheimers, Amyloidosis, Anaemia, Anaesthetics, Angina, Anxiety, Arrhythmia, Asthma, Atherosclerosis, Atrial Fibrillation, Autoimmune, Back and Neck Pain, Basal Cell Carcinoma, Bipolar Disorder, Birth, Bladder, Bladder Cancer, Bloodborne Viruses and Sexual Health Hepatitis A, Bone Cancer, Brain Cancer, Brain Ischemia, Breast Cancer, Cancer, Cardiology, Cardiovascular, Cardiovascular Diseases, Cellular therapies, Central Nervous System Stroke, Cerebral Palsy, Cervical Cancer, Chemically-induced Disorders, Chronic Bronchitis, Chronic Heart Failure, Chronic Kidney Disease, Chronic Lymphocytic Leukaemia, Chronic Myelogenous Leukaemia, Chronic Obstructive Pulmonary Disease (COPD), Cirrhosis, Colorectal Cancer, Community Services, Complementary medicine research, Congestive Heart Failure, Coronary Artery Disease, Critical Care, Crohn's Disease, Cystic Fibrosis, Cystitis, Dementia, Depression, Devices, Diabetes, Diabetic Kidney Disease, Dialysis, Digestive System Diseases, Diverticulitis, Ear Nose Throat (ENT), Early Onset Dementia, Emergency Medicine, Emphysema, Endocrine System Diseases, Endometriosis, Erectile Dysfunction, Eye Diseases, Family, Febrile Neutropenia, Female Urogenital Diseases and Pregnancy Complications, Fluids, Follicular Lymphoma, Gastro Intestinal Solid Tumours, Gastro Oesophageal Reflux Disease (GERD), Gastroenterology, General Medicine, General Paediatrics, Geriatric and Rehabilitation, Geriatric Medicine, Gerontology, Gynaecology, Head and Neck Cancer, Heart Failure, Hepatic, Hepatitis, Hepatitis A, Hepatitis B, Hepatitis C, Hepatocellular Carcinoma, Hereditary Angioedema, Herpes Simplex, Herpes Zoster, HIV – AIDS, HR Prostate Cancer, Human Papilloma Virus, Hypertension, Hypocalcaemia, Hypotension, ICU, Idiopathic Pulmonary Fibrosis, Imaging, Immune System Diseases, Incontinence, Infection and Inflammation, Infectious Diseases, Inflammatory Bowel Diseases, influenza, Insulin, Integrated Care, Interventional Cardiology and Cardiothoratics, Iron Deficiency Anaemia, Iron Overload, Irritable Bowel Syndrome (IBS), Ischaemia, Ischemic Heart Disease, IV Chemotherapy Services, Joint, Joint Replacement, Kidney Disease, Kidney Health and Nephrology, Kidneys, Leukaemia, Leukopenia, Liver Cancer, Liver Disease, Lung, Lung and Allergy, Lung Cancer, Lung Transplant, Lymphocytic Leukaemia, Lymphoma, Male Urogenital Diseases, Maternity, Medical Devices, Medical Oncology and Haematology, Medicine, Melanoma, Melanoma and Bowel, Mental Disorders, Mental Health, Mental Health Psychiatry and CNS, Mental Illness, Metabolic Diseases, Migraine, Mild Cognitive Impairment, MRI, MRSA, Multiple Myeloma, Muscle/Tendon Strain, Muscular Dystrophy, Musculoskeletal Diseases, Myasthenia Gravis, Myeloma, Narcolepsy, Nephrology, Nervous System Diseases, Neurodevelopmental Conditions, Neurological, Neurology, Non- Hodgkin's Lymphoma, Non-Small Cell Lung Cancer (NSCLC), Nursing, Nursing Research, Nutrition,

	Nutritional and Metabolic Diseases, Obstetric Medicine, Obstetrics, Occupational Diseases, Older, Older Persons, Oncology, Oncology and Haematology, Oncology Malignances, Ophthalmology, Organ Support, Orthopaedics, Osteoarthritis, Osteomyelitis, Osteoporosis, Otorhinolaryngologic Diseases, Outpatient Clinics, Ovarian, Ovarian and Solid Tumours, Ovarian Cancer, Ovarian Epithelial Carcinoma, Overactive Bladder, Pain, Palliative Care, Palliative Care & Renal, Pancreatic, Pancreatic Cancer, Pancreatitis, Parasitic Diseases, Parkinsons, Pathological Conditions, Pathological Conditions, Signs and Symptoms, Pericarditis, Perioperative, Perioperative Pain Management, Phlebitis, PHN, Pneumonia, Pneumothorax, Pregnancy Options, Prodromal Dementia, Prostate, Prostate Cancer, Psychiatry, Pulmonary Arterial Hypertension, Pulmonary Embolism, Pulmonary Oedema, Rehabilitation, Renal, Renal Cell Carcinoma, Renal Failure, Renal Medicine, Renal Research, Respiratory, Respiratory and Sleep, Respiratory Tract Diseases, Rheumatoid, Rheumatoid Arthritis, Rheumatology, Sarcoma, Schizophrenia, Seasonal Flu, Sedation, Sepsis, Sexual Diseases, Sexual Health, Sickle Cell Anaemia, Signs and Symptoms, Sinusitis, Skin and Connective Tissue Diseases, Sleep, Smoking Addiction, Soft Tissues Sarcomas, Solid tumours, Squamous & Non Squamous Sarcomas, Staph, Stomatognathic Diseases, Strep, Stroke, Structured Heart, Substance Abuse, Surgery, Surgical, Surgical Site Infections, Telehealth, Telemedicine, Teletrials, Thoracic, Throat Cancer, Thrombocytopenia, Thromboembolic Disease, Thryroid, Thyroid Cancer, Transcather Implantation, Transgender Care, Trauma, Ulcerative Colitis, Upper GI Disorders, Urinary Tract Infection, Urological Cancers, Urology, Vaccines, Vascular Disease, Vasculitis, Venous Thromboembolism, Virology, Virus Diseases, VRE, Women, Women and Family, Wound care and Pressure injury prevention, Wounds and Injuries
<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
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	Two meetings per week in NMA
Does the HREC Committee require payment prior to the release of final approval documents?	Yes

Consent:	
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)?	Yes
Training:	
Does your Facility have a training program for the research staff?	Yes
Does the 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 and A-CTEC

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
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
Facility And Equipment:	
Facility Capabilities:	
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
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?	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?	No
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
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
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?	Microsoft 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)?	No
Labs:	
Is your Facility using a local pathology lab?	Yes
Select local Pathology Queensland laboratory	Pathology Queensland-Mackay Hospital
IP Storage Details:	
IP Recipient Name	Mackay Hospital Pharmacy
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
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
Source Documents:	
Does your Facility have secure storage for patient records?	Yes
Does your Facility have patient record archiving on-site?	No