



Government of **Western Australia**
North Metropolitan Health Service
Sir Charles Gairdner Osborne Park Health Care Group



Sir Charles Gairdner Hospital and Osborne Park Health Care Group

Human Research Ethics Committee

Project Summaries for Approved Projects
July to September 2022 Quarter

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Project summaries for proposals approved by the SCGOPHCG Human Research Ethics Committee – July to September 2022 quarter.

The material contained in this document is made available to assist researchers, institutions and the general public in searching for projects that have ethics approval from the SCGOPHCG HREC. It contains summaries of projects approved in the July to September 2022 quarter.

Project Title	Project AFTERMATH: State-wide preparedness for post-pandemic antibiotic resistance
Principal Investigator	Tim Inglis
Institution	PathWest Albany, PathWest Fiona Stanley Hospital, PathWest QEII
Approval Date	01 July 2022

This project aims to detect and characterise emerging multidrug resistant infection in Western Australia in preparation for new forms of antibiotic resistance that will arrive as international mass travel returns to previous levels. Researchers will assess the suitability of wastewater testing as a real time AMR surveillance tool. Researchers will therefore analyse common bacterial pathogens in wastewater routinely tested by PCR for SARS-CoV-2, including wastewater from regional centres throughout the year.

Project Title	Muscle growth and anabolism in intensive care survivors
Principal Investigator	Matthew Anstey
Institution	Sir Charles Gairdner Hospital, Royal Perth Hospital, Fiona Stanley Hospital
Approval Date	13 July 2022

The loss of muscle mass in critical illness is related to immobility and a complicated process that causes muscle and nerve dysfunction called critical illness polymyoneuropathy. Another contributory factor is low levels of anabolic (muscle building) hormones such as testosterone – with testosterone levels in critically ill patients are extremely low, even in the recovery phase from acute illness. [3,4] One potential treatment may be to provide anabolic support in the recovery phase from prolonged critical illness.

This project aims to test whether giving a synthetic testosterone (nandrolone), will improve muscle strength in ICU survivors, when compared to placebo. Previous research has already established that early physiotherapy in the ICU can reduce length of stay and improve patients outcomes. In this study, both groups will receive standard care, which includes early physiotherapy.

Project Title	Pilot study: the prevalence and short-term outcomes of sarcopenia in Upper Gastrointestinal Cancer surgical patients at Sir Charles Gairdner Hospital
Principal Investigator	Chanelle Curnuck
Institution	Sir Charles Gairdner Hospital
Approval Date	13 July 2022
<p>Sir Charles Gairdner Hospital (SCGH) is the comprehensive cancer centre for upper gastrointestinal (UGI) cancer patients in the Perth North Metropolitan area. The identification of poor muscle function is routinely used in clinical practice through the use of Dynamometers. Sarcopenia is not routinely diagnosed due to lack of practical, non-invasive techniques and equipment for determining muscle mass.</p> <p>The Sozo® Bioelectrical Impedance Spectroscopy (BIS) machine is to date, the best available, most cost-efficient way to body composition and hence a mechanism to routinely diagnose sarcopenia. This clinical measurement using this tool will become part of standard practice in nutrition assessment of UGI cancer surgical patients at SCGH.</p> <p>This Pilot prospective observational study aims to identify the prevalence and short term outcomes (30 days post hospital discharge) of sarcopenia in UGI Cancer surgical patients.</p>	

Project Title	Attitudes and opinions towards family and domestic violence among Saharan African women and service providers in Australia
Principal Investigator	Wei Hao Lee
Institution	Armadale Health Service, Fiona Stanley Hospital, King Edward Memorial Hospital, Osborne Park Hospital
Approval Date	13 July 2022
<p>Domestic and family violence (DFV) is one of the most widespread and serious human rights violations in Australia. It includes physical, sexual, psychological-emotional violence and/or financial coercive control, committed by a family member. One in six Australian women over the age of fifteen experience one or more incidents of physical and/or sexual violence by a current or previous cohabiting partner.</p> <p>This proposed research project will explore the lack of data on DFV among Sub Saharan African immigrant and refugee women in Australia by conducting two consultative processes: (1) with health services and organisations in WA servicing significant numbers of Sub Saharan African immigrant and refugee women and (2) with a sample of Sub Saharan African women on their interest in participating in a future larger study aimed at reducing DFV in this population, and also their opinions on various evidence-based interventions.</p>	

Project Title	An exploration of health care providers' experience with Mental Health First Aid training at a Western Australian health service
Principal Investigator	Ravani Duggan
Institution	Graylands Hospital, King Edward Memorial Hospital, Osborne Park Hospital, Sir Charles Gairdner Hospital
Approval Date	13 July 2022

This study will utilise a multi-phase mixed method approach to explore the impact of Mental Health First Aid (MHFA) training amongst staff within the North Metropolitan Health Service (NMHS). A quantitative descriptive survey using a validated tool will be used to collect data relevant to study aims and objectives. Phase 2 will use a qualitative descriptive approach to collect data related to how NMHS staff have used their MHFA training and to identify their support needs to strengthen future training and provide related continuing education.

Project Title	Primary cardiac lymphoma: a genomic and clinicopathological analysis
Principal Investigator	Chan Cheah
Institution	Sir Charles Gairdner Hospital, PathWest QEII, St Vincent's Hospital Sydney
Approval Date	20 July 2022

The aim of this study is to allow genomic characterization of this unique subtype of diffuse large B-cell lymphoma, with the goal of developing better therapeutic strategies. Analysis of clinical data will provide further understanding of the demographics, clinical features, response rates to therapy according to intervention type and progression free and overall survival with first line therapy.

In summary, the information obtained from the proposed study will identify prognostic factors and molecular characteristics that will predict outcomes in our patient population.

Project Title	The Effects of Novel Light Therapy with Neurological Disorders – Traumatic Brain Injury (ENLighTIND-TBI)
Principal Investigator	Travis Cruickshank
Institution	Sir Charles Gairdner Hospital
Approval Date	22 July 2022

Excessive daytime sleepiness (EDS) and fatigue are common complaints following traumatic brain injury (TBI). EDS and fatigue interfere with daily activities, including work productivity, and negatively impact quality of life (QoL). Treatment of EDS and fatigue in TBI are therefore paramount. Light therapy has been shown to reduce EDS and fatigue in several clinical populations including TBI, however whether these benefits translate into meaningful outcomes, including enhanced work productivity and quality of life, has not been robustly investigated. The proposed study aims to evaluate the effects of light therapy on EDS, fatigue, work productivity and QoL outcomes in people post-TBI.

Project Title	Development of an automated pipeline to assess potential radiomics biomarkers predictive of patient progression to improve the management of glioblastoma
Principal Investigator	Martin Ebert
Institution	Sir Charles Gairdner Hospital
Approval Date	27 July 2022

Radiomics is the high-throughput extraction of quantitative features from medical image data, which has gained a large amount of interest within the last decade. This project aims to establish an evaluation pipeline for glioblastoma in order to develop quantitative metrics that can reliably predict a patient's PFS and differentiate PsP from true progression (TP) within the post radio-chemotherapy (RCx) setting. This will be attained by incorporating hand-crafted quantitative features (radiomics) in combination with the predictive power of current machine learning algorithms. Identifying those at risk of tumour recurrence early after treatment will result in improve patient management.

Project Title	NHL35 ALLG (PACIFIC) - An ALLG open label phase II study of Pembrolizumab And Chemo-Immunotherapy as First-line therapy for primary mediastinal B-Cell lymphoma
Principal Investigator	Chan Cheah
Institution	Sir Charles Gairdner Hospital
Approval Date	29 July 2022
<p>This is a small, non-randomised, open-label, single arm phase II study (target sample size 35). The focus of the study is the efficacy (in terms of 18-month Event Free Survival) of R-CHOP in combination with pembrolizumab in patients with newly diagnosed primary mediastinal B-cell lymphoma. The secondary objective is to evaluate the safety of incorporating pembrolizumab, efficacy of R-CHOP in combination with pembrolizumab in treatment-naive patients with PMBL and to evaluate the Patient Reported Outcomes over the course of treatment and follow-up.</p>	

Project Title	EBUS-TBNB in thoracic malignancy: An open-label, pragmatic, prospective study of endobronchial ultrasound trans-bronchial needle biopsy (EBUS-TBNB) with macroscopic on-site evaluation (MOSE) and rapid on-site evaluation (ROSE) in the diagnosis, staging, next generation sequencing (NGS) and comprehensive genomic profiling in thoracic malignancy
Principal Investigator	Calvinjit Sidhu
Institution	Sir Charles Gairdner Hospital, Royal Adelaide Hospital, The Prince Charles Hospital, The Royal Brisbane and Women's Hospital
Approval Date	04 August 2022
<p>Annual lung cancer incidence and mortality has continued to increase. Lung cancer involvement of thoracic lymph nodes is important to determine optimal treatment. Endobronchial ultrasound transbronchial needle aspiration (EBUS-TBNA) has become the standard procedure for diagnosis and staging of malignant disease involving thoracic lymph nodes but provide smaller specimen size. This can require multiple aspirations or procedures, to obtain sufficient material for detailed pathological analysis. The Franseen needle tip has been designed to potentially improve larger specimen acquisition without increasing the size of the needle, termed transbronchial needle biopsy (TBNB).</p> <p>Objectives:</p> <ol style="list-style-type: none"> 1) Determine suitability of TBNB needles in obtaining specimens for diagnosis and staging of malignant disease. 2) Determine suitability of TBNB needles in obtaining specimens for next-generation sequencing and comprehensive genomic profiling of malignancies. 	

Project Title	Collection of discarded brain tissue from neurosurgery patients for neuroscience research purposes
Principal Investigator	Alex Tang
Institution	Sir Charles Gairdner Hospital
Approval Date	10 August 2022

Knowledge of the structure and function of different cells in the brain is largely based on data collected from rodents. While this has provided a solid foundation to understand the functions of the human brain, fundamental differences between rodent and human brains have meant that translation of animal research to clinical applications have largely been ineffective.

For over 10 years, researchers have been investigating the use of non-invasive brain stimulation to promote structural changes in the brain as a potential treatment for a range of neurological disorders (e.g., depression). Our work has largely centered around using rodent models to perform in vivo and in vitro experiments. However, given the unique properties of cells in the human brain, there is a great need to validate rodent research in 'live' human brain tissue as a means of providing a translational step for our research towards clinical trials.

By collecting human neurosurgical samples, this project aims to:

- Characterise the molecular/cellular properties of different cells (neurons and glia) in the human brain.
- Implement a human-focused approach to characterise how brain stimulation alters the structure and function of cells in the brain, considering the effect of different biological factors (e.g., age and gender).

Project Title	The Sir Charles Gairdner Hospital Theranostics Outcomes, Research, and Quality registry: A Western Australian tertiary hospital based clinical registry for Peptide Receptor Radionuclide Therapy (PRRT) in somatostatin-receptor (SSTR) expressing solid tumours, and Prostate Specific Membrane Antigen (PSMA) Radioligand therapy in metastatic prostate cancer.
Principal Investigator	Te-Jui Jung
Institution	Sir Charles Gairdner Hospital
Approval Date	09 September 2022

Theranostics is a relatively new and rapidly expanding field of targeted, personalised medicine that combines elements of diagnostic imaging and therapy within nuclear medicine. The practical aspects of theranostics involves the coupling of diagnostic and therapeutic radionuclides (a Theranostic pair) to the same molecular ligand, allowing both precise diagnosis and treatment of cancers.

To date, there has been no cohesive collection of data from theranostic treatments performed at SCGH. Collection of data, including patient characteristics, imaging findings, treatment details and patient outcomes, will allow benchmarking of the SCGH Theranostics Service against other Theranostic Centres and existing literature. Data collected will also so be used to improve and streamline local practice and increase research and collaboration opportunities

Project Title	The Australian Inherited Retinal Disease Registry and DNA Bank
Principal Investigator	John De Roach
Institution	Sir Charles Gairdner Hospital
Approval Date	29 September 2022

Inherited retinal disease (IRD) is the most common cause of blindness in working-age Australians. It is a degenerative, hereditary and, as yet, incurable suite of diseases, caused by mutations in any of >260 genes. The aim of this project is to establish and maintain a registry of genetic, clinical and family history information and an associated DNA bank for individuals suffering from inherited retinal diseases and their family members. This resource is called the Australian Inherited Retinal Disease Registry and DNA Bank (AIRDR). Information and DNA is sought from participants Australia-wide. This project provides a secure, central and comprehensive resource for epidemiological, clinical and genetic research into these diseases.

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