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

January to March 2023 Quarter

Project summaries for proposals approved by the SCGOPHCG Human Research Ethics Committee – January to March 2023 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 January to March 2023 quarter.

Project Title	BioGrid Australia: A National Data Linkage Platform (Western Australia)
Coordinating Principal Investigator	Professor Richard Carey Smith
Institution	Sir Charles Gairdner Hospital
Approval Date	19 January 2023
This project relates to linking the West Australian Sarcoma database housed at the University of Western Australia to the BioGrid Data Linkage Platform. NB. We refer to the database as the WA Sarcoma database as it is part of a national project being led by the Australia and New Zealand Sarcoma Association which collects from various sites. This database referred to here as the WA Sarcoma database is separate to the sarcoma database listed in the WA Health System Information Register.	

Project Title	INNER-B-APAC - Asian Pacific post market clinical follow-up study in patients with thoracoabdominal aortic aneurysm treated with E-nside TAAA Multibranch stent Graft System
Coordinating Principal Investigator	Professor Shirley Jansen
Institution	Sir Charles Gairdner Hospital, Royal North Shore Hospital, Gold Coast University Hospital, Alfred Health

Approval Date	01 February 2023

This is an observational, prospective, non-randomized, multicentre study and not an interventional clinical trial. Around 5 clinical centres experienced in the endovascular treatment of thoracoabdominal aortic aneurysms will participate in this PMCF study. 30 patients with degenerative, atherosclerotic thoracoabdominal aortic aneurysm will be included. The Enside TAAA Multibranch Stent Graft will be implanted at the discretion of the treating physician. Participating physicians will be asked to provide their observations collected during routine care for patients he/she had decided to treat with the E-nside TAAA Multibranch Stent Graft System.

Project Title	Non-Invasive Intracranial Pressure Measurement via a Modified Photoplethysmography Technique. Non-Invasive Intracranial Pressure Measurement via a Modified Photoplethysmography Technique.
Coordinating Principal Investigator	Professor William Morgan
Institution	Sir Charles Gairdner Hospital, Royal Perth Hospital, Lions Eye Institute
Approval Date	03 February 2023

The aim of this study is to develop a safe, non-invasive method for measuring the brain fluid pressure. If successful, this will remove the need for lumbar puncture (needles in the back) or intracranial monitors (devices inserted directly into the brain). The past work has shown a relationship between the brain fluid pressure and the pressure in the retinal veins. The difference between the two is, however, affected by other factors (retinal vein resistance), which we can estimate using mathematical analysis of video footage. This research has been initiated by the study doctor, Professor William Morgan and is co-ordinated by the Lions Eye Institute at the University of Western Australia.

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Project Title	Multimodal prehabilitation for Upper Gastrointestinal Cancer surgery patients: standardisation of pathways, assessment of feasibility and evaluation of service
Coordinating Principal Investigator	Dr Yang Jian Ong
Institution	Sir Charles Gairdner Hospital
Approval Date	15 February 2023

Prehabilitation prior to surgery leads to better post-operative outcomes, through optimising a patients' physical fitness, and nutritional and functional status before their operation. Prehabilitation involves a multidisciplinary team and is tailored to a patient's needs. At North Metro Area Health Service, multimodal prehabilitation service is available for patients undergoing upper gastrointestinal tract cancer surgery, as this is particularly high-risk surgery.

This service consists of physiotherapy, dietician, geriatrician, and anaesthetic input. However, currently there is no standardised prehabilitation referral pathway. Referrals are made at the discretion of the treating surgical or oncological team. Implementation of a standard screening tool (Multi-modal Prehabilitation UGI Surgery Guideline and Checklist) will promote standardisation of care, to ensure all patients are considered for these evidence-based interventions.

Project Title	A Randomised Clinical Trial to Evaluate Efficacy of Topical Hyaluronic Acid and Vitamin D/E to Reduce the Impact of Vaginal Atrophy in Breast Cancer Survivors
Coordinating Principal Investigator	Dr Michelle McMullen
Institution	Sir Charles Gairdner Hospital, King Edward Memorial Hospital
Approval Date	01 March 2023

Primarily, this study aims to assess the efficacy of three separate topical treatments: 1) vitamin D/E, 2) hyaluronic acid, and 3) placebo, on reducing the overall impact of vaginal atrophy in breast cancer survivors. Secondary objectives include assessing the efficacy of these treatments on reducing specific symptoms of vaginal atrophy; to assess acceptability and impact on quality of life; and to assess treatment safety.

Using a double-blinded, placebo-controlled crossover trial design, breast cancer survivors experiencing vaginal atrophy symptoms will be invited to participate in a 16-week trial, allowing four weeks for each topical treatment (vitamin D/E, hyaluronic acid, placebo) with a 2 week break in between each one. Patient reported outcome measures (PROMs) will be collected at baseline, before and after each treatment. This research protocol has been developed using the SPIRIT 2013 guidelines for the inclusion of patient reported outcomes in clinical trial protocols (SPIRIT 2013, SPIRIT-PRO Extension).

A third study objective is to qualitatively explore experiences of breast cancer survivors, their partners and primary care practitioners, discussing and managing vaginal atrophy. Participants and partners, and primary care practitioners will be invited to participate in semi-structured interviews to explore in-depth any issues or challenges that could be better addressed and will be used to develop constructive suggestions for future improvement.

Project Title	GOlDiLOX - NHL37 ALLG - An open-label, single-arm, phase 2 trial of GlOfitamab anD pIrtobrutinib (LOXo-305) in patients with mantle cell lymphoma and prior exposure to a BTK inhibitor
Coordinating Principal Investigator	Dr Chan Cheah
Institution	Sir Charles Gairdner Hospital, Royal Melbourne Hospital, Peter MacCallum Cancer Institute
Approval Date	01 March 2023
This is a study to test the combination of glofitamab and pirtobrutinib in patients with mantle cell lymphoma (MCL) who have had previously taken a Bruton's Tyrosine Kinase (BTK) inhibitor. MCL that has returned or worsened after receiving a BTK inhibitor is difficult to treat. Glofitamab and pirtobrutinib have been shown to work for most patients in this situation when given on their own.	

Project Title	Australian Genomics of Cardiovascular Disease Risk following Preeclampsia Study
Coordinating Principal Investigator	Dr Phillip Melton

Institution	PathWest QEII, Department of Health, Royal Women's Hospital
Approval Date	18 March 2023

This project addresses the critical gap for understanding the underlying biology between those women who have had PE and their subsequent increased risk of developing later-life CVD. There is strong evidence that genetic variants and epigenetic modifications are associated with both PE and CVD. These genomic sites and regions represent potential biomarkers for PE and the early identification of CVD risk in women. To address the gap between PE and increased risk of later-life CVD in women, this project leverages our internationally recognised Australian PE cohorts (6-19) to develop a novel machine learning based risk score.

To accomplish this ambitious task, we will generate new high-throughput genome-wide epigenetic and metabolomic data then leverage these with our existing genomic data to generate this innovative risk score. The resulting score will stratify these women into those who are higher risk and those at lower risk for CVD following a complicated pregnancy. This score will then allow for improved management of CVD risk following PE and translate into enhanced patient care for pregnant women; fewer clinical tests for those women at low risk and targeted guidance to those at higher risk, ultimately reducing the health-care burden for these women and their families.

Project Title	Validation of GMP-compliant manufacture of corneal endothelial cells for injection
Coordinating Principal Investigator	Dr Evan Wong
Institution	Royal Perth Hospital, Lions Eye Institute
Approval Date	28 March 2023

We propose a pilot study to determine the feasibility of culturing high quality CEC therapy products in a GMP-compliant facility in Western Australia.

We aim to produce five batches of CEC cultures, which will then undergo morphometric and gene expression analysis. Donor corneas will be provided by the Lions Eye Bank of Western Australia. CEC culture protocols will be based on protocols developed by the Tissue Engineering and Cell Therapy research group at the Singapore Eye Research Institute, Singapore.

If successful, we aim to apply for ethics approval to conduct a phase 1 clinical trial for patients in Western Australia. This will represent the first such in-human trial in Australia and provide an opportunity to develop better understanding of this advanced therapy in a clinical setting.

Project Title	AMPLE-4: Topical Antibiotic Prophylaxis for Infections of Indwelling Pleural Catheters in Patients with Malignant Pleural Effusions
Coordinating Principal Investigator	Professor Gary Lee
Institution	Sir Charles Gairdner Hospital
Approval Date	29 March 2023
The Australasian Malignant PLeural Effusion (AMPLE) trial-4 is a multicentre RCT that will evaluate the use of regular prophylactic topical mupirocin (vs no antibiotics) to reduce catheter-related infections in patients fitted with an IPC for malignant fluid drainage. Mupirocin is a topical antibiotic used worldwide for 25 years with a strong safety record. Primary outcome is the proportion of patients who developed a catheter-related (pleural, tract or skin) infection from catheter insertion until death (or 6-month follow up). Secondary outcomes include infection rates adjusted for days of catheter in situ, infection-related hospitalisation (episodes and days), treatment acceptability for patients, complications, and survival.	

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