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
October to December 2022 Quarter

nmhs.health.wa.gov.au

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

Project Title	A Multi-center Observational Study to Determine the Laboratory Concordance Between PD-L1 22C3 PharmDx Testing and 22C3 antibody concentrate based Laboratory Developed Test (LDT) on VENTANA Platform (Benchmark Ultra) using Immuno-histochemistry (IHC) in Triple-Negative Breast Cancer (TNBC)
Principal Investigator	Elain Unwin
Institution	PathWest QEII, Royal Prince Alfred Hospital, Peter MacCallum Cancer Institute, St Vincent's Hospital Sydney
Approval Date	14 October 2022
PDL-1 testing is a predictive biomarker for predicting effective treatment with pembrolizumab. In Australia 80% of labs use the VENTANA platform. There is data in terms of reliability and reproducibility for a local developed test (LDT) using the 22C3 antibody on ASL-48 or VENTANA platform in other tumours, there is no data on triple negative breast cancer (TNBC). This study will compare the concordance of PD-L1 22C3 PharmDx Test and 22C3 antibody concentrate based Laboratory Developed Test on VENTANA Platform and determine the inter-observer/ laboratory variability in scoring between the two tests.	

Project Title	Does Myovista high sensitivity ECG -detected early diastolic dysfunction predict adverse cardiac events in patients undergoing vascular intervention?
Principal Investigator	Shirley Jansen
Institution	Sir Charles Gairdner Hospital
Approval Date	19 October 2022
Myocardial injury after non-cardiac surgery (MINS) approaches approximately 20% in vascular surgical patients undergoing procedures. MINS is an independent predictor of increased mortality in vascular surgical patients. This subset of patients remain at higher risk of major adverse cardiac events. The project aims to use Myovista, a machine that not only captures ECG data but also provides information on early diastolic dysfunction to explore whether this is linked to MINS	

and MACE. This information could be used to risk stratify vascular patients into high and low risk groups prior to their procedures and attempt to minimise adverse cardiac events post procedure which not only increase patient morbidity and mortality but also increase hospital length of stay which comes with its own associated costs.

Project Title	A multicenter, prospective, observational study to evaluate the Merit WRAPSODY™ Endoprosthesis for treatment of stenosis or occlusion within the dialysis outflow circuit of an arteriovenous AV fistula or AV graft (The **WRAP Registry**)
Principal Investigator	William Ormiston
Institution	Austin Health, Fiona Stanley Hospital, Liverpool Hospital, Royal Adelaide Hospital, Sir Charles Gairdner Hospital
Approval Date	03 November 2022
The study is designed to enable the collection, analysis, reporting and presentation of data from use of the WRAPSODY Endoprosthesis System purchased by the hospital or clinic and used in accordance with the Instructions for Use associated with the product's CE Mark approval. The intent of this post-market observational study is to increase the understanding of the performance of the WRAPSODY Endoprosthesis System in a larger population of patients representative of a 'real-world' patient population.	

Project Title	Whole exome sequencing in a family with normal tension glaucoma
Principal Investigator	Jonathan Lai
Institution	Lions Eye Institute, Royal Perth Hospital
Approval Date	23 November 2022
This study will identify a family of patients with glaucoma and normal intraocular pressures (normal tension glaucoma). Genetic samples will then be collected from these patients to look for any markers of impaired axonal transport i.e. genes involved in maintaining the normal transport mechanisms essential for a healthy optic nerve.	

Project Title	Early use of in-line speaking valve to facilitate earlier weaning from ventilation and improved patient experience
Principal Investigator	Bradley Wibrow
Institution	Sir Charles Gairdner Hospital, Fiona Stanley Hospital
Approval Date	30 November 2022

This project aims to evaluate whether the early use of a speaking valve within the ventilator circuit in suitable patients results in earlier weaning from mechanical ventilation and earlier communication.
This will be an unblinded randomised controlled trial in WA intensive care units.
The primary outcome will be feasibility and safety with the ability to pivot to a primary outcome of duration of mechanical ventilation post tracheostomy utilising the pilot results if safety and feasibility are confirmed. Secondary outcomes include duration of mechanical ventilation post tracheostomy, time to phonation, time to decannulation, patient satisfaction and length of stay.

Project Title	Does virtual delivery of an Occupational Therapy Home Visiting Service provide a non-inferior alternative to face-to-face delivery of the same service? A case control study
Principal Investigator	Toni Heinemann
Institution	Sir Charles Gairdner Hospital, Osborne Park Hospital
Approval Date	01 December 2022

This study aims to determine whether delivery of an occupational therapy home visiting service using a virtual care hybrid model reduces therapy time while being non-inferior to a traditional face-to-face model of care in regard to adverse events and is supported by patient satisfaction.

A non-inferiority model will be utilised as we are interested in whether the new treatment (virtual care) is “not worse” than the existing treatment (face-to-face home visit delivery).

Primary Objective:
To examine the total patient therapy time provided from the occupational therapy home visiting service from referral to discharge for patients who receive virtual care compared to face-to-face care. Both approaches will employ standard care including an initial home assessment, intervention and follow-up until the patient is discharged from occupational therapy (generally 4-6 weeks).

Project Title	Can early referral to allied health impact on hospital admissions and quality of life after diagnosis of high-grade glioma?
Principal Investigator	Brooke Russell
Institution	Sir Charles Gairdner Hospital
Approval Date	01 December 2022

This study aims to identify and quantify the impact of early referral to allied health for patients with HGG on subsequent healthcare use while evaluating the patient and carer experience.

Primary Objective:
To examine the rate of unplanned healthcare use over a 6-month period following early allied health intervention for patients with HGG including ED presentations, hospital admissions and the associated length of stay (LOS).

Secondary Objectives:
* To determine the time from diagnosis to receipt of allied health input.
* To determine the time from diagnosis to care service approval i.e. National Disability Insurance Scheme (NDIS) approval with associated access to appropriate home care supports and services.
* To quantify patient outcomes regarding functional performance and quality of life (QOL) pre and post intervention.
* To quantify carer outcomes including carer QOL pre and post intervention.

Project Title	The Telenutrition and Kidney Health Study. A randomised controlled trial comparing the effect of digital health to standard care on serum phosphate control in patients on dialysis.
Principal Investigator	Neil Boudville
Institution	Sir Charles Gairdner Hospital, Fiona Stanley Hospital, Royal Adelaide Hospital, Princess Alexandra Hospital, Western Health - Sunshine, Footscray, Williamston, Royal Perth Hospital, Royal Hobart Hospital, Monash Health, St George Hospital, The Queen Elizabeth Hospital, Alfred Health, Shoalhaven District Memorial Hospital, Wollongong Hospital, Camden Hospital, Campbelltown Hospital, St Vincent's Hospital (Melbourne), Gold Coast University Hospital, Royal Melbourne Hospital, Maitland Hospital, Barwon Health, Tamworth Hospital, Royal North Shore Hospital, Flinders Medical Centre, Austin Health, Noarlunga Hospital
Approval Date	01 December 2022

The aim of this study is to assess the feasibility and effectiveness of digital health intervention compared to standard care to improve management of serum phosphate in patients on dialysis.
A total of 154 patients receiving maintenance haemodialysis or peritoneal dialysis will be identified in outpatient clinics and satellite/hospital dialysis units. Patients will be randomised

to either control or intervention group in a 1:1 ratio.
The control group will continue to receive standard dietetic care as per normal procedure for their treating unit for the duration of the study.
The intervention group will receive standard care plus personalised phosphate lowering dietary education via bi-weekly targeted App messaging, infographics, and visual cartoons over a 3-month intervention period. After the 3-month intervention phase all participants will go to standard care for the remaining 3 months follow up phase of the 6-month study.

Project Title	Surgical Management of Atrial Fibrillation
Principal Investigator	Rong Hui Chia
Institution	Fiona Stanley Hospital, Royal Perth Hospital, Sir Charles Gairdner Hospital
Approval Date	01 December 2022

Atrial fibrillation (AF) is associated with increased risk of stroke and hospitalization. Maze procedure is the gold standard in treating persistent AF. However, many surgeons modify the lesion set in the Maze procedure, which are then variably reported as ‘left atrial ablation’ or even as the complete ‘Maze procedure’. This makes interpretation of results difficult and hence a lack of Australian recommendation for surgical practice.

This study will evaluate:
-the perioperative and longer-term outcomes of AF surgery in Perth; and
-the variance in the conduct of AF surgery and the use of surgical nomenclatures; and whether this variance has a direct impact on both patient outcome.

Project Title	Outcomes in patients with high-risk intramucosal cancer and superficial submucosal oesophageal adenocarcinoma managed initially with endoscopic local resection – a multi-centre retrospective study
Principal Investigator	Spiro Raftopoulos
Institution	Fiona Stanley Hospital, Lyell McEwin Hospital, Monash Health, PathWest QEII, Princess Alexandra Hospital, Royal Adelaide Hospital, Royal Melbourne Hospital, Royal Perth Hospital, Sir Charles Gairdner Hospital, St Vincent’s Hospital, the Royal Brisance and Women’s Hospital, Western Health – Sunshine, Footscray, Williamston
Approval Date	01 December 2022

Contemporary treatment of early oesophageal (food pipe) cancer, involves minimally invasive endoscopic procedures; while surgery is reserved only for cases with the highest-risk of the cancer spreading into the surrounding tissues .
The risk of cancer spread is determined by samples removed at endoscopy, in which a pathologist is looking to see the depth of cancer spread into the wall of the oesophagus or for

abnormal characteristics of the cancer. Conventionally, higher risk of cancer spreading is linked to whether the cancer has reached the deeper layers of the oesophagus containing (lymphatic) draining vessels or if the cancer has very abnormal characteristics. However, many patients who are considered high-risk of cancer spreading and then go on to have surgery were later found to have no left-over cancer making the surgery unnecessary.
Thus, the prognostication of cancer spread, disease recurrence, morbidity and cancer-related mortality based histopathological findings after endoscopic resection of these oesophageal cancers requires further study.
Therefore, the purpose of this study is to try and identify patients who are considered higher risk by conventional practice, who are actually at low risk for cancer spread; and, thus can forgo the need for a major operation with poor post-operative outcomes with respect to quality of life, morbidity and mortality.

Project Title	The influence of the COVID-19 pandemic on new graduates' transition to practice and career planning
Principal Investigator	Shelley Gower
Institution	Sir Charles Gairdner Hospital, Osborne Park Hospital
Approval Date	14 December 2022

The transition to practice for new nurses is known to be a time of anxiety, emotional challenge and adjustment. Feelings of inadequacy and instability may leave them questioning their career choice. Graduates who have commenced nursing since February 2020 have done so in a pandemic context, potentially exacerbating known tensions.
Aim: To explore graduates' expectations of the transition to practice, to describe the reality of that transition during the COVID pandemic, and to identify how this has influenced their career intentions.

Project Title	Clinical utility of Phosphatidylethanol (Peth) measurements to detect alcohol consumption in emergency department patients.
Principal Investigator	Daniel White
Institution	Sir Charles Gairdner Hospital, PathWest QEII
Approval Date	14 December 2022

This is a non-interventional, observational study, consisting of patients whose alcohol consumption is being investigated as a causative factor in illness or injury.
The study will involve the secondary use of routinely collected blood samples that have completed their clinical purposes and are in storage, awaiting disposal. The clinical study is a single time-point (snapshot) experiment, where patients will not be contacted, and their treatment will not be affected by the outcome of the research.

This document can be made available in alternative formats on request for a person with a disability.