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 2021 Quarter

nmhs.health.wa.gov.au

Project summaries for proposals approved by the SCGOPHCG Human Research Ethics Committee – October to December 2021 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 2021 quarter.

Project Title	IgG4 expression and PDGFRA gene mutation in gastrointestinal inflammatory fibroid polyps
Principal Investigator	Tze Khor
Institution	PathWest QEII
Approval Date	08 October 2021

Objectives: The primary objective of this study is to quantify the subset of IFPs which display elevated lymphoplasmacytic cell numbers and to test for the presence of IgG4 plasma cells within this subset.

Secondary objectives include:
1. To determine if IFPs containing increased numbers of IgG4 plasma cells also show platelet-derived growth factor receptor alpha (PDGFRA) gene mutation.
2. To describe the clinicopathologic features of IFP without elevated IgG4 plasma cells and IFP with elevated IgG4 plasma cells.

Methods: Retrospective study of gastrointestinal IFPs reported at PathWest QEII between 2010 and 2020. Cases will be reviewed by a Consultant Pathologist (SK) and the presence of increased lymphoplasmacytic cells will be assessed. Those cases identified as having increased lymphoplasmacytic cells will undergo Ig and IgG4 immunohistochemistry to determine the numbers of IgG4 plasma cells present. Cases identified as having increased IgG4 plasma cells will then undergo molecular testing for a platelet-derived growth factor receptor alpha (PDGFRA) gene mutation.
.

Project Title	Use of midline catheters compared with those without a midline catheter in neurosurgical patients: a retrospective cohort study and economic analysis
Principal Investigator	Linda Coventry
Institution	Sir Charles Gairdner Hospital
Approval Date	21 October 2021

Midline catheters are 8 to 20 cm in length and are inserted via the Nurse-led intravenous access team with ultrasound guidance in the upper arm. Midline catheters can be used when vascular access is required for more than 5 days. The dwell time of a midline catheter of 2 to 4 weeks is much longer than a peripheral intravenous cannula.

The objectives of this study are to:
1. Determine efficacy of patients with a midline catheter compared with patients without a midline catheter in neurosurgical patients with subarachnoid haemorrhage.
2. Conduct a cost-effectiveness analysis to explore and quantify the costs associated with midline catheter use compared with patients without a midline catheter.

Project Title	Exploring practising mature age nurses' and midwives' experience of working in clinical healthcare settings in Western Australia
Principal Investigator	Ravani Duggan
Institution	Sir Charles Gairdner Hospital, Osborne Park Hospital, King Edward Memorial Hospital and 17 additional sites within the North Metropolitan Health Service.
Approval Date	25 October 2021

The study aims to explore practising mature age nurses' and midwives' experience of working in clinical healthcare settings in Western Australian. In doing so, it seeks to address the following specific research objectives:

1) To explore how increasing age has impacted the mature age nurses' and midwives' experience of engaging in the workforce.

2) To identify challenging issues for mature age nurses and midwives in relation to their ability to actively engage in the workplace setting.

3) To identity supportive mechanisms/factors which enable mature age nurses and midwives to actively engage in the workforce.

4) To describe recommendations from mature age nurses and midwives about how the organisation and profession can support them within the workforce.

Project Title	Evaluating the cardiovascular effects of the Compressive Redistribution Air Blanket on healthy volunteers.
Principal Investigator	Christopher Mitchell
Institution	Sir Charles Gairdner Hospital
Approval Date	28 October 2021

The Compressive Redistribution Air Blanket (CRAB) is a recent invention, developed in Western Australia by Coco Industries Pty Ltd and Dr Chris Mitchell. It is an inflatable blanket, which is positioned over the abdomen and legs of the patient and is held in position by straps passing under the table. The air blanket is inflated by an electric pump to pressures up to 60cm H20. The blanket evenly compresses the abdomen and legs to physically squeeze the “unstressed” pooled venous blood of the lower body to the upper body, increasing CVP and preload.

This is the first study investigating and documenting the CRAB.

There are 4 aims:

1) To find the relationship between increasing compression of the CRAB and Central venous pressure (CVP) in both mildly hypovolaemic and normovolaemic volunteers.

2) To document safety of the CRAB.

3) To compare the rise in CVP produced by the inflation of the CRAB to Passive Leg Raise (PLR) and 15 degrees of Trendelenburg.

4) To investigated if the rise in CVP induced by the CRAB on a healthy volunteer, results in any transitory change in blood pressure (BP) or heart rate (HR)

Project Title	Computational Modelling of Visceral Artery Aneurysms
Principal Investigator	Shirley Jansen
Institution	Sir Charles Gairdner Hospital, Harry Perkins Institute of Medical Research - North
Approval Date	01 November 2021

This project aims to use computer models of the cardiovascular system and **retrospective de-identified routine medical imaging in unhealthy patients aged 18-70+ years**, to investigate how and why these aneurysms develop, how they may progress and insights into the risk of complications such as vessel rupture. Specifically, we aim to investigate blood flow in both symptomatic and asymptomatic SKS aneurysms to determine if low frictional force between the blood and artery is also associated with rupture risk in this vascular region.

Project Title	Early Valve Replacement guided by Biomarkers of Left Ventricular Decompensation in Asymptomatic Patients with Severe Aortic Stenosis
Principal Investigator	Graham Hillis
Institution	Royal Perth Hospital, Department of Health
Approval Date	02 November 2021

A parallel-group multicentre prospective randomised open--label blinded endpoint trial of early aortic valve intervention in asymptomatic patients with severe aortic stenosis and evidence on left ventricular (LV) decompensation as defined as mid-wall fibrosis on cardiac magnetic resonance imaging (MRI). Patients will be screened for likelihood of myocardial fibrosis using plasma high sensitivity cardiac troponin (hsTnI) and ECG demonstrating left ventricular strain pattern. An observation arm will consist of patients without evidence of LV decompensation on cardiac MRI.

The primary endpoint is a composite of all-cause mortality or unplanned aortic stenosis-related hospitalisation between randomisation and final follow up visit for study participants with mid-wall fibrosis.

This project will look at the optimal timing for valve replacement in severe aortic stenosis based on sub-clinical LV decompensation, which is currently based on the development of symptoms.

Project Title	Early detection of sepsis in the Emergency Department using data analytics
Principal Investigator	Matt Anstey
Institution	Sir Charles Gairdner
Approval Date	04 November 2021

We aim to explore whether
1. Free text descriptions entered by the triage nurse may contain terms that increase the probability of a patient having sepsis, and furthermore, requiring admission to hospital or the intensive care unit.
2. Whether addition of available data at the point of triage improves the discrimination of the tool (from a subset of patients, both admitted and discharged, with a diagnosis of an infection/sepsis, we will review their medical charts for the first recorded heart rate, blood pressure and lactate (if possible).

We will link and then deidentify the Emergency Department and Hospital admission datasets, to use data analytic techniques to explore these associations.

Project Title	Pilot study of fibroblast activation factor expression in recurrent/ progressive pancreatic cancer and mesothelioma using [68Ga]Ga-FAPI-46 PET imaging.
Principal Investigator	Laurence Morandeau
Institution	Sir Charles Gairdner Hospital
Approval Date	10 November 2021

Fibroblast Activation Protein (FAP) is overexpressed in cancer-associated fibroblasts in several tumour entities. [68Ga]Ga-FAPI-04 (FAP Inhibitor), a novel PET imaging tracer has shown remarkably high tumour uptake in 28 different types of cancer-associated fibroblast combined to low uptake in normal tissue. 68Ga]Ga-FAPI-46 was later developed with enhanced tumour uptake and retention for use as a theranostic (combination of imaging and therapy) agent. In this pilot study we are interested in the potential of [68Ga]Ga-FAPI-46 for imaging pancreatic cancer and malignant pleural mesothelioma and its application in the treatment of these two cancer types.

This prospective pilot study will compare conventional PET/CT imaging tracer [18F]FDG with [68Ga]Ga-FAPI-46 in a cohort of 30 patients with advanced pancreatic cancer or mesothelioma.

The primary objectives of this study are to:
1. Characterise patterns of fibroblast activation protein (FAP) expression in advanced pancreatic cancer and mesothelioma.
2. Compare FAP expression in tumour using [68Ga]Ga-FAPI-46 PET with [18F]FDG tumour uptake, in patients with advanced pancreatic cancer or mesothelioma.
3. Gain preliminary evidence of [68Ga]Ga-FAPI-46 distribution and tumour uptake for potential theranostic applications.

Project Title	Impact of a structured after-hours multidisciplinary team in a tertiary metropolitan hospital
Principal Investigator	Dr Francis Lee
Institution	Sir Charles Gairdner Hospital
Approval Date	18 November 2021

In this study, we are looking at whether the intervention (the implementation of a structured after-hours multidisciplinary team) made a difference in patient outcomes. The primary outcome is the difference in MET call rates per inpatient activity before and after the implementation of the service, with secondary objectives looking at differences in repeat MET call rates, ICU/GHDU rates and mortality rates per inpatient activity in our tertiary metropolitan hospital. This will be a quantitative, retrospective before-and-after analysis of data collected by the MET/ICU research nurses.

Project Title	**LEADER PAD** Feasibility Pilot
Principal Investigator	Shirley Jansen
Institution	Sir Charles Gairdner Hospital
Approval Date	06 December 2021
This protocol is to conduct the LEADER PAD FEASIBILITY PILOT trial, a low-risk, open label, two-week trial of low dose colchicine in patients with lower limb peripheral vascular disease. It is confined to SCGH patients. It will involve negligible risk for patients. It will run for an accrual period of 3 months. It will be a stand-alone trial but will provide valuable data to confirm the feasibility of recruitment for a large international multicentre randomized trial of low dose colchicine versus placebo in lower limb peripheral artery disease and the tolerability of any side effects.	

Project Title	The efficacy of foot mobilisation/preparation on balance responses in healthy young adults
Principal Investigator	Robyn Fary
Institution	SCGH, Curtin university
Approval Date	16 December 2021
This study aims to compare unilateral stance test results between the gold-standard (SMART equitest system) and a smartphone application (SwayApp). This study will recruit healthy adults aged 18-40 years will be recruited. Participants will be asked to perform three trials of unilateral stance test for 10 seconds for each of the following conditions: 1) with eyes open standing on right leg, 2) with eyes open standing on left leg, 3) with eyes closed standing on right leg, and 4) with eyes closed standing on left leg. These trials will be conducted with the participant standing on the SMART EquiTest System while holding a mobile phone on which the Sway App is installed. This means balance will be measured by the two tools at the same time. Participants will also complete a timed (up to 30 seconds) UST standing on the floor. These measures will be done before and after foot mobilisation.	

Project Title	The sedentary behaviour and physical activity patterns of adults in hospital: A prospective observational study
Principal Investigator	Kristie Harper
Institution	Sir Charles Gairdner Hospital
Approval Date	16 December 2021

This research project is a prospective cross-sectional observational study of adults that aims to use the activPAL to examine patterns of sedentary behaviour and physical activity in hospital. This study will allow for rich characterisation of adult activity patterns in hospital and will include a patient and staff survey regarding acceptability of wearing the activPAL. The study will be completed over a 12 month period and will collect data from adult patients that consent to wear the activPAL during their inpatient stay and participate in the survey.

Project Title	An artificial intelligence driven pipeline for adaptive radiotherapy
Principal Investigator	Martin Ebert
Institution	Sir Charles Gairdner Hospital
Approval Date	16 December 2021

The proposed research aims to develop an adaptive radiotherapy pipeline driven by cone-beam CT imagers, taking advantage of the tremendous advances in computer vision based deep learning applications [10-13] to reduce cost burdens on departments whilst outperforming contemporary clinical approaches to online adaptive radiotherapy, the benefits of which have been demonstrated for head & neck, thoracic, and pelvic regions [2, 5, 6]. By reducing uncertainty relating to interfractional anatomic changes, planners can reduce margins added to target volumes and better protect organs-at-risk by adapting the dose distribution based on the current anatomy. This allows for dose escalation to the tumour site, resulting in increased tumour control probability.

Project Title	Assessment of balance, balance confidence, gait and quality of life measures in persons with above-knee amputation, comparing those fitted with an osseointegrated prosthesis to those with a conventional socket prosthesis: A feasibility study.
Principal Investigator	Andrea Becker
Institution	Sir Charles Gairdner Hospital
Approval Date	17 December 2021

This project aims to determine the feasibility of conducting a longitudinal cohort study at Sir Charles Gairdner Hospital (SCGH) to assess balance, balance confidence, gait, and quality of life outcomes of persons with above-knee amputation, comparing those fitted with an osseointegrated prosthesis to those fitted with a conventional socket prosthesis.

Project Title	Evaluation of the utility of the Quantiferon Monitor in predicting infectious complications in patients with Common Variable Immunodeficiency
Principal Investigator	Grace Thompson
Institution	PathWest QEII, Sir Charles Gairdner Hospital
Approval Date	22 December 2021

Common variable immunodeficiency (CVID) is a heterogeneous primary immunodeficiency disorder characterised primarily by humoral immunodeficiency and hypogammaglobulinaemia which leads to the cardinal clinical presentation of recurrent infections. In addition to this multiple other abnormalities in the immune system including both the T cell compartment and the innate immune system have been described in CVID. It is possible that these additional defects may account in part for the significant clinical heterogeneity seen in CVID. Specific antibody deficiency (SAD) is another humoral immunodeficiency disorder in which defects in other areas of the immune system would not be expected. Current assays of T cell and innate immune system function such as proliferation in response to mitogens PHA, ConA and chemotaxis and phagocytosis studies are available but are labour intensive, expensive and not routinely performed in this patient group. The Quantiferon Monitor test is a commercial assay which provides an assessment of the functional immune status of a patient by looking at their ability to produce interferon gamma in response to Toll Like Receptor (one of the innate immune receptors) and T cell receptor agonists. In contrast to currently available assays this test is significantly less labour intensive and time consuming. This assay has been shown to predict patients more likely to suffer with infective complications post solid organ transplantation but has not been, to date, studied in patients with primary immunodeficiencies.

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