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

April to June 2020 Quarter

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Project summaries for proposals approved by the SCGOPHCG Human Research Ethics Committee – April to June 2020 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 April to June 2020 quarter.

Project Title	Virucidal pilot study of Nasodine antiseptic nasal spray(povidoneiodine 0.5%) in people with COVID-19 and confirmed nasal shedding of coronavirus.
Principal Investigator	Associate Professor Peter Friedland
Institution	Sir Charles Gairdner Hospital
Approval Date	09/04/2020
COVID-19 is a respiratory infection caused by SARS-CoV-2, which is believed to be spread primarily through respiratory droplets. The purpose of this pilot study is to provide an initial indication that the in-vitrodisinfectant activity against SARS-CoV-2 virus translates to disinfection of the nasal cavity in-vivo of COVID-19 patients, as well as collect data to guide an understanding of the mechanism of action and how to configure follow-on clinical studies. The study will provide important insights into the potential role for a PVP-I nasal spray in managing the risk of infection by the virus. A total of up to 20 COVID+ patients, who have recently displayed first COVID-19 symptoms and are confirmed by mid-turbinate nasal swab to be shedding virus from the nose, will be recruited.	

Project Title	FASTtrack sepsis diagnosis study
Principal Investigator	Dr Tim Ingliss
Institution	PathWest QEII
Approval Date	15/04/2020
The primary objective of this project is to describe the performance of a multi-pronged clinical laboratory workflow to predict positive blood cultures, allowing early selection of predicted positive cultures for rapid bacterial identification and susceptibility testing. A secondary objective is to assess the turnaround time improvements for clinically critical results, and potential for accelerated critical clinical decisions concerning bacteraemic infections and prediction of sepsis. Due to the need for rapid diagnosis and management of sepsis, the greatest patient benefit likely to be obtained is from the rapid laboratory tests, when the tests are used at the point of hospital admission via the Emergency Department.	

Project Title	The Contribution of Interpersonal Interactions to the Comfort of Patients Attending a Day Surgery Unit: A Grounded Theory Study of the Patient's Perspective
Principal Investigator	Associate Professor Caroline Bulsara
Institution	University of Notre Dame Fremantle
Approval Date	15/04/2020
This grounded theory study will involve in-depth semi-structured interviews with patients attending short stay units (SSUs). The study will form a rich understanding of short stay surgery patients' core concern in regards to their experience of interpersonal interactions and identify their behaviours and responses to address this core concern. In so doing this study will create a novel social, psychosocial substantive theory to explain how patients resolve the identified core concern. The substantive theory will be sufficiently abstract to be applied in other SSUs but, also be location-specific to inform service improvements and inform the refinement of nursing praxis within the SSUs in which the study is undertaken.	

Project Title	The Contribution of Interpersonal Interactions to the Comfort of Patients Attending a Day Surgery Unit: A Grounded Theory Study of the Patient's Perspective
Principal Investigator	Associate Professor Caroline Bulsara
Institution	Sir Charles Gairdner Hospital
Approval Date	15/04/2020
Few studies have used qualitative study methodologies to examine day surgery patient's perceptions of how interpersonal interactions influence the patient's sense of personal control and associated experience of emotional comfort during day surgery. This grounded theory study will involve in-depth semi-structured interviews with patients attending a DSU. The study will form a rich understanding of day surgery patients core concern in regards to their experience of interpersonal interactions and identify their behaviours and responses to address this core concern. In so doing this study will create a novel social, psychosocial substantive theory to explain how patients resolve the identified core concern.	

Project Title	The COVID-19 pandemic: Nurse leaders' experiences of decision-making to prepare a tertiary hospital in Western Australia
Principal Investigator	Dr Susan Slatyer
Institution	Murdoch University
Approval Date	06/05/2020

This qualitative descriptive study aims to explore the experiences and perceptions of nurse leaders as they prepare to meet surge capacity and maintain peak service levels at Sir Charles Gairdner Hospital, Osborne Park Hospital, Fiona Stanley Hospital and Fremantle Hospital during the evolving COVID-19 pandemic. Purposive sampling will be used to recruit nurse leaders across the four hospitals to participate in individual semi-structured interviews conducted via telephone, skype, Facetime, or Zoom. Interviews will last about 30 minutes and capture: the types of decisions nurse leaders are making; factors influencing these decisions; barriers and facilitators to their decision-making; how their decisions are communicated; perceptions of organisational responses; and the professional and personal impact of undertaking this decision-making role during the pandemic. It is envisaged that the findings will articulate the complexity of the decisions nurse leaders must make in preparation for a pandemic, which may assist future nurse leaders at state, national or international levels.

Project Title	**The NIPU Study** - Nivolumab and Ipilimumab +/- UV1 vaccination as second line treatment in patients with malignant mesothelioma (the NIPU study)
Principal Investigator	Professor Anna Nowak
Institution	Sir Charles Gairdner Hospital
Approval Date	08/05/2020

The objective of the phase II study is to induce a meaningful progression-free survival benefit in patients with MPM after progression on first line standard platinum doublet chemotherapy, by treating with nivolumab and ipilimumab with or without UV1.

The participants who will be enrolled in this study have a poor prognosis, with the current standard of care in place being insufficient to improve their prognosis. The combination of a cancer vaccine with immunotherapy as will be done in the current study, might assist in developing new treatment regimes which in turn may aid in the prognosis for this group of patients.

Project Title	Identification of liquid biopsy biomarkers for diagnosis and prognosis of cancer
Principal Investigator	Dr Elin Gray
Institution	Edith Cowan University
Approval Date	08/05/2020

In this study we propose that blood, urine, cerebrospinal fluid (CSF), pleural fluid and ascites represent accessible bio-resources suitable for marker analysis prior to and during treatment. Markers of diagnostic or prognostic significance can be identified through the analysis of cell free DNA, RNA, proteins, platelets, metabolites, exosomes, circulating tumour cells (CTCs) or immune cells. We aim to analyse all the above potential biomarkers in patients affected by melanoma (cutaneous, mucosal and uveal), prostate, colorectal, breast, gynaecological cancer and/or lung cancer in relation with clinical outcomes. Clinical data regarding tumour staging, treatments, blood results, radiological images, co-morbidities and survival will be collected with support by the treating clinician. For comparison purposes, tumour and urine samples will be also collected and analysed. Isolated CTCs from blood, cerebrospinal and/or pleural fluid will be cultured *in vitro* for establishment of cell lines for further studies into the metastatic potential.

Project Title	Identifying risk factors for hepatocellular carcinoma in non-alcoholic steatohepatitis cirrhosis
Principal Investigator	Associate Professor Leon Adams
Institution	Sir Charles Gairdner Hospital
Approval Date	21/05/2020

Liver cancer (or hepatocellular carcinoma – HCC) remains a feared complication of patients who have fatty liver (or non-alcoholic steatohepatitis [NASH]) related cirrhosis, due to its high mortality rate. Factors which predispose to HCC in these patients remain unclear. We aim to identify modifiable risk factors for the development of HCC by comparing demographic, biochemical and liver-specific factors in NASH cirrhosis patients with and without HCC. This will enable the development of a predictive HCC risk score, thereby identifying patients at greatest risk who need increased surveillance for HCC. Secondly, it will identify risk factors which may be modified to reduce future risk of HCC.

Project Title	Central line catheter bacterial colonisation patterns
Principal Investigator	Dr Matthew Anstey
Institution	Sir Charles Gairdner Hospital
Approval Date	21/05/2020

Central line associated bloodstream infections account for thousands of potentially preventable deaths and added costs to the healthcare system every year in all countries. There have been significant efforts to reduce these infections through improved hygiene during insertion, manipulation and handling and frequent inspection to remove unnecessary lines. Antibiotic or silver impregnated catheters, and use of antimicrobial dressings have also become more widely used.

However, there is currently no readily available way of detecting whether a central line has become infected, and confirmation relies on removal of the CVC and sending the tip for microbiological diagnosis. When a central line infection is suspected, the line is removed and the tip is sent for culture. Two techniques are used for diagnosis of catheter tip infection: semiquantitative roll – plate culture or sonication/agitation of the tip in liquid followed by plating and incubation. This study will undertake baseline work to understand the colonization of bacteria on central lines, in order to plan further studies about early detection of CVC infections.

Project Title	Perceptions of loss and grief in tertiary healthcare
Principal Investigator	Ms Pamela Scott-Gale
Institution	The University of Divinity
Approval Date	27/05/2020

The aim of this study is to gather information and evidence through interviewing senior nurses using semi-structured questions at one-on-one interviews to share their lived professional and personal experiences and what they envisage loss and grief education would look like. The researcher will utilise interpretative phenomenological analysis (IPA), which is a qualitative methodology that explores the meaning of the experiences of the research participants. Qualitative research is a method that examines information collected from participant's personal interpretations, stories and explanations of their unique experience and strives to identify themes or ideas within the collected information. IPA advocates the use of smaller numbers of participants, which supports the researcher's time-frame to complete the research project for Masters without jeopardising integrity of the research.

Project Title	ITHACA - EFC15992 A Phase 3 randomized, open label, multicenter study of isatuximab (SAR650984) in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone in patients with high-risk smoldering multiple myeloma
Principal Investigator	Dr Bradley Augustson
Institution	Sir Charles Gairdner Hospital
Approval Date	27/05/2020

Smoldering multiple myeloma (SMM) is an asymptomatic plasma cell disorder, which is a precursor stage of myeloma disease, diagnosed before any symptoms occur. Currently, SMM patients do not have treatment until the development of active Multiple Myeloma (MM). This is a Phase 3 randomized, open-label, multicenter study of isatuximab (SAR650984), lenalidomide and dexamethasone (ILd) versus lenalidomide and dexamethasone (Ld) in participants with high-risk SMM. The primary objective of this study is progression free survival (PFS). Prior to the randomized portion of the study, 20 participants will be treated with isatuximab, lenalidomide and dexamethasone to confirm the isatuximab dose and feasibility of the ILd regimen. After confirmation of the isatuximab dose and eligibility criteria, participants will be randomly assigned in a 1:1 ratio to Isatuximab with Ld or LD. Approximately 300 participants will be randomly assigned to study intervention.

Project Title	Assessing the effectiveness of CNS prophylaxis strategies in patients with diffuse large B-cell lymphoma and CNS-IPI ≥4 and high-grade B-cell lymphoma: a multi-center, retrospective analysis
Principal Investigator	Associate Professor Chan Cheah
Institution	Sir Charles Gairdner Hospital
Approval Date	05/06/2020

This is an international, multi-centre study, which will be a collection of 'real-world' retrospective data in a large group of participants with aggressive lymphoma who share clinical high-risk features for central nervous system progression. The study will investigate the impact of preventative measures against central nervous system lymphoma, with a particular focus on the impact of administering high dose methotrexate.

The central nervous system international prognostic index (CNS-IPI) is widely used in clinical practice to guide which patients may benefit from additional therapeutic intervention to reduce their risk of CNS lymphoma relapse. However, despite the score being widely adopted into clinical practice, there remains little consensus as to which patients are truly ‘high risk’ and therefore which patients should be offered CNS prophylaxis, what therapy they should be offered, and how treatment should be incorporated into systemic lymphoma therapy.

Project Title	Akesobio 201: A Phase 2, multicenter, single-arm, open-label study to evaluate the efficacy and safety of AK104 in subjects with recurrent or metastatic cervical cancer
Principal Investigator	Dr Tarek Meniawy
Institution	Sir Charles Gairdner Hospital
Approval Date	05/06/2020

This is a Phase 2, global, multicenter, open-label, single-arm study designed to evaluate the efficacy, safety, tolerability, pharmacokinetic (PK), and immunogenicity of AK104 monotherapy in adult subjects with previously treated recurrent or metastatic cervical carcinoma.

Approximately 40 subjects with recurrent or metastatic cervical cancer who had disease progression during or following prior platinum-based doublet chemotherapy with or without bevacizumab will be enrolled in this study.

Project Title	Midodrine for the prevention and treatment of orthostatic hypotension after total hip arthroplasty (MiHip study).
Principal Investigator	Dr Dale Currigan
Institution	Sir Charles Gairdner Hospital
Approval Date	12/06/2020

A significant number of patients have delayed mobilisation following surgery for total hip replacement. A common, and potentially preventable, cause of failure to mobilise is orthostatic hypotention and orthostatic intolerance. Treatment options for orthostatic hypotension are limited. They include bed rest and intravenous (IV) fluids. IV drugs to raise blood pressure are effective but can only be administered in high dependency areas with limited resources.

One potential simpler and cheaper alternative is oral midodrine. Midodrine is an oral drug that binds to α1-receptors in blood vessels to increase blood pressure. Our hypothesis is that midodrine will improve success at achieving independent mobilisation following hip arthroplasty predominantly by improving orthostatic tolerance. We intend to conduct a prospective, single centre, double-blinded, placebo-controlled, randomised trial, to assess if midodrine 20mg orally, given 2 hours prior to physiotherapy on day 1 post-op, is superior to placebo, in achieving successful 5m independent mobilisation.

Project Title	SAfety, toleraBility and effect on inflammatory marker of Colchicine in Individuals with Chronic Kidney Disease
Principal Investigator	Dr Wai Lim
Institution	Sir Charles Gairdner Hospital
Approval Date	12/06/2020

Death from heart disease is up to 40-times higher in patients with chronic kidney disease (CKD) compared to age-matched general population. To date, effective treatments that target known traditional heart disease risk factors such as high cholesterol and high blood pressure have been largely disappointing with substantial residual burden of heart disease-related hospitalisations and deaths, suggesting the urgent need for novel treatment that may reduce the risk of heart disease and related complications in patients with CKD. Colchicine is widely used in the treatment of gout and there is increasing trial-based evidence to suggest that colchicine may reduce complications from heart disease in the general population. Before a trial can be designed to answer the question of whether colchicine can reduce the incidence of heart disease in patients with CKD, it is essential to determine the safety, tolerability and effect on inflammatory markers of colchicine in these patients

Project Title	Staff lived experience of working in an Australian tertiary adult intensive care unit during the COVID-19 pandemic - a phenomenology study
Principal Investigator	Ms Jing Ning
Institution	Sir Charles Gairdner Hospital
Approval Date	25/06/2020

The aim of this study is to explore and document the lived experience of staff working in an Australian adult ICU during the COVID-19 pandemic. The proposed study will document and describe staff lived experience of working in the ICU during the COVID-19 pandemic, and explore their emotional and psychosocial journeys. The results will serve as an acknowledgement and validation of staff experience, their shared feelings, stresses and challenges during the pandemic. Study findings may assist in future pandemic planning, and influence policy-making and resource allocation to help build resilience in these frontline healthcare workers in both crisis and non-crisis situations.

Project Title	Does Physiotherapy led exercise prehabilitation reduce cancer surgery patients' length of stay and risk of post operative complications?
Principal Investigator	Ms Luisa Perrella
Institution	Sir Charles Gairdner Hospital
Approval Date	25/06/2020

Elective upper abdominal surgery (UAS) is planned surgery involving an open incision above the umbilicus, generally used to remove abdominal cancer. These are usually large surgeries that impose high metabolic demand, long anaesthesia time and substantial periods of post-operative recovery, including care in the intensive care unit (ICU). Prior to these surgical procedures the implementation of presurgical neoadjuvant chemoradiation treatment (CRT) is common practice, and may be associated with a reduction in physical capacity, lean mass and increased fatigue.

The goal of this pilot study is to implement an active physiotherapist-led supervised six week prehabilitation exercise program for patients scheduled to undergo complex UAS during their CRT phase, and measure their functional improvement preoperatively and as they recover, post-surgery. There will be pre and post-exercise program assessment, and the program will include resistance and aerobic training.

Project Title	Determining novel markers of bone marrow failure in myeloproliferative neoplasms
Principal Investigator	Professor Wendy Erber
Institution	PathWest QEII
Approval Date	25/06/2020

Myeloproliferative neoplasms (MPN) are a group of bone marrow cancers where the marrow's ability to make blood is affected. MPN can progress from over-producing blood cells to failure to make new cells as a result of marrow fibrosis (scarring) or acute myeloid leukaemia. At this stage, treatment options are limited and most therapies only provide symptomatic relief. Currently we are unable to predict which patients will progress to these end-stages or when, as the processes that lead to fibrosis and leukaemia are poorly understood. If we can identify at-risk patients, personalised interventional strategies may be able to be introduced leading to improved outcomes and quality of life

This study aims to perform sequential studies of megakaryocytes, platelets and CD34 cells in patients with MPN to identify changes associated with and which may predict disease progression. This may lead to the generation of new and more sensitive diagnostic and prognostic tests.

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