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 2020 Quarter

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

Project Title	Is there a role for gait aids to improve stability and reduce falls risk for older people with dementia? Hospital staff survey and case study analysis of the final algorithm
Principal Investigator	Dr Den-Ching Angel Lee
Institution	Monash University
Approval Date	01/07/2020

Research indicates that appropriate use of a gait aid can improve walking stability for people with balance impairment. There are additional benefits to using a gait aid, for example, it can significantly improve the quality of life of older adults by allowing greater ability for ambulation and social participation. Yet some research indicates that gait aid use may be independently associated with increased fall risk in people with dementia.

This research aims to fill the evidence gap to guide clinical decision making among hospital and community care staff regarding appropriate gait aid use for people with dementia who have balance or gait impairments, and to support decision making regarding gait aid use for people with dementia by informal caregivers. It also aims to improve current practice in gait aid recommendations for this population with high risk of falls and injurious falls, with the overall goal of improving quality of life for people living with dementia and their caregivers.

Project Title	The Noisy Guts Project: A feasibility study for the use of an acoustic belt for differential diagnosis of gastrointestinal diseases and disorders.
Principal Investigator	Professor Barry Marshall
Institution	The University of Western Australia
Approval Date	01/07/2020

Irritable bowel syndrome (IBS) is a gut function disorder which causes chronic pan, bloating, diarrhoea and constipation. IBS affects 11% of the world's population and is notoriously difficult to diagnose, because it causes no obvious structural changes.

An acoustic belt and associated software will be used to analyses gut noises. This allows researchers to tell apart people with healthy guts and IBS with 91% accuracy. However, IBS diagnosis also involves differentiation between IBS and organic diseases, with similar symptoms. The objective of this

study is to develop and test the differential diagnosis capabilities of the acoustic belt. Researchers will collect gut sound recordings from patients with coeliac disease, Crohn's disease and ulcerative colitis at the time of diagnosis by gastroenterologists. Features from the sound recordings will be used to build optimal models (software) that characterise the conditions, with the accuracy of these models tested with a new set of study participants.

Project Title	Persistent lung and arterial inflammation following COVID-19 pneumonia (04057)
Principal Investigator	Dr Roslyn Francis
Institution	Sir Charles Gairdner Hospital
Approval Date	03/07/2020

Inflammation has an important role in the development and progression of cardiovascular disease. COVID-19 is associated with a high rate of lung infection (pneumonia), and it is uncertain for how long the inflammatory changes of pneumonia remain in the lungs once people have recovered from their symptoms and whether this is associated with adverse long-term outcomes. This study aims to determine if there are persistent areas of inflammation in the lungs in patients who have recovered clinically from COVID-19 pneumonia, and also to assess whether there is evidence of increased blood vessel inflammatory activity in these patients, which may be a predictor of increased risk for future heart disease. ^{18}FDG-PET/CT is an imaging test which is very sensitive to detection of inflammation. In this study, it is proposed that ^{18}FDG-PET/CT imaging is performed at 30 days after COVID-19 infection, when patients will have clinically recovered from the disease. Previous studies with community acquired pneumonia have shown that 68% of patients who had clinically recovered from pneumonia still had persisting lung inflammatory changes on ^{18}FDG-PET/CT imaging at 30-45 days after the infection. Based on this experience, it appears very likely that there will be persisting inflammatory lung changes post COVID-19 pneumonia.
This study will also measure the inflammatory activity of the aorta, in order to determine if there is evidence of increased blood vessel inflammation post COVID-19

Project Title	First Few "X" research study to enhance the public health response to COVID-19 in Australia
Principal Investigator	Jodie McVernon
Institution	The University of Melbourne
Approval Date	08/07/2020

Public health units around the country are urgently collecting detailed information on confirmed cases of COVID-19 and their household contacts to help support the public health and clinical response to the COVID-19 pandemic. This activity, co-ordinated through the Australian Government Department of Health, is known as the 'First few X' (FFX) study, and in total should involve a few hundred cases

and their household contacts. The Australian FFX study is based on a World Health Organisation protocol and is one of many similar studies being conducted worldwide.
The overall aim of 'First Few X' studies is to gain an early understanding of the infectiousness and severity of the first few hundred cases of COVID-19 presenting in different countries around the world. This information helps to support international understanding of this new disease. The generated information helps to support international understanding of this new disease and within Australia, it will be used to guide public health recommendations, and support preparedness planning in hospitals and other parts of the health service, to ensure that needed care is available for patients throughout the epidemic.

Project Title	Cross-sectional association between measures of sleepiness in obstructive sleep apnoea and cardiovascular disease
Principal Investigator	Nigel McArdle
Institution	Sir Charles Gairdner Hospital
Approval Date	20/08/2020
We aim to study the association between obstructive sleep apnoea (OSA) and heart disease. OSA is a common condition which occurs when the throat repeatedly collapses during sleep, which interrupts sleep and causes drops in the levels of oxygen in the blood. OSA can cause sleepiness during the daytime in some but not all people with the condition. Heart disease is the major cause of death in the world and occurs more commonly in people with OSA. A number of studies now suggest it may be the sleepy OSA people that are most likely to get heart disease. However, sleepiness is not easy to assess and the best way to assess sleepiness in OSA is unknown. We wish to understand whether some measures of sleepiness are better than others to work out which people with OSA are most likely to also have heart disease.	

Project Title	**DREAMM3 -** Protocol Title: A Phase III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Single Agent Belantamab Mafodotin Compared to Pomalidomide plus Lowdose Dexamethasone (pom/dex) in Participants with Relapsed/Refractory Multiple Myeloma (RRMM) (03823)
Principal Investigator	Bradley Augustson
Institution	Sir Charles Gairdner Hospital
Approval Date	26/08/2020
This is an open-label, randomised study for evaluating the efficacy and safety of single agent belantamab mafodotin when compared to pomalidomide/dexamethasone (pom/dex) in participants with Relapsed Refractory Multiple Myeloma RRMM. Participants will be randomised in a 2:1 ratio to receive either single agent belantamab mafodotin or pom/dex. Participants in both arms will be	

treated until disease progression, death, unacceptable toxicity, withdrawal of consent, and lost to follow-up or end of study, whichever comes first. Approximately up to 380 participants will be randomised.

Project Title	**NAVIGATE:** A Phase 2 Basket Study of the Oral TRK Inhibitor larotrectinib in Subjects with NTRK Fusion-Positive Tumors (03925)
Principal Investigator	Anne Long
Institution	Sir Charles Gairdner Hospital, Royal North Shore Hospital
Approval Date	28/08/2020
This is a Phase 2, multi-center, open-label study of subjects with advanced cancer harboring a fusion of NTRK1, NTRK2, or NTRK3. This study proposes to evaluate the selective TRK inhibitor larotrectinib in patients with NTRK fusion–positive solid tumor cancers. The primary objective of this research project is to determine the overall response rate (ORR) as determined by an independent radiology review committee and measured by the proportion of subjects with best overall confirmed response of complete response (CR) or partial response (PR) by the Response Evaluation Criteria in Solid Tumors, version 1.1 (RECIST v1.1) or Response Assessment in Neuro-Oncology (RANO) criteria, as appropriate, following treatment with larotrectinib in subjects with an advanced cancer harboring a fusion involving human neurotrophic tyrosine receptor kinase (NTRK)1, NTRK2, or NTRK3 (collectively referred to as NTRK fusions).	

Project Title	Investigating Oncologists' attitudes towards the transition of patients to primary care for treatment follow-up **OTTR**
Principal Investigator	Joshua Dass
Institution	Sir Charles Gairdner Hospital
Approval Date	23/09/2020
The number of people diagnosed with cancer is increasing, and due to improvements in cancer treatments, more patients may survive for many years after completing treatment. As a result, treatment clinics at tertiary centres such as Sir Charles Gairdner Hospital (SCGH) must manage large numbers of both newly diagnosed patients and patients who have entered post treatment follow-up. This Study will provide an understanding of the current follow-up practices and perspectives of oncologists, about the ongoing management of patients who have received cancer treatment. This will be used to inform the development of evidence-based practice and improved patient centred care. Creating a more standardised approach to follow-up after treatment will improve patients' access to follow-up care as the number of cancer survivors continue to increase.	

Project Title	Cancer Treatment Summaries: Development of Electronic Forms for Lung and Lymphoma Survivors (TS-DELL)
Principal Investigator	Leanne Monterosso
Institution	Sir Charles Gairdner Hospital
Approval Date	30/09/2020

There is an increasing awareness that communication between health care professionals and cancer patients is suboptimal, and that important information is often not provided at treatment completion to patients and primary care providers. A key recommendation for all cancer survivors is provision of a survivorship care plan and treatment summary. Optimal Care Pathways have been endorsed by Cancer Australia to guide the delivery of consistent, safe, high-quality and evidence-based care for people with specific tumour types. Within the Optimal Cancer Care Pathway, Step 5 guides 'Care after initial treatment and recovery' and recommends a treatment summary be provided to the patient and general practitioner (GP).
In the preparatory phase of this project reserachers aim to develop an electronic treatment summary for blood and lung cancer patients. The study will: identify barriers and solutions related to the treatment summary's creation and dissemination; and explore patients', medical specialists' and GPs' experiences of the electronic treatment summary.

Project Title	How much thiamine is enough in malnourished patients receiving total parenteral nutrition? (TIE study)
Principal Investigator	Matthew Anstey
Institution	Sir Charles Gairdner Hospital
Approval Date	30/09/2020

Patients who are malnourished are at risk of thiamine deficiency, which can have serious consequences, such as heart failure or delirium. Traditionally, replacement is given for patients at risk, who are malnourished patients, which includes patients receiving total parenteral nutrition. However, the duration of replacement is "eminence based" and there has only been one study to guide the duration of replacement, which is currently 1 week of intravenous thiamine. This prospective randomized trial would look at thiamine levels in these patients, at baseline, day 3, 7 and 10, and assign them to replacement for 3 or 7 days. Patients would be allowed to cross over if they were still deficient in thiamine at day 3. This trial would enhance the reputation of the SCGH TPN team - a multi-disciplinary team with a dietitian, pharmacist and intensive care specialist, as well as providing information to the rest of the world about the ideal duration of thiamine replacement in malnourished patients. The analysis would also include a cost comparison between the two options.

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