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 2021 Quarter

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

Project Title	**PYRAMID-1:** A Phase 3, Randomized, Open-label, Multicenter Study of the Efficacy and Safety of Pyrotinib versus Docetaxel in Patients with Advanced Non-squamous Non-small Cell Lung Cancer (NSCLC) Harbouring a HER2 Exon 20 Mutation who Progressed on or after Treatment with Platinum Based Chemotherapy
Principal Investigator	Kevin Jasas
Institution	Sir Charles Gairdner Hospital, Royal North Shore Hospital, St Vincent's Hospital
Approval Date	15 January 2021
This is a randomized, controlled, open-label, international multi centre, Phase 3 clinical study to compare the efficacy and safety of pyrotinib versus docetaxel in patients with advanced non-squamous NSCLC harbouring a HER2 exon 20 mutation who progressed on or after treatment with platinum-based chemotherapy. Primary endpoint is that progression-free survival be evaluated by the blinded independent review committee (BIRC) based on Response Evaluation Criteria in Solid Tumours Version 1.1 (RECIST v1.1).	

Project Title	**ESCALADE - Acerta ACE-LY-312** - A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Acalabrutinib in Combination with Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in Subjects ≤65 Years with Previously Untreated Non-Germinal Center Diffuse Large B-Cell Lymphoma
Principal Investigator	Chan Cheah
Institution	Sir Charles Gairdner Hospital
Approval Date	29 January 2021
This Phase3, randomized, double-blind, placebo-controlled, study will evaluate the efficacy & safety of acalabrutinib plus R-CHOP as compared with placebo plus R-CHOP in patients ≤65 years of age with previously untreated, non-Germinal centre B-cell DLBCL. This is a global multicenter study with approx 250 sites & 600 patients. Patients will be randomized to study treatment only after gene expression profiling-confirmation of non-GCB DLBCL.	

Patients will be randomized in a 1:1 ratio into 2 treatment arms to receive either acalabrutinib in combination with R-CHOP (Arm A), or placebo in combination with R-CHOP (Arm B). Patients will receive treatment in the study for up to 8 cycles. After completion or discontinuation of treatment patients will be followed-up every 4 months for the first 3 years and every 6 months for another 2 years thereafter. Clinical assessments will be performed, collection of blood, imaging scans every 4 months for 3 years, then every 6 months for another 2 years.

Project Title	Virtual reality training for early identification and de-escalation of violent and aggressive behaviour in WA Emergency Departments
Principal Investigator	Brennan Mills
Institution	Sir Charles Gairdner Hospital, Fiona Stanley Hospital, Royal Perth Hospital, Rockingham General Hospital
Approval Date	02 February 2021

This project aims to determine the effectiveness of an alternative method of training early aggression identification and de-escalation techniques for frontline emergency department healthcare workers utilising virtual reality (VR) technology. Frontline emergency department workers will be exposed to a VR education and training resource created by Edith Cowan University, funded by the WA Department of Health. Evaluative data on training efficacy and suggested changes to be made prior to resource finalisation will be obtained. VR training can be made readily available to hospital workers to be completed in their own time, working to better prepare healthcare workers to identify and de-escalate potentially violent situations.
This project will expose frontline healthcare emergency department workers from Fiona Stanley, Rockingham General, Royal Perth, Joondalup and Sir Charlie Gairdner Hospitals to a novel virtual reality education and training package. Pre- and post-training exposure surveys will be completed, as well as a follow-up online survey 3-months after initial data collection.

Project Title	The impact of patient bed moves on nurse-sensitive outcomes: An economic evaluative
Principal Investigator	Gemma Doleman
Institution	Sir Charles Gairdner Hospital
Approval Date	04 February 2021

In recent times, hospital occupancy has increased to full capacity, which has resulted in managers using bed management strategies, such as shortening length of stay and transferring of patients to other units, to augment patient flow through the organisation. The impact of patient transfers and bed space moves on nurses' ability to safely monitor patients and intervene when necessary is not well known, although

some research has linked it to an increase in negative patient outcomes and greater costs associated with patient care. The aim of this study is to identify the impact of patient transfers and bed space moves on the development of a nurse-sensitive outcome and the economic impact of these transfers and bed space moves for the healthcare system.

Project Title	Proteins related to COVID-19 infection and response
Principal Investigator	Scott Bringans
Institution	Harry Perkins Institute
Approval Date	12 February 2021

The proposed research seeks to identify potential biomarkers in moderate and severely infected COVID-19 patients and to predict susceptibility and severity of response from a proteomics perspective. The plasma and any biological specimens will be collected from moderate, severe and critical COVID-19 patients as the source of samples for analysis. The project has been designed to identify protein biomarkers that have significantly different concentrations when comparing a healthy control group against COVID-19 positive patients from moderate, severe and critical groups. This project could also enable earlier medical intervention in patients through identification of those patients susceptible to a severe or critical infection, leading to significant improvements in patient outcomes.

Project Title	Optimising donor cornea preparation and testing the use of Rho-kinase inhibitors to improve the longevity of endothelial grafts for corneal transplantation.
Principal Investigator	Lisa Buckland
Institution	Lions Eye Institute
Approval Date	12 February 2021

This project will firstly examine the effects of various processes on endothelial cell viability during the preparation of endothelial grafts in order to optimise this procedure for transplantation. Further, we will test the potential of Rho-kinase inhibitors, which have been shown to promote wound healing and proliferation of corneal endothelial cells, to improve the longevity of endothelial grafts.

Project Title	Myocardial protective effect of pre-operative melatonin in CABG surgery: A randomised controlled trial
Principal Investigator	Marli Smit
Institution	Sir Charles Gairdner Hospital
Approval Date	19 February 2021
This study is a prospective, randomised, double-blind, placebo-controlled, phase 2 study investigating the oral, preoperative administration of melatonin in order to better understand whether it provides cardiovascular benefit, particularly in the context of reducing reperfusion injury. This study will randomly allocate participants to receive either placebo, low dose (10mg) or higher dose (30mg) melatonin prior to CABG surgery. Participants will be asked to provide blood pre- and post-operatively, at 12, 24 and 48 hours post-surgery. These bloods will be analysed to assess the presence of anti-oxidative and anti-inflammatory biomarkers. Participant's outcomes will also be tracked and analysed.	

Project Title	An investigator initiated and conducted, prospective, multicentre, randomised, outcome-blinded, study of antiplatelet *monotherapy* in patients with a history of stroke due to intracerebral haemorrhage (ICH)
Principal Investigator	Prof. Graeme Hankey
Institution	Sir Charles Gairdner Hospital, Austin Health, Fiona Stanley Hospital, Royal Adelaide Hospital, Liverpool Hospital
Approval Date	19 February 2021
The aim is to determine if antiplatelet monotherapy is of overall net benefit in reducing the incidence of serious vascular events compared to avoiding antiplatelet therapy for adults with a history of a previous stroke due to spontaneous (non-traumatic) intracerebral haemorrhage (ICH). The study design is an investigator led, multicentre, prospective, randomised, open-label, blinded outcome (PROBE), parallel-group clinical trial. The expected outcome is that survivors of spontaneous (non-traumatic) ICH will be shown to have vascular disease(s) that predispose(s) them to future vaso-occlusive, ischaemic vascular events, which can be reduced by prophylactic antiplatelet therapy without increased risk of recurrent ICH.	

Project Title	Immediate effects of the MetaNeb® on regional lung perfusion, ventilation and other measures of lung function compared to those of huff and cough in adults with stable cystic fibrosis.
Principal Investigator	Naomi Chapman
Institution	Sir Charles Gairdner Hospital
Approval Date	19 January 2021
This study will be a single-group, mechanistic cross-over study in 20 adults with stable CF (i.e. have not had a flare up of their lung disease in the last four weeks). The objective of this study in this population is to examine the effect of a single 30-minute session using the MetaNeb® versus a single session of directed huff and cough (control) on the primary outcome of lung structure, regional perfusion and ventilation and secondary outcomes of respiratory mechanics, airflow obstruction, sputum expectoration and symptoms related to CF. Our hypothesis is, in this population, a single MetaNeb® treatment, will be more effective in changing and/or improving these primary and secondary outcomes than control treatment alone.	

Project Title	Development and validation of a visuoperceptual measure for the analysis of the Videofluoroscopic Swallow Studies for adults with dysphagia
Principal Investigator	Katina Swan
Institution	Sir Charles Gairdner Hospital, Townsville Hospital
Approval Date	05 March 2021
This project will validate a newly developed measure used for analysis of videofluoroscopic swallow studies (a moving x-ray of swallow, known as VFSS) for adults with dysphagia (swallowing disorders). A total of 300 patients across three countries, who were scheduled to have a VFSS as part of their standard care for dysphagia, will be recruited prospectively. Part of their VFSS procedure will be conducted according to a standardised protocol, to ensure consistency between sites and eliminate the possibility of variations in scores being due to test administration practices rather than measure instability. The recording of the standardised component of the VFSS will be anonymised and rated by three members of the research team using the new VFSS measure. The results of these ratings will be pooled and the psychometric properties of the new measure will be established, to assess suitability for wide-spread use in clinical practice.	

Project Title	Investigating needs, access, awareness, and use of psychosocial support by Western Australians living with a solid cancer diagnosis and their caregivers: A cross-sectional study
Principal Investigator	Professor Georgia Halkett
Institution	Sir Charles Gairdner Hospital, Curtin University
Approval Date	23/03/2021

This study aims to investigate the needs and support service awareness and use by people living with solid tumour cancers in Western Australia, and their caregivers. The secondary aim of this project is to examine advanced cancer as a predictor of unmet need, distress, and support service use. The specific project objectives are to:

1. Describe the supportive care needs and support service awareness and use of adult Western Australians living with a solid tumour cancer diagnosis and their caregivers
2. Identify predictors of unmet need, distress, and support service awareness and use for adult Western Australians living with a solid tumour cancer diagnosis and their caregivers
3. Examine advanced cancer as a predictor of greater unmet need, distress, and support service use
4. Describe the costs of accessing supportive care experienced by Western Australians living with a solid tumour cancer diagnosis and their caregivers

Project Title	Evaluation of the ICMP SNP Panel and Next Generation DNA Sequencing for the Identification of Distant Family Members and DNA Analysis of Highly Degraded Human Remains in Forensic Casework
Principal Investigator	Dr Jasmine Tay
Institution	PathWest
Approval Date	29/3/2021

This study is investigating a new next generation DNA sequencing (NGS) method of forensic DNA human identification comparing single nucleotide polymorphisms (SNPs). SNPs are single base-pair mismatches in DNA sequences between individuals which are smaller than STRs. SNPs are highly abundant in our DNA, and different groups of SNPs provide information on a person's appearance such as hair and eye colour, ethnicity or family relations between people. As such, the chances of obtaining useful leads in forensic investigations using SNP analysis from highly degraded DNA are higher.

Project Title	Effects of CPAP Therapy on Blood Pressure and Heart Rate Variability in Obstructive Sleep Apnoea: Role of Symptom Subtypes
Principal Investigator	Prof Nigel McArdle
Institution	Sir Charles Gairdner Hospital, Royal North Shore Hospital (NSW)
Approval Date	18/3/2021
The current study will offer CPAP therapy to all eligible subjects as part of routine clinical care. Not all patients accept CPAP therapy but we will follow them up irrespective of whether they accept therapy. Data will be collected on all patients who accept CPAP therapy and on those who do not. This information includes the OSA symptoms that may be important to the chance of developing heart disease. We will match these groups using a sophisticated statistical method (propensity score matching) which mimics a randomised controlled trial.	

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