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 2022 Quarter

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

Project Title	The use of post-operative imaging to guide the audiological mapping of cochlear implantation recipients
Principal Investigator	Jafri Kuthubutheen
Institution	Sir Charles Gairdner Hospital, Fiona Stanley Hospital, Royal Perth Hospital, Fremantle Hospital Health Service
Approval Date	12 January 2022

A small number of studies have shown that postoperative CT guided cochlear implant mapping may provide individualised pitch mapping to cochlear implant (CI) recipients4,5. These studies suggest that an image-based approach toward cochlear implant mapping may improve pitch perception outcomes by reducing place-pitch mismatch.

This study aims to study this relatively new method in our cochlear implant recipients to determine if improvement in hearing outcomes can be achieved. A post-operative low dose CT scan of the ear will be performed in recruited patients. CT scans of the temporal bones are not uncommonly used after cochlear implantation to check the position of the electrode after surgery and to exclude complications. However, the use of the CT scan to aid with cochlear implant mapping to aid programming of the device has not been performed routinely.

This study will investigate the use of low dose postoperative CT imaging in combination with OtoPlan software in the CI programming to improve hearing outcomes.
The study hypothesis is that image guidance can improve tonotopic pitch matching during CI mapping improving hearing outcome and quality of hearing. This method allows specialised cochlear implantation software to assign a specific frequency to a particular electrode based on its position in the cochlear where it usually codes for a specific frequency if the patient was able to hear normally.

Project Title	Establishing correlation between the Video Head Impulse Test to Functional Gait Assessment in patients with suspected vestibulopathy through a cross-sectional study
Principal Investigator	Cameron Mead
Institution	Sir Charles Gairdner, Hospital, Fiona Stanley Hospital
Approval Date	19 January 2022
This study aims to establish correlation between assessment measures used in individuals with vestibulopathy. Individuals with suspected vestibulopathy will be recruited to examine correlation between the diagnostic test of Video Head Impulse Test (vHIT) and the rehabilitation dynamic balance assessment of the Functional Gait Assessment (FGA). Within the current literature no correlation has been established, however it is hypothesised that there exists a moderate-to-strong correlation. Importantly, this correlation would enable translation of experimental laboratory-based research to the clinical setting, in turn enabling improved clinical outcomes.	

Project Title	Audit of Patient Blood Management (PBM) implementation in tertiary hospitals: A pilot project in Western Australia.
Principal Investigator	Darren Falconer
Institution	Sir Charles Gairdner Hospital, Women's and Newborns Health Service, Royal Perth Hospital, Fiona Stanley Hospital
Approval Date	28 January 2022
To develop and then pilot an Australian Patient Blood Management (PBM) implementation Assessment Tool and Gap Analysis in tertiary hospitals in Western Australia.	

Project Title	Surveillance, genomic epidemiology and antimicrobial susceptibility of clinically important pathogens in patients with cystic fibrosis and bronchiectasis in Western Australia
Principal Investigator	Anna Tai
Institution	Sir Charles Gairdner Hospital
Approval Date	09 February 2022

Aims

The overarching aim of this project is to establish a program of genomic and phenotypic surveillance for airway (initially for P. aeruginosa) and gastrointestinal tract (C. difficile) pathogens, and to investigate risk factors for severe disease. The information obtained will result in improved health outcomes for patients with CF or non-CF bronchiectasis in WA. This will be achieved by pursuing the following objectives.

Objective 1: Establish a systematic longitudinal airway and gastrointestinal collection of bacterial pathogens from adults with CF or non-CF bronchiectasis in WA.

Objective 2: Use high-resolution WGS to provide enhanced genomic epidemiology of P. aeruginosa and C. difficile strains from patients with CF or non-CF bronchiectasis. Genomic data will facilitate phylogenetic and strain transmission analysis which will be crucial in evaluating the effectiveness of current infection control policies.

Objective 3: Characterise clinically important AMR loci in common P. aeruginosa and C. difficile strains from patients with CF or non-CF bronchiectasis through genotypic/phenotypic correlation of WGS data and in vitro antimicrobial susceptibility phenotype. Identification of these AMR loci will inform the development of novel antimicrobial therapies which targets AMR mechanisms.

Objective 4: Establish a systematic longitudinal blood sample collection from adults with CF or non-CF bronchiectasis in WA and investigate the relationship between airway infection and systemic inflammation in patients with CF or non-CF bronchiectasis.

Project Title	How does Trikafta® effect airway clearance and exercise? The patient perspective.
Principal Investigator	Naomi Chapman
Institution	Sir Charles Gairdner Hospital
Approval Date	15 February 2022

This study will be qualitative in design and recruit 10 to 15 adults with CF who are either currently taking Trikafta® or meet the criteria for accessing Trikafta® and are in the process of applying for access. The objective of this study in the above mentioned population is to explore the lived experience of adults with CF who have access to Trikafta® regarding their symptoms, and need for ACT and inhalation therapy. Participants will be recruited from the adult CF service at Sir Charles Gairdner Hospital (SCGH). Participants who meet the criteria will complete either one 90-minute or two 45-60 minute semi-structured interviews either in person or online. Participant's descriptive characteristics will also be recorded from their medical records. During the interview participants will be asked a series of open-ended questions, particularly related to the symptoms they experienced prior to and while taking Trikafta®, along with questions regarding their previous and current ACT, inhalation therapy and exercise habits. Data collected from this study will contribute important information to the literature regarding ACT while taking Trikafta in adults with CF worldwide.

Project Title	Does adding a FIBTEM/EXTEM Clotting Time ratio >1.0 improve the diagnostic accuracy of the ROTEMsigma® for the identification of hypofibrinogenaemia post cardiopulmonary bypass, compared to using FIBTEM amplitude thresholds alone?
Principal Investigator	James Preuss
Institution	Sir Charles Gairdner Hospital
Approval Date	18 February 2022

Cardiac surgery is associated with conditions where the blood does not clot effectively resulting in bleeding and significant blood loss. There are devices that assess the ability of blood to form clots, one of which is the ROTEM® SIGMA.
The aim of study is to confirm observations and assess if we can improve the accuracy of ROTEM SIGMA to identify patients with low fibrinogen by implementing these new findings. We will include data, previously collected as a part of a clinical governance project, from 120 patients who had simultaneous ROTEM SIGMA and other laboratory tests performed during their cardiac surgery procedure. As all data is collected retrospectively there will be no change to the anaesthetic or surgery procedure the patient undergoes.
Our primary outcome is the diagnostic accuracy (sensitivity, specificity, positive predictive value and negative predictive value) of ROTEM SIGMA to identify patients with a lower than normal blood protein, fibrinogen.

Project Title	SNDX-5613 - A Phase 1/2, Open-label, Dose-Escalation and Dose-Expansion Cohort Study of SNDX-5613 in Patients with Relapsed/Refractory Leukemias, Including Those Harboring an MLL/KMT2A Gene Rearrangement or Nucleophosmin 1 (NPM1) Mutation
Principal Investigator	Carolyn Grove
Institution	Sir Charles Gairdner Hospital
Approval Date	22 February 2022
This study will test an experimental drug called SNDX-5613 in treating patients with Relapsed/Refractory Leukemias.	

Project Title	Inflammation and endocrine function in Intensive Care Survivors: an observational study
Principal Investigator	Matthew Anstey
Institution	SCGH
Approval Date	25 February 2022
Critical illness is associated with dysregulation of the hypothalamopituitary axes, and the more severe the illness, the more disruption that can occur. Furthermore, in ICU survivors, it is estimated that one quarter to one half will suffer from ICU acquired weakness, the result of prolonged catabolism, immobility and critical illness polymyoneuropathy, but is also associated with misalignment between catabolic and anabolic hormones. Testosterone levels in critically ill patients are extremely low, even in the recovery phase from acute illness. Supplementation of testosterone in the recovery phase may assist patients to build muscle strength faster and return to a functional status earlier. Understanding the time points of recovery of these hormones is essential for designing any interventions to improve this.	

Project Title	Mapping Maternal Health and Gynaecological Services in Rural, Regional and Remote Australia: Uptake, Barriers and Recommendations - Research Project.
Principal Investigator	Jared Watts
Institution	WA Country Health Service
Approval Date	10 March 2022
The mapping research project aims to map the geographic distribution of services, the O&G workforce, levels of service, and population demographics in rural, regional and remote Australia; and to explore consumer perspectives on facilitators and barriers when accessing services.	

Project Title	Validation of a digital remote monitoring platform to improve clinical data collection, mental health screening and exacerbation detection in chronic respiratory patients.
Principal Investigator	Wayne Aston
Institution	Sir Charles Gairdner Hospital, Institute of Respiratory Health
Approval Date	18 March 2022

This is a minimally interventional research project that will investigate the use of a remote monitoring platform in order to validate the collection of meaningful clinical data from chronic respiratory patients. Due to the impact of COVID-19 on healthcare provision, new ways of monitoring at risk populations are needed to reduce the likelihood of viral spread.

Standard telehealth technology currently involves either a phone call or video conferencing which is both time consuming and does not provide objective clinical measures to the care team in order to make informed decisions. Hospital clinic visits for respiratory patients are often time-poor which leaves little time for discussion around disease education and the patient's own motivation and management skills to handle a successful treatment regime. This project aims to validate the use of a remote monitoring platform that runs on a smartphone which provides eDiary symptom monitoring, treatment reminders, video coaching on airway clearance and exercises prescribed by the multidisciplinary medical, nursing and physiotherapy team.

Project Title	Australian Genomics of Cardiovascular Disease Risk following Preeclampsia Study
Principal Investigator	Phillip Melton
Institution	Sir Charles Gairdner Hospital, University of Tasmania, Menzies' Institute for Research
Approval Date	18 March 2022

Currently, there is limited research focused on developing effective screening, follow-up, and intervention strategies for women after preeclampsia (PE). The European and American Heart Associations both recommend that at-risk women should educate themselves regarding CVD reduction techniques including improved diet, increased exercise, and smoking cessation. However, more sophisticated studies are urgently required to better understand the biological relationship between PE and CVD as well as to facilitate the appropriate strategies for determining the short- and long-term CVD risk for women following PE. This project addresses the critical gap for understanding the underlying biology between those women who have had PE and their subsequent increased risk of developing later-life CVD.

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