



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 2021 Quarter

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

Project Title	The REsolution of LEft VENTricular thrombus vanguard trial
Principal Investigator	Graham Hillis
Institution	Concord Repatriation Hospital, Flinders Medical Centre, Liverpool Hospital, Royal Perth Hospital, University Hospital Geelong
Approval Date	01/07/2021
<p>The primary aim in the treatment of patients with Left Ventricular (LV) thrombus is to reduce the risk of the clot traveling elsewhere, which can result in a stroke or other major tissue injury by abruptly occluding blood flow. To reduce this risk, the standard treatment is blood-thinning (anti coagulation) with warfarin, but this is inconvenient and increases the risk of bleeding. Newer direct oral anticoagulants (DOACs) are easier for patients to use and in other conditions have been shown to be safer and more effective. There are, however, settings where warfarin remains the better treatment. The first phase of this work is, therefore, to establish the feasibility of the RELEVANT trial, which will test whether DOACs are as good as warfarin in the treatment of LV thrombus. This vanguard trial will hopefully be expanded to greater numbers, pending further successful grant applications.</p>	

Project Title	Associations between novel Polysomnography Metrics in obstructive sleep apnoea with health outcomes
Principal Investigator	Nigel McArdle
Institution	Sir Charles Gairdner Hospital
Approval Date	01/07/2021
<p>Obstructive sleep apnoea (OSA) is common and associated with poor health outcomes, many of which are not well characterised. We are in an excellent position to further investigate these outcomes because of our unique database of 21,000 patients who have undergone sleep studies over the past 20 years (RGS0000001515).</p> <p>The objectives are to determine whether novel markers of OSA severity, and treatment of novel OSA markers, predicts future risk of problems such as heart attacks, strokes, cancers and death, independent of known risk factors.</p>	

Project Title	Phase II, Multicenter, Open-label Safety Study of Bilateral NT-501 in Participants with Macular Telangiectasia Type 2.
Principal Investigator	Ian Constable
Institution	Lions Eye Institute, Royal Victoria Eye and Ear Hospital, Sydney Hospital and Sydney Eye Hospital
Approval Date	19/07/2021

This is a Phase II, Multicenter, Open-label Safety Study of Bilateral NT-501 in Participants with Macular Telangiectasia Type 2. This study will assess whether an experimental bilateral implant (NT-501) which releases Ciliary Neurotrophic Factor (CNTF) can be used to treat the second eye in people with MacTel. CNTF is a small molecule that may help keep some nerve cells in the eye healthy.

Project Title	Neo-antigen immune response in tumour draining lymph nodes, non-tumour draining lymph nodes and peripheral blood in patients with non-small cell lung cancer.
Principal Investigator	Bruce Robinson
Institution	Sir Charles Gairdner Hospital
Approval Date	16/08/2021

This study is a prospective longitudinal pilot cohort study aimed to evaluate tumour neo-antigen specific immune responses in tumour draining lymph nodes (TDLN), non-tumour draining lymph nodes (NTDLN) and peripheral blood in patients with non-small cell lung cancer (NSCLC). Tumour tissue will be sequenced for neo-antigens and TDLNs, NTDLNs and peripheral blood will be analysed for neo-antigen induced immune responses and other immune parameters. Results from the different immune compartments will be compared and correlated with patient outcomes of treatment response, disease free survival/progression free survival and overall survival.

Project Title	Healthcare workers perceptions of aggression and violence in the acute care setting in WA: A cross-sectional survey
Principal Investigator	Amanda Towell-Barnard
Institution	Osborne Park Hospital, Sir Charles Gairdner Hospital
Approval Date	27/08/2021

The aim of this study is to gain an understanding of healthcare workers perceptions of the nature and frequency of aggression and violence in the acute care setting in Western Australia. The need to identify which professions and which areas are particularly at risk will help to target preventative action, training and education of staff, increased security and additional resources where needed but more detailed research is still needed.

Project Title	Does cardiopulmonary exercise testing provide short term prognostic information in advanced cystic fibrosis lung disease?
Principal Investigator	Samantha Crute
Institution	Sir Charles Gairdner Hospital
Approval Date	27/08/2021

The aim of this international, multicentre study is to determine the prognostic value of submaximal and maximal CPET variables in a group of patients with advanced CF lung disease including a careful assessment of known predictors used for selection of LTX candidates. The primary combined endpoint is death/LTX at 2 years after CPET. Secondary endpoints include number of exacerbations, intravenous antibiotic treatments and hospitalisations.

Project Title	Exploring the role of early geriatrician input for older adults with mesothelioma
Principal Investigator	Anna Nowak
Institution	Sir Charles Gairdner Hospital
Approval Date	28/08/2021

This project aims to explore the role of early geriatrician input for older patients with mesothelioma. Specifically, the project aims to investigate whether early geriatrician assessment impacts cancer and non-cancer care of the patient, and detection of age-related issues such as cognitive impairment, falls, mobility issues, polypharmacy, depression and functional impairments.

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	01/09/2021

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 identify 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	Patient and family's perceptions of their involvement in nursing bedside handover – a case study
Principal Investigator	Manonita Ghosh
Institution	Sir Charles Gairdner Hospital
Approval Date	09/09/2021

This study will measure the patient and family's involvement in bedside handover and highlight the strengths and weaknesses of the current bedside handover practices in SCGOPHCG. Examining patient and family's perceptions will provide information for SCGOPHCG to inform future bedside handover processes to address patient needs and encourage their participation. Understanding this information will drive local policy development to adequately fund for nursing education and skill development in communication and consumer involvement to provide patient-centred care.

Project Title	Does patient activation matter? An examination of the relationships between patient activation and healthcare use in older adults with mild frailty after discharge from an Emergency Department.
Principal Investigator	Kristie Harper
Institution	Sir Charles Gairdner Hospital
Approval Date	13/09/2021
<p>Question: Can patient self-management ability measured using the Patient Activation Measure (PAM®) predict early ED representations and future healthcare use in older adults attending the ED?</p> <p>Methodology: A prospective observational study design where the PAM® will be completed with patients in the ED. The primary outcome variable is time to ED representation within 30 days of enrolment.</p>	

Project Title	Validation of a Rapid Colorimetric & Fluorometric RT-LAMP Protocol for large scale SARS-coV2 surveillance testing on the Avicena Sentinel Instrument
Principal Investigator	Paul Watt
Institution	PathWest, QEII
Approval Date	13/09/2021
<p>The research project is aiming to evaluate the accuracy of a convenient and rapid saliva test designed for application in large scale surveillance settings to detect infection from viruses such as the COVID-causing virus SARS-coV2. The particular LAMP test we are evaluating in this trial (the Hayat Genetics <i>Rapid Colorimetric & Fluorometric One Step LAMP SARS-CoV-2 Test</i>), was designed to detect the genome of SARS-CoV-2 in upper respiratory specimens (such as nasal and nasopharyngeal swabs) and saliva). This LAMP test has already obtained European regulatory approval (as a CE Marked IVD diagnostic test), but currently can only be run at a scale of up to 96 samples at a time. Avicena Systems have developed a robotic instrument known as the 'Sentinel' to run thousands of LAMP tests each hour for surveillance applications in high traffic locations such as airports and entertainment venues. This study is designed to confirm the accuracy of the Hayat Genetics saliva test run on the Avicena Sentinel Instrument, when compared against the RT-PCR gold standard on the same saliva samples.</p>	

Project Title	A mixed methods study to establish older women's view on frailty and an Emergency Department evidence-based frailty intervention team (FIT) program.
Principal Investigator	Kristie Harper
Institution	Sir Charles Gairdner Hospital
Approval Date	28/09/2021

The aim of this project is to use the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework (17-18) to evaluate the effectiveness of an evidence-based frailty intervention (FIT) tailored to female older adults. This will involve a prospective mixed methods approach for a three-month period. These pilot data will be utilised to further develop intervention and services provided in the ED setting.

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