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 2021 Quarter

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

Project Title	Digital Image Analysis of Ki67 and visual analysis of PHH3 as adjunctive tools for grading of breast carcinoma in core biopsies.
Principal Investigator	Nathan Harvey
Institution	PathWest QEII
Approval Date	08/04/2021
The aim of this project is to determine if the histological grading of breast cancer on core biopsy can be improved through the use of digital image analysis (DIA) of a proliferation marker, Ki-67 and by visual counting of a mitosis marker, phosphohistone H3 (PHH3), stained by immunohistochemical techniques (IHC).	

Project Title	Understanding the incidence, prevalence and rates of progression of chronic kidney disease in Western Australia
Principal Investigator	Aron Chakera
Institution	PathWest QEII, Sir Charles Gairdner Hospital
Approval Date	08/04/2021
This project aims to develop a Chronic Kidney Disease (CKD) Patient Registry to examine the life course of patients with CKD to inform evidence-based clinical recommendations to support the continuum of care and enhance the long-term health and quality of life of CKD patients in Western Australia. This study will create a state-wide dataset using pathology data from the Western Australian population. The profile of patients with CKD in Western Australia will help determine the rate and progression of CKD and availability of appropriate treatment services. This will also generate a baseline dataset for future research to inform practitioners and researchers about CKD health service utilisation, cost and patient outcomes.	

Project Title	Adherence to CFTR modulator therapy in patients with Cystic Fibrosis in Australia
Principal Investigator	Natalia Popowicz
Institution	Alfred Hospital, Canberra Hospital, Gold Coast University Hospital, Gosford Hospital, John Hunter Hospital, Monash Health, Royal Adelaide Hospital, Royal Prince Alfred Hospital, Sir Charles Gairdner Hospital, The Prince Charles Hospital, Westmead Hospital
Approval Date	20/04/2021
Cystic fibrosis (CF) is the most common genetic disease in Caucasian populations. Cystic fibrosis transmembrane conductance regulator (CFTR) modulators are a novel drug class that target the underlying defects of this genetic disease. This project aims to evaluate adherence to CFTR modulator therapy in adult patients with CF in Australia. Specific outcome measures include to 1) report adherence to CFTR modulators as well as concomitant CF medications 2) compare respiratory related health outcomes, at different levels of CFTR modulator adherence and 3) investigate factors that are potentially associated with CFTR modulator adherence.	

Project Title	Impact of missed nursing care: A Western Australian study
Principal Investigator	Alfia Sarpong
Institution	Sir Charles Gairdner Hospital
Approval Date	21/04/2021
Missed nursing care has increased across health care systems in the past two decades mainly due to insufficient staffing and poor resources. Evidence suggests that missed care is often associated with adverse patient outcomes such as a higher risk for falls, pressure injuries, medication errors and increased length of hospital stay. The study aims to; (1) identify nurses and patients perceptions of missed care on acute medical and surgical wards, (2) explore possible causes for missed care, (3) identify the role of nurse staffing in adverse patient outcomes, and (4) to identify the relationship between perceived missed care, nurse staffing and adverse patient outcomes in Western Australia.	

Project Title	Implementing the 'Focus on the Person' form: A partnership approach to person-cent red hospital care for people with dementia
Principal Investigator	Susan Slatyer
Institution	Osborne Park Hospital, Sir Charles Gairdner Hospital
Approval Date	27/04/2021

This current project aims to implement and evaluate the systematic use of the Focus On the Person (FOP) form in the Emergency Department (ED) and four wards at SCGH to enhance person-centred hospital care for patients with dementia and their carers.
The research objectives are to:
Apply the COM-B framework to implement the FOP form in the care of patients with dementia in the ED and four wards at SCGH using the process developed in 2019.
Assess the barriers and facilitators to implementing the FOP in hospital practice from the perspective of hospital staff.
Monitor use of the FOP form and process during implementation.
Assess the impact of using the FOP form on staff members' perceived ability to provide person-centred care.
Evaluate the impacts of using the FOP form on family carers' levels of stress and experience of acute care, and on patient outcomes during admission and (where possible) their experience of care.

Project Title	**ASPEN-03:** A PHASE 2 STUDY OF ALX148 IN COMBINATION WITH PEMBROLIZUMAB IN PATIENTS WITH ADVANCED HEAD AND NECK SQUAMOUS CELL CARCINOMA
Principal Investigator	Samantha Bowyer
Institution	Peter MacCallum Cancer Institute, Sir Charles Gairdner Hospital, The Royal Brisbane and Women's Hospital
Approval Date	03/06/2021

This is a non-comparative open-label, randomized phase 2 multi-center study of the anti-tumor efficacy of ALX148 + pembrolizumab and of pembrolizumab alone in patients with metastatic or unresectable, recurrent HNSCC that is PD-L1 positive (CPS ≥1 by an FDA-approved test) who have not yet been treated for their advanced disease. The study comprises of an initial safety lead-in followed by a randomized portion. At least six patients will be enrolled into the safety lead-in. These lead-in patients will be observed for toxicity for the first 21 days (Cycle 1). Once review of the safety lead-in is complete a non-comparative randomized phase 2 Simon admissible study design will be used to evaluate the anti-cancer activity of ALX148 + pembrolizumab and that of pembrolizumab alone. The control arm of single-agent pembrolizumab will serve as a validation of historical controls rather than a direct comparator.

Project Title	**ASPEN-04:** A PHASE 2 STUDY OF ALX148 IN COMBINATION WITH PEMBROLIZUMAB AND CHEMOTHERAPY IN PATIENTS WITH ADVANCED HEAD AND NECK SQUAMOUS CELL CARCINOMA
Principal Investigator	Samantha Bowyer
Institution	Peter MacCallum Cancer Institute, Sir Charles Gairdner Hospital, The Royal Brisbane and Women's Hospital
Approval Date	18/06/2021
This is a non-comparative phase 2 open-label, multi-center study of the anti-tumor efficacy of ALX148 + pembrolizumab + chemo versus pembrolizumab + chemo in patients with metastatic or unresectable, recurrent HNSCC who have not yet been treated for their advanced disease HNSCC. The study comprises of an initial safety lead-in followed by a randomized portion. At least six patients will be enrolled into the safety lead-in. These lead-in patients will be observed for toxicity for the first 21 days (Cycle 1). Once review of the safety lead-in is complete a non-comparative randomized phase 2 Simon minimax study design will be used to evaluate the anti-cancer activity of ALX148 + pembrolizumab + chemotherapy versus pembrolizumab + chemotherapy for the treatment of patients with metastatic or with unresectable, recurrent HNSCC who have not yet been treated for their advanced disease. The control arm of pembrolizumab + chemo will serve as a validation of historical controls rather than a direct comparator.	

Project Title	The power of virtual reality (VR) in the critically ill - a feasibility study
Principal Investigator	Natalie Tran
Institution	Sir Charles Gairdner Hospital
Approval Date	23/06/2021
The intensive care environment can be perceived by patients to be threatening & bewildering. Virtual reality (VR) provides an opportunity for patients to be transported from this stressful environment & be immersed into a safe & calming virtual world which may reduce the stress, improve moods & subsequently may result in better engagement with their treatment. This study aims to investigate the feasibility of using VR in a general intensive care and high dependency population requiring intensive care management.	

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