



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 2020 Quarter

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

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| Project Title | Testing for phosphatidylethanol (PEth) in red blood cells as a measure of past alcohol exposure. |
| Principal Investigator | Professor David Joyce |
| Institution | PathWest QEII |
| Approval Date | 15/01/2020 |

Introduction of PEth testing into clinical practice requires a comprehensive understanding of normal background levels of PEth (it does form to a small degree even without alcohol consumption), credible threshold levels for proven ongoing drinking, rates of disappearance after cessation of drinking and variability within and between people. The overall objective of this project is to determine this information. The primary objectives are to determine:

- How much PEth is formed normally in the absence of alcohol consumption (abstainers substudy of Study 1, below);
- how PEth levels relate to contemporary alcohol intake (Study 1, all participants);
- how quickly PEth levels fall after a transition from drinking to abstinence (Study 2).

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| Project Title | Current indirect calorimetry practices for the determination of energy expenditure in critically ill patients in Australasian hospitals |
| Principal Investigator | Ms Emma Osnain |
| Institution | Edith Cowan University |
| Approval Date | 23/01/2020 |

The aim of this study is to explore the use of indirect calorimetry in Trans-Tasman intensive care units (ICU). In this study a telephone questionnaire will be conducted with practitioners who are using indirect calorimetry in Australian ICUs. The interviews will seek to collect data on how indirect calorimetry is used, barriers and enablers to use, and the reliance on alternative methods to determine energy requirements. It is expected that the findings of this study will be used to define the current Australian indirect calorimetry practices within the context of best practice guidelines.

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| Project Title | Clinical correlation of disease with 3-hydroxy-3-methyl-glutaryl- CoA reductase (HMGCoA R) antibody levels in patients with antibody positive immune-mediated necrotising myopathy - a retrospective study. |
| Principal Investigator | Dr Anna Bruschi |
| Institution | Sir Charles Gairdner Hospital |
| Approval Date | 24/01/2020 |

The aims of the study are to review cases of histologically confirmed immune mediated necrotising myopathy (IMNM) (the current “gold standard” for diagnosis) and determine the proportion positive for Anti-3-hydroxy-3-methyl-glutaryl-CoA reductase (HMG CoA R) antibodies, those positive for other myositis antibodies, and those with a negative antibody profile. This will help confirm antibody profiles seen in IMNM in a local cohort. In addition, the study aims to characterise the HMG CoA R antibody positive cohort, and potentially identify features that are associated with anti-HMGCoA R associated myopathy in particular. For example, HMGCoA R antibody positive patients might have more significant muscle weakness, higher creatine kinase levels, a history of malignancy, or disease that requires more lines of treatment. This will be useful in clinical practice and may help identify patients with a high pre-test probability, versus those with features of a low pre-test probability that would help minimise unnecessary testing.

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| Project Title | Using the ‘Escape Room’ concept to foster teamwork in ad-hoc groups: an observational pilot study |
| Principal Investigator | Dr Diane Dennis |
| Institution | Sir Charles Gairdner Hospital |
| Approval Date | 31/01/2020 |

This project seeks to design and apply a novel ER activity in order to improve team work and communication in ad-hoc teams of physiotherapists within the Physiotherapy Department at Sir Charles Gairdner Hospital. The ER will take place in a low fidelity environment within the Physiotherapy Department, utilising props and purpose-designed resources. Team members who do not normally work together will be allocated to do so for the purpose of the project. Teams will undertake the activity at a mutually suitable non-clinical time, with a maximum timeframe of 60 minutes to ‘escape the room’

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| Project Title | The umbilical fissure vein, anatomical variation and potential surgical application |
| Principal Investigator | Dr Marwan Idrees |
| Institution | Albany Hospital |
| Approval Date | 31/01/2020 |

This project seeks to identify the prevalence of the umbilical fissure vein, its anatomical variation and its potential surgical anatomical application. The primary outcome is to identify the prevalence of the Umbilical Fissure Vein in normal population. The secondary outcomes are to identify anatomical variation of UFV and to investigate the line of projection from the falciform ligament extending to the umbilical fissure vein as a potential line of dissection when performing extended right hemihepatectomy or extended segment II resection.

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| Project Title | Prevalence of pelvic floor injury and clinical symptoms in post-partum primiparous women at Osborne Park Hospital |
| Principal Investigator | Ms Mieke Tye |
| Institution | Osborne Park Hospital |
| Approval Date | 03/02/2020 |

During vaginal delivery it is hypothesised that many women experience pelvic floor muscle tearing. This results in the pelvic organs such as rectum, bladder and uterus being unsupported and leaves the woman at risk of developing pelvic organ prolapse and incontinence. There are no studies that examine the extent of the problem in WA so the aim of this study is to:

- Identify the prevalence of pelvic floor injury in post-partum primiparous women who delivered at Osborne Park hospital
- identify the relationship between ultrasound diagnosed defects and clinical bowel and bladder symptoms at 8 weeks post-partum
- identify any commonalities/ differences between birth details and anatomical defects at 8 weeks post-partum.

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| Project Title | The use of novel magnetic resonance imaging techniques to investigate lung structure and ventilation pre and post airway clearance techniques in adults with cystic fibrosis |
| Principal Investigator | Mr Jamie Wood |
| Institution | Sir Charles Gairdner Hospital |
| Approval Date | 06/03/2020 |

This study aims to investigate new techniques in magnetic resonance imaging (MRI) pre and post airway clearance techniques (ACT). Adults with CF will be invited to participate, and to perform their usual ACT (i.e. breathing exercises to clear mucus from their airways). This will allow for innovative cutting edge imaging to be performed before and after the ACT are performed, to provide information on airway structure and function; specifically in regard to the movement of mucous (sputum) and trapped air, and well as dynamic function of the larger airways.

While lung imaging is appealing, until recently only computed tomography (CT) has been available to provide the necessary imaging. Unfortunately, CT exposes the patient to ionising radiation exposure which limits its use for especially functional imaging. Using MRI avoids radiation risk, therefore is an excellent option for structure and function imaging in relation to ACT. This is the first study of its kind, utilising novel MRI techniques.

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| Project Title | The Western Australian Barrett's Oesophagus Registry |
| Principal Investigator | Professor Krish Ragnath |
| Institution | Royal Perth Hospital |
| Approval Date | 06/03/2020 |

The aim of this study is to establish a clinical registry for adults with Barrett's oesophagus (BO). Barrett's oesophagus is a condition where the normal cells of the inner lining of the oesophagus (the tube that connects the mouth to the stomach) are replaced with abnormal cells. Many conditions predispose to the development of BO including acid reflux, obesity, family history and smoking. Whilst BO itself doesn't cause any symptoms, patients experience symptoms due to acid reflux including heart burn, central chest pain and burning sensation in the throat due to acid regurgitation.

This is a prospective registry and all patients diagnosed with BO in WA public metropolitan hospitals will be invited to participate. Diagnosis is made by visual changes seen during endoscopy and confirmation of pathological changes in biopsy samples collected during endoscopy. Patients will be invited to participate in this registry during visits to their gastroenterologists in the public hospitals to discuss their newly diagnosed BO or their ongoing monitoring for BO. Additional data will be collected when the patients attend routine follow-up endoscopies.

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| Project Title | Repeatability of quantitative measures in metastatic prostate cancer using PSMA-based PET |
| Principal Investigator | Dr Jeremy Ong |
| Institution | Sir Charles Gairdner Hospital |
| Approval Date | 11/03/2020 |

Prostate-specific membrane antigen (PSMA) positron emission tomography (PET) imaging is a powerful prostate cancer staging modality that has the potential to transform prostate cancer imaging and treatment. While basic quantitative analysis is routine in clinical PSMA PET imaging, more complex research and clinical applications of PSMA PET scans will depend on the repeatability of quantitative data. With both F18 and Ga68 based PSMA compounds being used in Western Australia, the repeatability of PSMA PET scan quantitation needs to be evaluated for each of these tracers.

We propose to image patients with unfavourable prognosis metastatic prostate cancer, who have been referred for PSMA-PET imaging with Ga68-PSMA or F18-PSMA-PET CT in a test-retest study. Each patient will undergo an initial clinical scan followed by an additional repeat scan within two weeks. We will quantify the repeatability of quantitative PSMA-PET metrics and compare this repeatability between Ga68 and F18 PSMA PET scans.

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| Project Title | Evaluation of the Clinical Response to Lumacaftor with Ivacaftor in a Real World Setting. |
| Principal Investigator | Ms Rebecca Brown |
| Institution | Sir Charles Gairdner Hospital |
| Approval Date | 12/03/2020 |

Cystic Fibrosis (CF) is an inherited condition characterised by dysregulated chloride ion transport and subsequent accumulation of thickened mucous in the lungs, digestive tract and other organ systems. A novel pharmacological treatment that targets the underlying genetic cause of the disease represents a significant breakthrough in the management of CF and is expected to significantly increase survival. Lumacaftor with Ivacaftor (LUM/IVA) is a combination medication belonging to this novel drug class.

This project will utilise demographic and clinical data collected as part of the LUM/IVA treatment pathway, to evaluate the post marketing safety and efficacy of LUM/IVA in adult patients with mild to moderate CF lung disease. The project will address important new research questions regarding the impact of LUM/IVA on depression and rhinosinusitis symptoms. Additional assessments conducted prospectively will for the first time explore patient adherence to LUM/IVA and inform potential interventions to address barriers to adherence.

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| Project Title | A Randomised Controlled Trial of Early valve replacement in severe ASymptomatic Aortic Stenosis (EASY-AS) |
| Principal Investigator | Professor Graham Hillis |
| Institution | Royal Perth Hospital |
| Approval Date | 17/03/2020 |

The EASY- AS trial will be a major pragmatic multi-centre prospective parallel group open randomised controlled trial. It will be conducted in the UK, Australia and New Zealand and funding is being sought in several other countries to expand recruitment internationally. The over-arching aim of the trial is to determine whether early aortic-valve replacement (AVR) results in better clinical outcomes and cost-effectiveness than a strategy of expectant management in asymptomatic patients with severe aortic stenosis (AS).

The primary hypothesis is that early AVR or transcatheter aortic valve replacement in asymptomatic patients with severe AS will result in a reduction in the composite primary outcome of cardiovascular death and hospitalisation for heart failure when compared to the conventional approach of expectant management. The EASY-AS study will provide crucial data on the relative merits of these differing approaches to management, in terms of important patient orientated outcomes, conventional cardiovascular end-points and cost effectiveness.

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| Project Title | Getting the MOST out of follow-up: a randomised controlled trial to compare three-monthly nurse-led telephone follow-up, including monitoring serum CA125 and patient reported outcomes using the MOST (Measure of Ovarian Symptoms and Treatment concerns) with routine clinic-based follow-up, following completion of first-line chemotherapy in patients with epithelial ovarian cancer. |
| Principal Investigator | Dr Paul Cohen |
| Institution | St John of God Hospital Subiaco |
| Approval Date | 27/03/2020 |

The aims of this phase IIb study are to demonstrate that follow-up of women with ovarian cancer after completion of first line treatment by three-monthly nurse-led remote video consultation is feasible, acceptable, safe and does not delay the diagnosis of recurrence. Secondary objectives are to investigate whether the intervention is associated with clinically meaningful improvements in emotional wellbeing, health-related quality of life patient satisfaction, the number of patients referred for treatment of symptoms, and cost-effectiveness of the intervention. The intervention will consist of three-monthly remote interviews with a nurse via video call, serum CA125 and completion of the patient-reported MOST questionnaire at home on a personal computer, mobile device or on paper, until recurrence.

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