

## Department of Health Western Australia Human Research Ethics Committee

**Project Summaries for Approved Proposals** 

January to March 2019 Quarter

## Project summaries for proposals approved by the Department of Health Human Research Ethics Committee – January to March 2018 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 Department of Health Human Research Ethics Committee (DOH HREC). It contains lay description/summaries of projects approved in the January to March 2019 quarter.

Project Title	Cardiac specific biomarkers for risk prediction in the general population		
Principal Investigator	Professor Stefan Blakenberg		
Institution	Harry Perkins Institute of Medical Research		
Start Date	04/03/2019	Finish Date	31/12/2020

Biomarkers are molecules, which are detectable in the blood stream. These markers are used for diagnostic and prognostic purposes in clinical routine. The two most important cardiac biomarkers are natriuretic peptides and troponin. The aim of this project is to perform the largest individual level meta-analysis on the cardiac specific biomarkers high-sensitivity troponin and natriuretic peptides in the general population. Individual-level data will be collected from population-based studies and clinical trials, the distribution of cardiac biomarkers will be evaluated and the cardiovascular risk associated with these biomarkers will be calculated. An investigation will be undertaken into the additional value of cardiac biomarkers when added to established models, such as the European Society of Cardiology (ESC) Score (with all its limitations) or the Pooled Cohorts Risk Equation. Finally, the project will model the effect of statin-treatment as primary prevention in those individuals who are classified as higher risk after addition of the biomarker.

At this stage, the project team has been able to harmonize individual-level data on cardiac biomarkers from more than 100,000 individuals from the BiomarCaRE consortium and clinical data from the LSAW study population would be included as well. This meta-analysis has been approved by the local ethics committee of the City Hamburg, Germany.

Project Title	Epidemiology of invasive beta Australia	-haemolytic st	treptococcal	disease	in	Western
Principal Investigator	Dr Laurens Manning					
Institution	The University of Western Australia					
Start Date	01/03/2019	Finish Date	30/06/2020	)		

Invasive, beta-haemolytic streptococcal disease can lead to serious complications, including bacteraemia, necrotising fasciitis, and bone and joint infections. The World Health Organization has set the development of a vaccine for Group A Streptococcus as a priority, and work on a Group B Streptococcus vaccine is also underway. Reporting the burden of severe streptococcal infection requiring hospitalisation is important for informing management and prevention strategies, defining the vaccine preventable disease burden, and for providing estimates on which to model future cost-effectiveness of a vaccine. This project will leverage Western Australia's world class data linkage capability to provide updated estimates of the disease burden, investigating distribution by age, sex, socioeconomic status and geographical remoteness.

Project Title	Health and psychological wellbeing in survivors of childhood cancer in Western Australia: a whole population data linkage study		
Principal Investigator	Dr Thomas Walwyn		
Institution	The University of Western Australia		
Start Date	01/07/2019	Finish Date	31/12/2024

Advances in treatments have resulted in substantial improvements in the survival rate of children diagnosed with cancer in many high-income countries. In Australia, while a significant improvement in survival rate has been observed in recent decades this is in parallel with an increase in the incidence of childhood cancers over the same period. Consequently, this has led to increased recognition of the need to investigate the long-term impacts associated with exposure to cancer treatments in childhood. To date, various aspects related to the impacts of cancer treatments on survivors remain sparsely explored at the international and national levels. In Western Australia, there has never been a comprehensive investigation of the late-effects of cancer therapy in childhood cancer survivors. This project aims to utilise a unique linked clinical and administrative dataset to investigate the outcomes of cancer and its treatments across the life-course for those diagnosed with childhood cancer in WA since 1982.

Project Title	How is birth by Caesarean section delivery associated with the risk of childhood type 1 diabetes?		
Principal Investigator	A/Professor Elizabeth Davis		
Institution	Perth Children's Hospital		
Start Date	01/04/2019	Finish Date	01/04/2024

The number of children being diagnosed with type 1 diabetes has been increasing but the cause for this remains unknown. Over the past decades there has been an increasing number of babies being born by Caesarean section, with 30% of Australian babies now born this way. Several studies around the world have shown that there is an increased risk of type 1 diabetes in babies born by Caesarean section. So, could the increasing number of babies born by Caesarean section be contributing to the increasing incidence of childhood type 1 diabetes? This project aims to address this question by looking for differences between babies born in Western Australia who go on to be diagnosed with type 1 diabetes under the age of 15 years, compared to those that do not.

Project Title	Evaluation of post-operative care following repair of gastroduodenal ulcer perforation, effect on patient outcomes and development of a new protocol			
Principal Investigator	Dr Amanda Foster			
Institution	Fiona Stanley Hospital			
Start Date	13/03/2019	Finish Date	31/12/2027	

This project will undertake a retrospective evaluation of post-operative inpatient and outpatient management practices in those who have had surgical repair of a perforated stomach or duodenal ulcer from 1 January 2010 to 31 December 2017. It will also determine how these affect immediate and long-term patient outcomes. The impact of factors before and during the operation will be assessed on how patients are managed post-operatively and thereby how this affects patient outcomes. Effectiveness of current prevention practices will be evaluated by reviewing hospital representation rates within two years of discharge. A pilot policy to optimize our management practices will be developed to improve patient outcomes.

Project Title	Impact of consensus guideline translation to clinical care in WA	es on margins	for breast	conserving	surgery:
Principal Investigator	Dr Luke Marinovich				
Institution	Curtin University				
Start Date	13/03/2019	Finish Date	31/12/2020	)	

Breast conserving surgery (BCS) is standard treatment for early breast cancer. BCS involves removal of the cancer along with a surrounding area of normal tissue (the "margin"). Historically, the optimum margin, balancing cancer control with treatment morbidity and cosmetic outcomes, has been controversial. Recommendations of varying scientific quality have specified different, often large margins. In late 2013, evidence-based consensus guidelines were published mandating smaller margins than previous recommendations. The guidelines sought to minimise practice variation and reduce reoperations to achieve unnecessarily large margins (and related harms). The effect of these guidelines has not been assessed in Australia.

The aims of this project are to:

- investigate reoperation rates after BCS (derived from the Hospital Morbidity
  Data System) in women with newly diagnosed breast cancer in WA (identified from the WA
  Cancer Register) from 2002 to 2018;
- 2. compare reoperation rates prior to 2014 versus 2014 and later, coinciding with the introduction of consensus guidelines for margins in BCS; and
- 3. identify characteristics that are associated with variation in reoperation rates, including those related to the cancer (e.g. invasive vs in situ histology; tumour grade), treatment (e.g. type of reoperation; adjuvant treatment; hospital setting) and patient (e.g. sociodemographic characteristics).

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