



Government of Western Australia  
Department of Health

# Human Research Ethics Committee

Project Summaries for Approved  
Proposals

October to December 2015 Quarter

**Project summaries for proposals approved by the Department of Health Human Research Ethics Committee - October to December 2015 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 available for the October to December 2015 quarter.

<b>Project Title</b>	<b>Comparison of human heat stress models across Australian cities [Short title: Heat stress models in Australian cities]</b>		
<b>Principal Investigator</b>	Associate Professor Lisa Alexander		
<b>Institution</b>	University of New South Wales		
<b>Start Date</b>	26 October 2015	<b>Finish Date</b>	14 August 2018
<p>This project will compare the ability of statistical models, incorporating temperature, humidity and other weather factors, to predict both hospital admission rates and the fraction of hospital admission rates that end in mortality across several Australian cities over a 10–20 year period. The study will also check how these models differ by age group and sex.</p>			

<b>Project Title</b>	<b>Defying the odds: Exploring the impact of perinatal outcomes, maternal social and health outcomes and level of culturally appropriate service availability on the health of Western Australian Aboriginal infants and children [Short title: Defying the odds]</b>		
<b>Principal Investigator</b>	Dr Bridgette McNamara		
<b>Institution</b>	Baker IDI Heart and Diabetes Institute		
<b>Start Date</b>	17 November 2015	<b>Finish Date</b>	30 June 2019
<p>A healthy start to life is essential for life-long health and wellbeing. It is well known that Aboriginal children have significantly worse health outcomes compared to non-Aboriginal children. However, the geographic variation in Aboriginal child health outcomes is currently unclear along with the impact that health and social services have had on child health outcomes. This information is vital to help inform the development of new effective health services and support the maintenance of existing programs that are making a difference, in order to help Aboriginal children to 'defy the odds' and thrive. This study aims to identify the determinants of infant and child health outcomes that derive from the perinatal period and maternal and grandmaternal medical history using whole-of-population linked health data from multigenerational Aboriginal families in Western Australia (WA) from 1980 to 2013. This project will also examine how Aboriginal early childhood health outcomes vary across different regions and across families with different characteristics. Furthermore, data from existing health and social services in WA will also be collected in order to examine the impact of these services on child health outcomes.</p>			

<b>Project Title</b>	<b>State-wide Specialist Aboriginal Mental Health Service (SSAMHS) Evaluation 2016 - Linked data [Short title: SSAMHS Evaluation 2016 - Linked data]</b>		
<b>Principal Investigator</b>	Mr Wynne James		
<b>Institution</b>	The Mental Health Commission		
<b>Start Date</b>	30 November 2015	<b>Finish Date</b>	31 December 2016
<p>The State-wide Specialist Aboriginal Mental health Service (SSAMHS) provides a culturally responsive 'whole of family' approach for Aboriginal people with low prevalence, persistent mental health issues. This project is a service evaluation of SSAMHS to:</p> <ul style="list-style-type: none"> <li>• determine its effectiveness</li> <li>• determine the extent to which the SSAMHS has met its objectives and key performance indicators</li> <li>• ascertain ways to improve the SSAMHS program</li> <li>• provide feedback to key stakeholders on the performance of the SSAMHS</li> <li>• gather evidence to underpin any future business case required to secure funding beyond June 2017.</li> </ul> <p>The evaluation will adopt a longitudinal mix methods design utilising both quantitative and qualitative methodologies. This application relates to the quantitative aspect, which will analyse linked data from state-wide data collections with the intent of evaluating the effectiveness of the SSAMHS program for consumers of the service.</p>			

<b>Project Title</b>	<b>Establishing integrated data for stroke to enable comprehensive monitoring of care and patient outcomes to provide evidence for clinical practice improvement [Short title: Stroke 123 data linkage sub-study]</b>		
<b>Principal Investigator</b>	Associate Professor Dominique Cadilhac		
<b>Institution</b>	Florey Institute of Neuroscience and Mental Health		
<b>Start Date</b>	9 December 2015	<b>Finish Date</b>	31 December 2017
<p>This data linkage project is a substudy of a larger NHMRC funded partnership grant (Stroke 123). This substudy was designed specifically to test the feasibility of linking government health information data (from multiple states) with non-government held clinical quality registry data. The linked data will be used to answer a range of important research questions and provide enhanced methods of monitoring and describing care variability and differences in patient outcomes for stroke. This information is intended to be used to inform policy and practice to improve stroke care in Australia.</p>			

<b>Project Title</b>	<b>Examining performance indicator data to enable improvements to the performance monitoring and evaluation within the WA public health system [Short title: Improving the effectiveness of health system performance monitoring]</b>		
<b>Principal Investigator</b>	Ms Karen Lopez		
<b>Institution</b>	Department of Health		
<b>Start Date</b>	26 October 2015	<b>Finish Date</b>	Ongoing

In Western Australia performance indicators are monitored and reported regularly. The Health Service Performance Report (HSPR) is a monthly report that consists of a core set of performance indicators that is used by the Department of Health (Department) and WA Health Services as a means for managing performance and supporting better decision making. Performance review meetings involve the Department of Health as the System Manager and each Health Service as the Service Provider. Performance is assessed against the target. These meetings are conducted as part of the monthly Board Meetings.

This project proposes giving Health Services the capacity to review patient identifiable data used to determine performance indicators reported in the HSPR.

This project objectives are:

- Provide Health Services with the capacity to review patient identifiable data that is used to determine performance indicators.
- Share patient identifiable data between Health Services when performance indicators involve more than one Health Service, allowing both services to investigate and review data used in a performance indicator measure.
- Improve the understanding of factors affecting performance indicators used to measure quality, safety, efficiency and effectiveness of the WA Health System.
- Use the enhanced understanding of performance indicator results to drive improvements, support decision making and rectifying under-performance.

<b>Project Title</b>	<b>Australian longitudinal study on women's health [Short title: ALSWH]</b>		
<b>Principal Investigator</b>	Professor Gita Mishra		
<b>Institution</b>	University of Queensland		
<b>Start Date</b>	15 December 2015	<b>Finish Date</b>	Ongoing

Australian longitudinal study on women's health (ALSWH) is a nationally representative, longitudinal cohort study of Australian women. Initially in 1996, three cohorts were recruited: the 1973 - 1978, 1946 - 1951 and the 1921 - 1926 birth cohorts who were aged 18 - 23 years, 45 -50 years and 70 - 75 years respectively when first surveyed. In 2013 a new cohort born in 1989 - 1995 was recruited. The aim of this project is to link ALSWH records with state and national datasets to estimate the health risks for morbidity, cancer and perinatal complications in Australian women, taking into account individual-level differences in socio-economic, behavioural, environmental and other risk factors.

<b>Project Title</b>	<b>Treatment and prevention of depression among older Western Australian adults living in regional and remote areas – The MIRROR pilot study: Randomised controlled trials of behavioural activation</b>		
<b>Principal Investigator</b>	Professor Osvaldo P. Almeida		
<b>Institution</b>	University of Western Australia		
<b>Start Date</b>	26 October 2015	<b>Finish Date</b>	31 December 2016
<p>Research suggests that engaging in both pleasurable and achievement-based activities is an effective technique for reducing symptoms of depression. This approach is known as Behavioural Activation (BA). The current pilot study aims to investigate the effects of BA treatment for older adults who live in remote and regional Western Australia who are experiencing symptoms of depression.</p>			

<b>Project Title</b>	<b>WA Register of Developmental Anomalies – Cerebral Palsy: Contribution of data to Australian Cerebral Palsy Register [Short title: WARDA-CP data transfer to ACPR]</b>		
<b>Principal Investigator</b>	Professor Caroline Bower		
<b>Institution</b>	King Edward Memorial Hospital		
<b>Start Date</b>	14 October 2015	<b>Finish Date</b>	Ongoing
<p>The Western Australian Register of Developmental Anomalies (WARDA) is a statutory data collection of the Department of Health WA. The cerebral palsy (CP) branch of the data collection (WARDA-CP) contributes data to the Australian Cerebral Palsy Register (ACPR) Clearing House at the CP Alliance Research Institute, Sydney, to enable the reporting of CP statistics for Australia as a whole. The ACPR and its activities have ethical approval from the Cerebral Palsy Alliance NHMRC recognised HREC (EC00402). We are requesting HREC approval to transfer data in two stages: first a limited data set containing potentially identifying data in the form of child's and mother's dates of birth to make it possible to identify duplicate records in the Australian data set. This preliminary data set will be destroyed once duplicates have been identified and eliminated, and transfer of a complete de-identified unit data set (re-identifiable only by WARDA-CP in the event that a record needs to be queried) will then be carried out.</p>			

<b>Project Title</b>	<b>Child Development Information System (CDIS)</b>		
<b>Principal Investigator</b>	Ms Elizabeth Buckton		
<b>Institution</b>	Department of Health (CACH)		
<b>Start Date</b>	14 October 2015	<b>Finish Date</b>	Ongoing
<p>Child Development Information System (CDIS) is a client information management system that records service activity for Child and Adolescent Community Health (CACH). This includes: metropolitan Child Health, School Health and Child Development Services, making it one of the most extensive and consistent data sources pertaining to child health, child development and school health services in Australia.</p> <p>The linkage of CDIS to the WA Data Linkage System will enable research into developmental trajectories, aetiology of developmental difficulties / disorders, populations utilising child health services, and evaluation of child health services. This research will assist in child health service planning and improve the capacity of child health services to employ evidence-based practice.</p>			

<b>Project Title</b>	<b>Does pneumococcal vaccination protect against cardiovascular disease? A randomised placebo-controlled double blind trial [Short title: AUSPICE - Australian Study for the Prevention through Immunisation of Cardiovascular Events]</b>		
<b>Principal Investigator</b>	Professor John Attia		
<b>Institution</b>	University of Newcastle		
<b>Start Date</b>	23 November 2015	<b>Finish Date</b>	31 December 2022
<p>Australian researchers will set up a novel multi-centre trial to investigate the effects of the pneumococcal vaccine in reducing heart attacks and stroke. People aged 55 to 60 from 6 sites around Australia will be invited to participate in the study. The 6 sites include Newcastle, the Central Coast, Canberra, Melbourne, Adelaide and Perth. The selected participants will attend a clinic in their area and will be randomly given the pneumococcal vaccine or a placebo (saline) vaccine. Outcomes on the expected 6000 participants will be ascertained by health record linkage with Commonwealth and State databases after 4-5 years. This work has been funded by the National Health and Medical Research Council (NHMRC) from 2014 to December 2018.</p>			

<b>Project Title</b>	<b>Transitions of care at discharge for paediatric patients: Communication practice</b>		
<b>Principal Investigator</b>	Professor Phillip Della		
<b>Institution</b>	Curtin University		
<b>Start Date</b>	11 November 2015	<b>Finish Date</b>	31 December 2017
<p>Recent evidence has revealed that when poor communication occurs at points of care transition, patients are at increased risk of an adverse event or unplanned hospital readmission. This project aims to investigate transitions of care for paediatric patients at discharge from acute to primary care settings by analysing and then informing strategies to improve communication practices at Princess Margaret Hospital, an acute tertiary hospital of Western Australia. This study will develop a safe discharge communication guideline to assist health care providers in improving outcomes related to the transition of care for paediatric patients.</p>			

<b>Project Title</b>	<b>Rheumatoid Arthritis as a risk factor for hospitalisation, emergency care use, cancer and mortality in Western Australia [Short title: Epidemiology of Rheumatoid Arthritis in WA]</b>		
<b>Principal Investigator</b>	Winthrop Professor Johannes Nossent		
<b>Institution</b>	University of Western Australia		
<b>Start Date</b>	11 November 2015	<b>Finish Date</b>	1 January 2019
<p>This project aims to describe trends in hospital-based disease presentations, the need for emergency care, and cancer development and mortality in patients with various rheumatic conditions in Western Australia over the period 1980-2012. The projects aims to measure the rheumatic disease burden and subsequent risk of chronic diseases, the need for joint operations, and early death in WA. Given the limited availability of specialist services, the project also aims to determine the impact on the use of health care resources in WA. The study is designed as a retrospective whole population cohort study using linked administrative data from all public and private hospitals in WA. The study cohort is defined as any person with a listed rheumatic disease condition (e.g. Chronic idiopathic arthritis, Spondylarthropathies, Connective tissue disease, Crystal induced arthritis, and Osteoarthritis) of interest across the entire time period from January 1980 through to December 2012 and across all age ranges. The condition can appear as either principal and/or additional diagnosis/cause of death and can include persons with a previous history of the condition of interest. A control group are persons, from the Electoral Roll, alive at the time of the case's index event, and matched 1:1 for year of birth and gender to the Cases. Controls should be free of any of the listed conditions of interest across the time period 1980 to 2012.</p> <p>The period of interest runs from January 1980 through December 2012. This time span encompasses several periods of distinct changes within the scope of Rheumatology such as the widespread introduction of Methotrexate throughout the 1990's followed by the introduction of TNF-blockers in 2002 for the treatment of various forms of chronic arthritis. Similar changes occurred with the accepted use of combined steroid and cytotoxic treatment for connective tissue disease and vasculitis in the late 1980's/early 1990's, again followed by the use of B cell depletion therapy since 2002. Although some WA wide databases have a shorter collection period (e.g. Emergency data from 2002 only) they will</p>			

still be of sufficient to provide sufficient length of observation.

The project aims to describe and compare the following outcomes in the West Australian context across rheumatic disease conditions: hospital admission rate trends per decade for cardiovascular events; oncological events; prosthetic joint operations; infectious complications; age and gender specific standardized all-cause mortality rates; emergency department visitations and frequency; and, fractures (all types).

<b>Project Title</b>	<b>Independent review of upper gastrointestinal surgical procedures at public health services in WA</b>		
<b>Principal Investigator</b>	Professor Gary Geelhoed		
<b>Institution</b>	Department of Health		
<b>Start Date</b>	16 October 2015	<b>Finish Date</b>	16 October 2016

In July 2015, the Director-General was advised of potential variation of outcomes between patients receiving Whipples in WA public tertiary hospitals. Hospitals provided data on their mortality rates over the past five years. Review of this data revealed further investigation into this variation, both in Whipples specifically and upper GI surgery generally, was warranted.

Reducing harm and death following (elective) surgery is a responsibility of healthcare professionals. Variation in the quality of clinical care may reflect patient, clinician and systemic factors. This Review seeks to examine outcomes for a cohort of patients undergoing upper gastrointestinal (GI) surgeries in WA public tertiary hospitals between 1 January 2010 and 31 July 2015 in order to examine variation in the outcomes and identify practice improvement measures which may be implemented.

To address patient factors, data sought seeks to capture the patient's acuity (e.g. measures relating to the type of intervention, pathology results, laparotomy but no resection, tumour resection margins). Such data will ensure that observations made regarding survival take into account, the patient's prognosis pre and post-surgery.

To identify variation in clinician factors, caseload by surgeon is sought, as are information about complications and mortality. Such data will permit analysis of outcomes to determine whether risk factors in the pre-, intra- and post-operative phases could have been addressed. As in other clinical incident reviews, it is anticipated that the lessons of such an analysis will be applicable across a range of surgeries and disciplines.

There is also accumulating evidence that complex procedures are most safely (and efficiently) performed at high volume centres. Consequently, for many complex procedures, the credentialing and training requirements imposed upon the surgeon includes a requisite number of procedures to be undertaken annually. Thus, this review will consider the relationship between quality of outcomes and volume of cases in the WA cohort and whether this should inform the future configuration of upper GI surgery across WA public tertiary sites.

<b>Project Title</b>	<b>Monitoring adverse events following immunisations administered in general practice using data extraction</b>		
<b>Principal Investigator</b>	Dr Paul Effler		
<b>Institution</b>	Department of Health		
<b>Start Date</b>	30 November 2015	<b>Finish Date</b>	Ongoing
To aggregate adverse event information collected by general practices for the purpose of assessing the safety of vaccines administered in general practice in real time.			

<b>Project Title</b>	<b>ACT Asbestos health study: Data linkage study on the risk of mesothelioma and other cancers</b>		
<b>Principal Investigator</b>	Dr Rosemary Korda		
<b>Institution</b>	The Australian National University		
<b>Start Date</b>	9 December 2015	<b>Finish Date</b>	30 June 2017
The aim of the ACT Asbestos Health Study is to investigate the health effects of living in a house with loose-fill asbestos insulation in the Australian Capital Territory (ACT), referred to throughout as an affected residential property (ARP). This project aims to estimate the incidence of mesothelioma and other cancers in people who have lived at an ARP and estimate the relative rate of mesothelioma in people who have lived at an ARP compared to those who have not lived at an ARP. The study will also estimate the projected incidence of mesothelioma in people who have lived at an ARP.			

<b>Project Title</b>	<b>Recent changes in IVF clinical practice: data linkage to investigate their impact on fetal growth, birth defects and cerebral palsy [Short title: IVF and child health]</b>		
<b>Principal Investigator</b>	Dr Michele Hansen		
<b>Institution</b>	Telethon Kids Institute		
<b>Start Date</b>	9 December 2015	<b>Finish Date</b>	31 December 2017

One in every 25 births or one child in every Australian classroom is conceived using in vitro fertilisation (IVF), rising to 1 in 7 for women over 37 years of age, and this is likely to increase with the continuing trend toward later childbearing. There have been substantial changes to IVF clinical practice in the last 10 years but little is known about child health outcomes following these shifts in treatment. Specifically, there are no reliable birth defects data available internationally following the use of recent techniques such as extended embryo culture and rapid embryo freezing (vitrification). Western Australia (WA) is the only State with a statutory Register of all IVF treatment that exists alongside an extensive system of population-based health datasets.

This project aims to undertake a data linkage study combining information from the Reproductive Technology Register, the Midwives' Notification System, the WA Register of Developmental Anomalies, the WA Registries of Births and Deaths, the WA Hospital Morbidity Data Collection and the Commonwealth Pharmaceutical Benefits Scheme (PBS). This will allow the identification of a retrospective cohort of all births (live and still born) and terminations of pregnancy for fetal anomaly in WA over a 13 year period (2002-2014) according to method of conception: natural conception, those conceived using IVF, and those conceived outside the fertility clinic setting using ovulation induction medications. This project will compare these births with regard to intrauterine growth, birth defects and cerebral palsy. The project will also examine trends in these outcomes over the time period of the study. This information is essential for appropriate pre-treatment counselling and to inform best practice in Australian IVF clinics.

<b>Project Title</b>	<b>Uptake of antenatal influenza and pertussis (whooping cough) vaccination in pregnant Aboriginal mothers and its association with influenza vaccination of their children [Short title: Survey of Aboriginal mothers about flu and whooping cough immunisations]</b>		
<b>Principal Investigator</b>	Dr Donna Mak		
<b>Institution</b>	Department of Health		
<b>Start Date</b>	16 September 2015	<b>Finish Date</b>	30 June 2016

The study aims to estimate antenatal influenza and pertussis vaccination uptake in 2015 among pregnant WA Aboriginal women and influenza vaccination uptake among the children of these women.

The following objectives will be addressed:

- Measure the proportion of pregnant WA Aboriginal women who were vaccinated against influenza and/or pertussis in 2015; and
- Measure the proportion of these women's children who were vaccinated against influenza in 2015.





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