

Human Research Ethics Committee

Project Summaries for Approved Proposals

July to September 2013 Quarter

Project summaries for proposals approved by the Department of Health Human Research Ethics Committee - July to September 2013 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 July to September 2013 quarter.

Project Title	Colonoscopic surveillance for colorectal cancer in lynch syndrome mutation carriers		
Principal Investigator	Dr Hooi Ee		
Institution	Sir Charles Gairdner Hospital		
Start Date	1 May 2013 Finish Date 14 August 2017		

Lynch Syndrome is a genetic disorder which increases a person's risk of developing bowel cancer. Colonoscopy is a test to examine the bowel for possible cancers and pre-cancerous lesions called polyps. If patients with Lynch syndrome undergo regular colonoscopy tests then their risk for developing bowel cancer decreases. This study is designed to look at all people in Western Australia known to have Lynch Syndrome and to determine how many of them have developed colorectal cancer, how many have had regular colonoscopies, what other cancers they have developed and what is the most common cause of death.

Project Title	Body mass index and risk of mortality		
Principal Investigator	A/Professor Dianna Magliano		
Institution	Baker IDI Heart and Diabetes Institute		
Start Date	14 August 2013	Finish Date	31 December 2014

While there is evidence that body mass index (BMI) affects mortality risk, much of the data comes from studies with self-reported obesity measures. These analyses are generally not well controlled. Few studies have been able to compare mortality risk with measured BMI and waist circumference. Among the studies which have explored this relationship, some are now showing that only the severely obese are at risk of increased mortality. Those who are overweight and who have class I obesity may have greater risk of mortality than those who have a normal weight.

There is also less known about the mortality risks in the elderly and the relationship between obesity and mortality according to socioeconomic status. As the Australian and New Zealand Diabetes and Cancer Collaboration cohort is population-based and Australia-wide, it provides an excellent opportunity to examine these risks across individual (using education) and area-based measures of socioeconomic advantage.

Project Title	Diabetes, obesity and liver disease-related mortality		
Principal Investigator	A/Professor Dianna Magliano		
Institution	Baker IDI Heart and Diabetes Institute		
Start Date	14 August 2013	Finish Date	31 December 2013

There is evidence that non-alcohol related fatty liver disease contributes to diabetes and obesity. The aim of this project is to evaluate the association between diabetes, obesity, fasting glucose and liver disease mortality. This study will use an already existing pooled cohort (Australian and New Zealand Diabetes and Cancer Collaboration cohort) as the primary data source and include all studies which have measured diabetes and obesity. This cohort was pooled in 2011 and linked to the National Death Index to obtain mortality outcomes. This pooled cohort consists of 18 established cohorts within Australia and New Zealand, including the Perth multinational monitoring of trends and determinants in cardiovascular disease studies (MONICA studies). This project will allow a better and fuller assessment of the likely burden and consequences of diabetes and obesity, as well as inform clinical practice about the appropriate care of diabetic and/or obese patients.

Project Title	National alcohol indicators project		
Principal Investigator	Professor Tanya Chikritzhs		
Institution	Curtin University of Technology		
Start Date	1 July 2004 Finish Date 30 June 2015		

The National Alcohol Indicators Project (NAIP) is an ongoing national monitoring system for tracking levels of alcohol consumption and harm throughout Australia over time. The project collects and maintains a range of secondary data sourced from various government departments. It aims to produce reliable and timely reports to policy makers, key stakeholders and the public on the impact of alcohol at the national, state and local levels. This project commenced in 2004. Examples of the NAIP output can be found at: http://ndri.curtin.edu.au/research/naip.cfm.

Project Title	Fremantle diabetes study phase II: a linkage study to provide detailed data on the contemporary prevalence, incidence, predictors and cost of established and novel complications of diabetes in a community setting		
Principal Investigator	Dr Wendy Davis		
Institution	The University of Western Australia		
Start Date	1 September 2013	Finish Date	31 December 2013

The Fremantle Diabetes Study Phase II (FDS2) is a longitudinal, observational study of diabetes in a contemporary, urban Australian setting. The study recruited 1,732 patients between the ages of 6 and 96 (52% males) from 2008 to 2011. These patients were selected from specific areas (defined by postcode) and have continued to receive comprehensive assessments twice a year. The FDS2 data will be considerably enhanced by data linkage with the available health datasets. This will enable a study of the prior, prevalent and incident diabetic complications and co-morbidities. The cost of diabetes will also be estimated.

Project Title	Long-term follow-up of Murray Valley Encephalitis survivors in Western Australia		
Principal Investigator	A/Professor Linda Selvey		
Institution	Curtin University of Technology		
Start Date	1 July 2013	Finish Date	30 June 2015

Murray Valley Encephalitis (MVE) is an uncommon but serious arbovirus infection in Australia. Since 1978, there have been 53 cases of MVE in Western Australia. It is estimated that over half of MVE survivors have ongoing neurological symptoms, however, the true picture of the long-term effects are unknown. This study seeks to follow-up all cases of MVE in Western Australia, and assess their quality of life using a standardised questionnaire. The results of this study will be used to better inform the development of long-term care plans for MVE patients following hospital discharge.

Project Title	Pharmacotherapy for smoking cessation during pregnancy and the interpregnancy period		
Principal Investigator	Dr Alys Havard		
Institution	University of Western Sydney		
Start Date	1 July 2013 Finish Date 31 December 2017		

Currently, little is known about the utilisation, effectiveness and safety of medications for smoking cessation during pregnancy, nor the extent to which they are used prior to pregnancy, or whether their use has changed in response to policy reforms. This study aims to address this gap by linking Australian pharmaceutical data to State-based perinatal records from New South Wales and Western Australia, and a wide range of other administrative health data collections including hospital admissions, emergency department presentations, deaths and birth defects. The findings regarding the safety of these medications will be important for informing guidelines regarding the prescription of these agents during pregnancy.

Project Title	Infrastructure linkage - WA hospital pharmacy data		
Principal Investigator	Mr Richard Wojnar-Horton		
Institution	Fremantle Hospital		
Start Date	10 July 2013	Finish Date	10 July 2017

This project will include hospital pharmacy records in the Western Australian Data linkage Infrastructure to allow a number of important studies, relating to a variety of chronic and acute conditions, to be progressed. The medical practice depends significantly on drug therapy, even in patients who have surgery. The inclusion of drug data will allow an important piece of additional data in analyses of patient care. Studies on cardiac and renal conditions in particular have been waiting for access to routine drug data for some time.

Project Title	Dementia and hospitalisations due to an injury: a population based study		
Principal Investigator	A/Professor Lynn Meuleners		
Institution	Curtin University of Technology		
Start Date	1 August 2013	Finish Date	30 August 2015

The prevalence of dementia is increasing due to changing population demographics. The clinical manifestations of dementia results in individuals being at an increased risk of injury, particularly from falls, motor vehicle crashes, accidental poisoning and other traumas. This study will make use of the Western Australian Data Linkage System to perform a retrospective, population-based cohort study. The study will quantify the impact of injury hospitalisations, including road crashes, and develop recommendations for people aged 65+ with and without dementia.

Project Title	Trend analysis of the physical activity patterns of the Australian adult population from 1997 to 2012		
Principal Investigator	Professor Kevin Norton		
Institution	University of South Australia		
Start Date	30 April 2013	Finish Date	31 December 2015

This is a trend analysis of the physical activity patterns of the Australian adult population from 1997 to 2012. Physical activity data from the Active Australia Surveys conducted throughout Australia will be amalgamated to quantify physical activity levels in the population, and within specific sub-groups of the population. This study will focus on the proportions that are sedentary, the proportions achieving sufficient physical activity to reduce risk of chronic disease and the extent to which these behaviours have changed over time.

Project Title	Western Australian register for developmental anomalies		
Principal Investigator	Professor Caroline Bower		
Institution	Department of Health		
Start Date	14 August 2013	Finish Date	14 August 2017

The Western Australian Register of Developmental Anomalies (WARDA) is a statutory Department of Health register. The purposes of this register are:

- to monitor developmental anomalies (birth defects and cerebral palsy) in Western Australia;
- to plan, monitor and evaluate services for the prevention and alleviation of developmental anomalies and the care of persons with a developmental anomaly in Western Australia;
- to compile and publish general and statistical information relating to developmental anomalies; and
- to carry out research into the causes of developmental anomalies and the effectiveness of prevention, screening and treatment services.

Project Title	Data linkage of WA health and wellbeing surveillance system		
Principal Investigator	Dr Sarah Joyce		
Institution	Department of Health		
Start Date	14 August 2013	Finish Date	14 August 2017

The Western Australian Health and Wellbeing Surveillance System is a population-based data collection system which monitors the health of Western Australians. Each month, a random sample of the Western Australian population is interviewed. People are asked questions on topics including lifestyle risk behaviours, socio-demographics and chronic conditions. The information is used to inform policy and programs and to support health service planning and development. Respondents are asked permission to link their survey responses with administrative datasets routinely collected by the Department of Health.

Project Title	Infrastructure linkage of aged care datasets: home and community care and aged care assessment program		
Principal Investigator	Mr Rob Willday		
Institution	Department of Health		
Start Date	14 August 2013	Finish Date	14 August 2017

This project aims to link the Home and Community Care and Aged Care Assessment Program datasets with the Department of Health core data collections to ensure linkages are in place for future requests for linkage of this data.

Project Title	Identifying genetic risk factors for cardiovascular disease in extended pedigrees in the Busselton health study		
Principal Investigator	Professor Eric Moses		
Institution	The University of Western Australia		
Start Date	1 August 2013	Finish Date	31 December 2015

The aim of this project is to identify genes and risk factors that are associated with cardiovascular disease in the Busselton Health Study. Data relating to genes, blood measures and the questionnaire will be sourced from the Busselton Health Study. Data relating to cardiovascular disease mortality and hospital morbidity will be sourced from the Department of Health data collections.

Project Title	Risk of osteoporotic and minimal-trauma re-fracture and costs related to incident osteoporotic fractures		
Principal Investigator	Ms Anna Huska		
Institution	Department of Health		
Start Date	1 June 2013	Finish Date	31 December 2014

The aim of this project is to quantify the direct health system costs to Western Australia associated with hospital admissions for people who sustained one or more fractures associated with osteoporosis over a 10 year period. System costs will be determined by using data from the Hospital Morbidity Data System. The information will be used to complement a similar preliminary analysis undertaken by the Agency for Clinical Innovation in New South Wales. In addition, findings will be used in the implementation plan for the Western Australian Osteoporosis Model of Care, currently being considered by members of the Western Australian Musculoskeletal Health Network.

The project is based solely on data extraction and analysis from the Hospital Morbidisty Data System and the Mortality Register and therefore no direct contact with consumers will be undertaken. The project is directly related to the Western Australian Osteoporosis Model of Care, providing a robust data analysis platform to inform implementation strategies.

Project Title	FluMum: A prospective cohort study of mother infant pairs assessing the effectiveness of maternal influenza vaccination in prevention of influenza in early infancy		
Principal Investigator	A/Professor Peter Richmond		
Institution	Telethon Institute for Child Health Research		
Start Date	1 June 2012	Finish Date	31 December 2014

The Flu Mum study is recruiting mother-infant pairs (38 weeks pregnant or have delivered), some of whom would have received a flu vaccination during their pregnancy. The aim is to find out if having a flu vaccination during pregnancy will protect their baby from getting influenza during their first six months of life. The child is not followed up beyond this point. A questionnaire is completed upon recruitment and again at the six month period post birth to find out if the child has been unwell with influenza-like symptoms during this period.

Project Title	Closing the gap on Indigenous birth registration		
Principal Investigator	A/Professor Jane Freemantle		
Institution	University of Melbourne		
Start Date	11 September 2013	Finish Date	31 December 2014

Many Indigenous Australians are unable to obtain a birth certificate because their birth was never registered, or they cannot satisfy the Births, Deaths and Marriages' (BDM) identification requirements. The result is a significant gap between the birth registration rates of Indigenous and non-Indigenous Australians. In international law, birth registration is a fundamental human right. This project will quantify the disparities in the registration of births to indigenous mothers according to the number of births to indigenous mothers as identified by the perinatal data collections in Western Australia, Queensland, the Northern Territory and Victoria.

Project Title	The role of tumour biology in influencing outcomes for Indigenous Australians diagnosed with breast cancer.		
Principal Investigator	A/Professor Andrew Redfern		
Institution	Royal Perth Hospital		
Start Date	1 July 2013	Finish Date	30 June 2014

The death rate for Indigenous women with breast cancer is double that of non-Indigenous women. Later treatment, lower socioeconomic status and remoteness account for half this difference. This project will examine whether there are more aggressive cancer types in Indigenous women in comparison to their non-Indigenous counterparts.

This study will aim to answer the following questions:

- 1. In Western Australian women did Indigenous women have a higher chance of dying from their cancer compared to their non-Indigenous contempories?
- 2. Did they suffer from more aggressive tumour types, and does this explain survival differences seen?
- 3. Did socioeconomic status and remoteness contribute to survival difference?

Project Title	A retrospective observational study of two types of pharmacotherapy treatment for opiate dependence in Western Australia.		
Principal Investigator	Dr Leigh Goggin		
Institution	Drug and Alcohol Office		
Start Date	11 September 2013	Finish Date	30 September 2015

The primary aim of this study is to compare the retention rate of clients prescribed methadone versus buprenorphine for the treatment of heroin or other opioid dependence. The study will also examine if any differences exist between the two groups in terms of the reason for a client ending treatment. Finally, the study will look at basic demographic characteristics of the two groups (e.g. age, gender, location) and level of dosing to determine their influence upon retention rates and outcomes.

Project Title	Assessment of the impact of the National bowel cancer screening program on the stage at diagnosis of colorectal cancer in WA		
Principal Investigator	Ms Kathleen O'Connor		
Institution	Department of Health		
Start Date	7 October 2013	Finish Date	31 January 2014

This project will link National Bowel Cancer Screening Program (NBCSP) participant details to the Western Australian Cancer Registry (WACR). The aim is to determine which colorectal cancers on the WACR were detected as a result of participation in the NBCSP during the period 29 January 2007 to 30 June 2011. Additionally, a comparison will be made between the stage of cancer at diagnosis between people who participated in the NBCSP and those who did not, in order to determine if there is evidence of a shift to earlier stage at diagnosis among NBCSP participants. The results of this comparison will inform on NBCSP efficacy in the community and will be the first assessment of its kind nationally using time- and age-matched datasets.

Project Title	WA Colorectal Research Group		
Principal Investigator	Professor Cameron Platell		
Institution	St John of God Hospital		
Start Date	1 September 2013	Finish Date	1 September 2017

This project is split into two components. One is the clinical registry and associated biospecimens. The second part is the actual work done using these. This application is to cover access to information from the Western Australian Cancer Registry to allow a review of the date and cause of death of all patients in the clinical registry. Those using specimens and associated data will not receive any identifiers that would enable them to readily re-identify any individuals. In this way the Western Australian Colorectal Research Group has a component that effectively acts as an 'honest broker' for those wishing to use samples and data. All patients will be asked for consent to use their biospecimens and associated health information.

Note: minor amendments have been made to summaries to comply with Department of Health WA Health Writing Style Guide

