Government of Western Australia
Department of Health

Human Research Ethics Committee

Project summaries for approved proposals

January to March 2013 quarter

Project summaries for proposals approved by the Department of Health Human Research Ethics Committee – January to March 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 January to March 2013 quarter.

Project Title	**Trends in hepatocellular carcinoma in Western Australia from 1983 to 2010**		
Principal Investigator	Professor David Preen		
Institution	The University of Western Australia, School of Population Health		
Start Date	1 January 2012	**Finish Date**	31 December 2015
This project will describe the trends in Hepatocellular Carcinoma (HCC) in Western Australia (WA) from 1983 through to 2010. The WA Cancer Registry will be utilised to identify cases of HCC in this time period. The WA Data Linkage System (WADLS) of the Department of Health (DOH) will be used to link relevant health variables available in separate databases to these particular cases. Statistical analysis will then be used to identify whether the epidemiology of HCC is changing, with regards to incidence, mortality, age at diagnosis and disease associations, amongst other things.			

Project Title	**QSkin sun and health study**		
Principal Investigator	Dr David Whiteman		
Institution	Queensland Institute of Medical Research		
Start Date	12 January 2012	**Finish Date**	23 January 2017
The QSkin project has previously recruited a cohort of almost 44,000 people aged 40-69 years to investigate prospectively the role of environment and host/genetic characteristics in the aetiology of cutaneous melanoma and other cancers of the skin. This application seeks approval from the Data Custodian of WA Cancer Registry for the Australian Institute of Health and Welfare to match records from the Australian Cancer Database for all consented participants of the QSkin study.			

Project Title	**Evaluation of a complex intervention to increase uptake in school HPV vaccination program**		
Principal Investigator	Dr Tanya Stoney		
Institution	Telethon Institute for Child Health Research		
Start Date	11 January 2012	**Finish Date**	31 December 2015
The primary aim of this study is to increase the school-based uptake of the human papillomavirus (HPV) vaccination. This will be achieved by implementing a number of interventions, which aim to help improve knowledge and attitudes, decision-making involvement and by reducing fear and anxiety in students receiving the vaccine. These interventions will be administered as part of the school curriculum. Another aim is to improve the vaccination program's logistical outcomes, including reduction in time spent vaccinating adolescents and increased number of consent forms returned to the school (regardless of decision).			

Project Title	**Effectiveness of rotavirus vaccine in preventing rotavirus and non-rotavirus acute gastroenteritis hospitalisations in Western Australia**		
Principal Investigator	Associate Professor Angus Cook		
Institution	The University of Western Australia, School of Population Health		
Start Date	2 January 2013	**Finish Date**	1 December 2013
The primary aim of this project is to look at the impact of rotavirus vaccine in preventing acute gastroenteritis in the WA population. This will be done by analysing the hospitalisation rates in all age groups for rotavirus associated acute gastroenteritis (AGE) and non-rotavirus AGE before and after the introduction of the rotavirus vaccine in the National Immunisation Program in WA. Vaccine effectiveness in preventing hospitalisation will be calculated using a subset of the data comprising of children in the vaccine eligible age group.			

Project Title	**Merkel cell carcinoma in Western Australia: the significance of Polyomavirus and p63 status**		
Principal Investigator	Dr Benjamin Wood		
Institution	PathWest		
Start Date	12 January 2012	**Finish Date**	1 June 2013
Merkel cell carcinoma (MCC) is a rare form of skin cancer. It is related to sun exposure, and it seems to occur more frequently in WA than in other parts of the world. It is an aggressive cancer, with one third of patients dying from the disease within five years of their diagnosis. Recent work has suggested that development of MCC is associated with infection by a new type of virus, known as Merkel cell polyomavirus (MPV). While some studies have suggested that this virus is less common in cancers seen in Australia, other studies have not found any difference. In addition, some studies have suggested that cancers which show positive staining for a protein called p63 are more aggressive than cancers which are negative for this protein. However, a recent study from Sydney found no such relationship in cancers diagnosed there.			

Thus there is a need for further testing to clarify the significance of both MPV and p63 status in MCC. As there is a high rate of MCC in WA, this project is well placed to add to the understanding of this tumour.

AIMS:

1. Determine the proportion of MCC which are positive for MPV in WA.

2. Determine the proportion of MCC which are positive for p63, and whether these had a worse outcome than the cancers which were negative.

The diagnosis of MCC is usually made by a pathologist examining a biopsy sample. Once the diagnosis has been made the tissue is stored in case it is needed again (for example, new tests may become available). This project plans to use small amounts of this stored tissue to test for the presence of HPV and the p63 protein by a technique known as immunohistochemistry. This involves the use of antibodies which specifically recognise the MPV or p63. In addition, this project intends to collect information on how each of these tumours has behaved and whether the patient has since died from the disease. The findings will then be correlated with the immunohistochemistry results, and compared with other studies.

Project Title	**The Western Australian pregnancy cohort (Raine) study**		
Principal Investigator	Ms Jennifer Mountain		
Institution	Telethon Institute for Child Health Research		
Start Date	12 December 2012	**Finish Date**	Ongoing

The Raine Study Cohort was established in 1989 when 2900 pregnant women were recruited into a research study at King Edward Memorial Hospital to examine ultrasound imaging. The mothers were assessed at 18 weeks pregnancy and then some of them again at 24, 28, 34 and 38 weeks of pregnancy. Their offspring (the Raine Cohort) have been assessed at birth, 1, 2, 3, 5, 8, 10, 14, 17, 18, 20 and now 23 years of age. Information collected over the past 23 years has been amassed into one of the most unique and important collection of data to identify and test theories regarding the complex causal pathways to health outcomes. The cohort is unique with detailed antenatal, postnatal and childhood measurements including biophysical, cardiovascular, reproductive, respiratory and metabolic function, as well as psychological and social assessments. The Raine Study now has over 95,000 phenotype measures over 10 cohort reviews with data on over 2.5 million genetic variants.

The purpose of this infrastructure linkage application is to enable the data collected on the Raine Cohort to be linked to their administrative records collected by the WA Departments of Health, Education, Child Protection, Disability Services, Housing, Corrective Services, Attorney General, WA Police and other publicly held records that may become available. The Raine Cohort have been contacted and have consented to having their data linked . Anticipated uses of the linked Raine Cohort data include, but are not limited to:

- the investigation of the relationship between parenting, health, mental health and educational outcomes;
- the relationship between nutrition and educational outcomes;
- the relationship between asthma and educational outcomes; and
- the incidence of hospital admission at difference ages.

Project Title	**Australian firefighters' health study**		
Principal Investigator	Dr Deborah Glass		
Institution	Monash University, Department of Epidemiology and Preventive Medicine		
Start Date	9 January 2011	**Finish Date**	1 September 2014

Australasian Fire and Emergency Service Authorities Council commissioned Monash University to conduct a retrospective cohort study of Australian firefighters. The study will involve assembling a cohort of current and former firefighters by extracting data from existing computerised records held by the participating firefighting agencies. The cohort will include men and women, career, part-time and volunteer firefighters.

Cancer and mortality outcomes will be measured through data linkage with the Australian Cancer Database and the National Death Index.

Existing historical occupational and incident data will be used to investigate links between various firefighting activities and later cancer and death outcomes. It will be possible to use duration of active firefighting as an exposure metric for most employees and volunteer firefighters. For many firefighters, it will be possible to measure the number and types of emergency incidents attended after 1997, and to measure the frequency of exposure to some hazardous materials. No previous published study has undertaken analyses based on such incident data, so the use of such data is likely to result in more refined exposure assessment methods than previously used.

Project Title	**The impact of *Chlamydia* infection on reproductive health in women – Western Australia data linkage study**		
Principal Investigator	Dr Bette Liu		
Institution	The University of New South Wales, the Kirby Institute		
Start Date	1 January 2013	**Finish Date**	1 January 2016

Chlamydia is the most commonly notified infection in young Australian women and reports of cases are increasing. While Chlamydia is thought to result in infertility, ectopic pregnancy and adverse birth outcomes such as premature babies, the evidence for this is limited. This study aims to provide more definitive evidence regarding these associations and the results will provide information to more cost-effectively plan strategies to control Chlamydia in Australia. It will be conducted by linking a number of administrative health datasets in WA through the WA Data Linkage Branch.

Project Title	**Exploring the impact of rare diseases on the Western Australian health system**		
Principal Investigator	Professor Hugh Dawkins		
Institution	Department of Health WA		
Start Date	1 January 2013	**Finish Date**	31 December 2015

This study will investigate the impact of rare diseases on the WA health system. Rare diseases are those which occur in Australia in less than 5 in 10,000 people. While each disease affects relatively few people, collectively, they affect 6-8% of the population. At present, there is limited data on the number of people affected by, and the burden of rare diseases on the WA health system.

This study will measure the impact of rare diseases on the WA health system using hospitalisation and emergency data. WA Health has committed to developing a state strategy for rare diseases and is sponsoring the need for a national plan at the Australian Health Ministers' Advisory Council. Information from this study will also inform the state and national planning for improved management of rare diseases in Australia.

Project Title	**Linkage of the Australian Childhood Immunisation Register and state based registers to evaluate and inform Australia's immunisation program**		
Principal Investigator	Dr Heather Gidding		
Institution	Telethon Institute for Child Health Research		
Start Date	1 January 2013	**Finish Date**	31 December 2016

To optimise the health and cost benefits of Australia's immunisation program, accurate data are required about how well the program is performing. Currently, this information is derived from stand-alone databases about vaccine coverage (the Australian Childhood Immunisation Register) and several separate databases about the occurrence of vaccine preventable diseases.

The project aims to link these datasets, for a cohort of children in WA and New South Wales, to enable more accurate and detailed studies on the relationship between vaccination uptake, timeliness of vaccination, and development of disease, particularly in specific at-risk populations who may experience a higher burden of infection.

Project Title	**Use of emergency departments by vulnerable groups at the end of life**		
Principal Investigator	Professor Lorna Rosenwax		
Institution	Curtin University of Technology, Centre for Research into Disability and Society		
Start Date	2 January 2013	**Finish Date**	31 December 2014
People in their last year of life who attended emergency departments (ED) could often be better cared for elsewhere. Our severely overcrowded ED, and the staff who work in them, are poorly equipped to provide appropriate end-of-life care. This research describes how people in their last year of life use ED, the impact of this use upon ED services and how the provision of adequate primary care and supportive care services in the community may be more appropriate and economically viable option for people at the end-of-life. The research will use population based data to look back at how people who died of one of ten conditions considered clinically suitable for palliative care used emergency services over the 12 months before death.			

Project Title	**A phase II, randomized, observer-blind with single-blind booster, multi-center, study to evaluate safety, tolerability and immunogenicity of an adjuvanted cell culture-derived H5N1 subunit Influenza virus vaccine at two different formulations in healthy elderly subjects**		
Principal Investigator	Associate Professor Peter Richmond		
Institution	Telethon Institute for Child Health Research		
Start Date	1 January 2013	**Finish Date**	31 December 2016
This project is conducting an Avian Influenza vaccine trial in the elderly population (65 years of age and above). Recruitment of 40 participants into this trial will test the safety and effectiveness of this investigational vaccine. The electoral roll will be used to send out invitation letters to people of eligible age and if they are interested in this study, they will be asked for further information. The length of time the participant will be involved in this study is around two years and during this time they will receive three doses of the vaccine with safety and follow up phone calls and visits to the clinic to see a doctor.			

Project Title	**Validating and enhancing population-based data linkage for infectious diseases research**		
Principal Investigator	Associate Professor Christopher Blyth		
Institution	Telethon Institute for Child Health Research		
Start Date	2 January 2013	**Finish Date**	31 December 2013

It is a recommendation for children requiring hospitalisation with a chest infection (like bronchitis or pneumonia) to have a laboratory test. From previous work, where information about hospital and laboratory records were linked together, it was found that few children, especially those in rural and remote hospitals of WA, had a laboratory test. This project will involve going around to various hospitals and manually checking hospital records to see how many children did have a laboratory test. This will help to determine whether previous data linkage work carried out by the team was inaccurate, or whether children are being under-investigated for chest infections.

Project Title	**Multidrug resistant tuberculosis in Western Australia**		
Principal Investigator	Dr Joshua Francis		
Institution	Princess Margaret Hospital for Children		
Start Date	2 April 2013	**Finish Date**	4 August 2013

This study aims to describe the clinical and epidemiological features of multidrug resistant tuberculosis (MDR-TB) cases diagnosed in WA between 1998 and 2012 inclusive. Treatment approaches and outcomes achieved will also be described, including documentation of adverse effects of treatment. Data indicating the complexity of management will also be obtained and used to compare with the management of non-multidrug-resistant TB. Approximately 15 cases of MDR-TB will be compared with approximately 45 control cases with non-multidrug-resistant TB. It is anticipated that the audit will demonstrate that management of MDR-TB is more complex and results in poorer outcomes.

Project Title	**Decreasing depression during the menopausal transition: a pilot study**		
Principal Investigator	Professor Osvaldo P. Almeida		
Institution	The University of Western Australia, WA Centre for Health and Ageing		
Start Date	1 January 2013	**Finish Date**	30 June 2014

Menopause is the point in time when a woman's menstrual periods stop. The years leading up to a woman's final period is referred to as the "menopausal transition" and on average lasts four to seven years. Previous research has found that about one in every four women experience symptoms of depression during this transition period. Some women may also notice changes that include: irregular menstrual periods, hot flushes, sleep disruption, night sweats, vaginal and urinary problems and low libido. Fortunately, the most bothersome features of the menopausal transition can be managed successfully, including the changes in mood.

This project aims to find out if changes in mood can be prevented from occurring altogether by addressing relevant risk factors for depression that might be present during the menopausal transition.

This project requires the participation of midlife women who are experiencing symptoms consistent with the lead up to menopause. Eligible participants will be randomly assigned into one of two groups: 1.Standard Medical Care or 2. Standard Medical Care and a Health Coaching Program

Women allocated to the health coaching program will have access to a health coach for a minimum of eight telephone coaching sessions. The health coach will offer educational material on menopausal transition, depression and healthy lifestyle behaviours, problem solving treatment and how to enhance motivation through activity scheduling of enjoyable and achievement based tasks. A series of validated self-report measures will be mailed to all study participants at four time points (baseline and at eight weeks, 26 weeks and 52 weeks). These measures will collect demographic, lifestyle and clinical information. The primary outcome of this study is whether participants develop major depression at follow up, a mood disorder characterised by at least two weeks of depressed mood and/or lack of motivation plus four additional symptoms drawn from a list that includes changes in appetite, sleep, decreased energy, feelings of worthlessness, physical agitation/slowing, diminished ability to think/concentrate and recurrent thoughts of death.

Project Title	**Validation of pertussis (whooping cough) vaccination uptake in mothers of newborns**		
Principal Investigator	Dr Paul Effler		
Institution	Department of Health WA		
Start Date	3 January 2013	**Finish Date**	31 December 2013

The Department of Health (DoH) funded a pertussis vaccination program for parents and household carers of newborns, from 1 January 2011 to 31 December 2012. A database was created to capture all pertussis vaccinations given to parents and reported to the DoH by immunisation providers. This database is used in the evaluation of the program. However, a recent study on influenza vaccination uptake in pregnant women found form return rate by immunisation providers was very poor.

This study aims to find out what proportion of new mothers who are not recorded on the database as having received a whooping cough vaccine were in fact vaccinated after the birth of their baby. The knowledge gained from this project will help validate pertussis vaccination uptake of mothers of newborns. This will ensure that health policy and funding decisions are informed by more accurate information than is currently available.

Project Title	**The accurate measurement of physical activity and sedentary time among non-Hodgkin lymphoma survivors study**		
Principal Investigator	Dr Terry Boyle		
Institution	The University of Western Australia, WA Institute for Medical Research		
Start Date	3 January 2013	**Finish Date**	28 February 2014

Non-Hodgkin lymphoma (NHL) and its treatment may result in ongoing physical and psychosocial difficulties for the 60% of patients who survive the disease. There is strong evidence that modifiable behavioural risk factors can influence the health of cancer survivors. Of note, a small body of research has shown physical activity to be a helpful method for improving the health and well-being of NHL survivors. However, past research has relied on self-reported physical activity, which is inaccurate and prone to overestimation. Accelerometers are devices that provide valid and reliable information about physical activity and sedentary time patterns. Using accelerometers, the physical activity and sedentary time of 200 NHL survivors will be accurately characterised, and associations examined with indicators of health and well-being. Participants will be male or female, have been diagnosed with an incident, primary NHL between 1 January 2007 and 31 December 2011 and will have completed treatment for their NHL.

Project Title	**The accurate measurement of physical activity and sedentary time among breast cancer survivors study**		
Principal Investigator	Dr Terry Boyle		
Institution	The University of Western Australia, WA Institute for Medical Research		
Start Date	3 January 2013	**Finish Date**	28 February 2014

Breast cancer and its treatment may result in ongoing physical and psychosocial difficulties for the 80% of patients who survive the disease. There is strong evidence that modifiable behavioural risk factors can influence the health of cancer survivors. Of note, a small body of research has shown physical activity to be a helpful method for improving the health and well-being of breast cancer survivors. However, past research has relied on self-reported physical activity, which is inaccurate and prone to overestimation. Accelerometers are devices that provide valid and reliable information about physical activity and sedentary time patterns. Using accelerometers, physical activity and sedentary time of breast cancer survivors will be accurately characterised and associations examined with indicators of health and well-being. Participants will be female, have previously participated in the Breast Cancer Environment and Employment Study and will have completed treatment for their breast cancer.

Project Title	**Predicting the impact of current obesity and diabetes trends on future prevalence of cardiovascular disease in Australia**		
Principal Investigator	Dr Tom Briffa		
Institution	The University of Western Australia, School of Population Health		
Start Date	24 February 2012	**Finish Date**	30 June 2014
This project proposes to develop an Australian projection model for heart disease. This model will be used to predict the impact of the current growth in the number of people with diabetes on future heart disease rates in Australia. This model will help to determine the extent to which health services will need to plan for increased services for heart disease as the number of diabetes cases grows. The model will also provide a way to evaluate what the best strategies might be to prevent the predicted rise in heart disease in the future.			

Project Title	**Successful ageing in older men – thriving not just surviving in the health in men study**		
Principal Investigator	Winthrop Professor Leon Flicker		
Institution	The University of Western Australia, WA Centre for Health and Ageing		
Start Date	18 March 2013	**Finish Date**	31 December 2015
The study aims to gather information about the health of men aged over 80 years to determine what factors are associated with successful ageing in men. Men willing to participate will complete a questionnaire about their health, physical functioning, mood and lifestyle (e.g. diet, smoking and exercise) and then if they are also willing, they will undertake simple tests of vision, mobility balance and memory. These tests will be conducted at the WA Centre for Health and Ageing, Royal Perth Hospital or at the participant's home. This data will then be linked to previous questionnaires and data provided by the Western Australian Data Linkage System to determine how these factors predict various outcomes including successful ageing, one component of which is that they are free of major illnesses.			

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


Delivering a **Healthy WA**