



Government of Western Australia
Department of Health

Human Research Ethics Committee

Annual Report 2012

Version: April 2013

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1. Background

The Department of Health (DOH) is responsible for collecting personal health information relating to Western Australians. Every time a patient is admitted into a public or private hospital, presents at an emergency department or attends an outpatient clinic, information is collected about them, their diagnosis and treatment. This personal health information is stored in specific data collections, each with a different focus. Some of these data collections include the Cancer Registry, Emergency Department Data Collection, Hospital Morbidity Data System, Mental Health Information System and Midwives Notification System. The data is an important resource used for funding, management, planning, monitoring, improvement, research and evaluation of health and health services in the state.

In 1989, an independent committee called the Confidentiality of Health Information Committee (CHIC) was established to provide advice on managing these data collections in such a way that the privacy of each individual featured in the database was protected.

In April 2008, the CHIC was decommissioned and replaced by the Department of Health Human Research Ethics Committee (DOH HREC). The DOH HREC was given responsibility for overseeing the use and disclosure of personal health information held in the DOH data collections.

The objectives of the DOH HREC are to:

- promote the ethical use of health information;
- promote ethical standards of human research;
- protect the welfare, rights and dignity of individuals; and
- facilitate ethical research through efficient and effective review processes.

The DOH HREC is registered with the National Health and Medical Research Council (NHMRC) and is constituted in accordance with the National Statement on Ethical Conduct in Human Research (National Statement). The NHMRC collates information about HRECs and monitors their compliance with the National Statement and with sections s95 and s95A of the *Privacy Act 1988*.

Consistent with the NHMRC reporting obligations, this report provides a summary of the DOH HREC activities from 1 January 2012 to 31 December 2012. It includes information on its members and their expertise, the number of applications submitted to the DOH HREC and their status, the number of complaints received and the predominant users of the data collections. For the 2012 reporting period, there were 77 new applications for ethics approval, which is a reflection of the continual interest and investment in health-related research in WA.

2. Membership

Members are appointed to fulfill specific roles as per the National Statement and the Terms of Reference. As a minimum, HRECs in Australia comprise of:

- a Chairperson with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;
- at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
- at least one person with knowledge of, and current experience in, the professional care, counselling and treatment of people;
- at least one member who performs a pastoral care role in the community for example, a minister of religion or an Aboriginal elder;
- at least one lawyer who is not engaged to advise the institution; and
- at least two people with current research experience that relates to research proposals to be considered at the meetings they attend.

In addition, the DOH HREC membership includes:

- one person with knowledge of and current experience in information security; and
- one person with knowledge of and current experience in the management and uses of large health data collections who is employed by WA Health.

Initially, members were appointed to the DOH HREC for a 3 year term. In October 2010 the Director General endorsed the implementation of a staggered approach for appointing members to the DOH HREC. The staggered approach appoints members to fixed term positions, rather than being appointed for a fixed 3 year term, to encourage the continuity of experience and knowledge within the DOH HREC. Sitting members may serve 1 term and deputy members may serve 2 consecutive terms, unless otherwise approved by the Director General. Deputy members with comparable expertise and experience are appointed to the DOH HREC as proxies when members are unable to attend meetings.

The sitting members that served on the DOH HREC in 2012 are shown in Table 1.

Table 1 Sitting members serving on the DOH HREC in 2012

Position	<i>Incumbent</i>
Chairperson	Assistant Professor Judith Allen
DOH Representative	Ms Mary Miller
Information Security	Mr John Wreford
Lay person	Ms Joyce Archibald
Lay person	Mr Ross Monger
Lawyer	Ms Kathryn Barker
Pastoral Care	Reverend Brian Carey
Professional Care	Professor Bryant Stokes (Deputy Chairperson)
Researcher	Dr Alison Garton
Researcher	Dr Katrina Spilsbury

Table 2 shows deputy members that served on the DOH HREC in 2012.

Table 2 Deputy members serving on the DOH HREC in 2012

Position	<i>Incumbent</i>
DOH Representative	Dr Janine Alan
DOH Representative	Dr Tim Threlfall
Information Security	Mr Gary Langham
Lay person	Mr Phillip Jacobsen
Lay person	Ms Michele Kosky
Lawyer	Ms Dianne Scaddan
Pastoral Care	Reverend Jenifer Goring
Professional Care	Ms Patricia Fowler
Researcher	Mr Tom Briffa

3. Training

This year the newly appointed sitting and deputy members attended an induction meeting which focused on the: (i) role and scope of the DOH HREC; (ii) National Statement; (iii) Terms of Reference; (iv) Standard Operating Procedures; and (v) legal obligations pertaining to health data.

Managers of the core health data collections held by the DOH were invited to give a presentation about their respective collection. The Data Linkage Branch also presented information about the data linkage system, which connects data about health events with individuals in Western Australia.

The induction meeting provided an opportunity for new members to increase their awareness of ethical considerations that apply to human research and the responsibilities of the DOH HREC. The meeting also provided members with important information about relevant privacy legislation and legal obligations.

4. Meetings and executive support

The DOH HREC meets on the second Wednesday of every month. In 2012, 11 meetings were held with the average meeting lasting about 2 hours.

A quorum for meetings of the DOH HREC exists when at least 5 members are physically present and include 1 of each of the following categories:

- chairperson/deputy chairperson;
- lay person;
- researcher who has knowledge of and current experience in the relevant areas of research; and
- at least one third of those present being from outside the DOH.

A quorum was present for all the meetings.

The DOH has employed an Executive Officer to provide administrative support to the DOH HREC.

5. Review of research projects

The number of new applications considered by the DOH HREC in 2012 and the status of the new applications are tabulated below. The titles of these new applications are shown in Appendix A.

Table 3 Number and status of new applications from 1 January to 31 December 2012

Total applications received in 2012	77
Approved applications	61
Not approved	0
Applications which were withdrawn	2
In progress	14
Applications discontinued	1

The DOH HREC received 77 new applications during the reporting period. As shown in figure 1, of these applications, 61 were approved in 2012, 14 were still in progress by 31 December 2012 and 2 were withdrawn because the researchers did not respond to a request for further information within the 3 month deadline. 1 project was discontinued after approval due to a key project team member being unable to fulfill their role on the project.

Figure 1 - Status of applications received in 2012

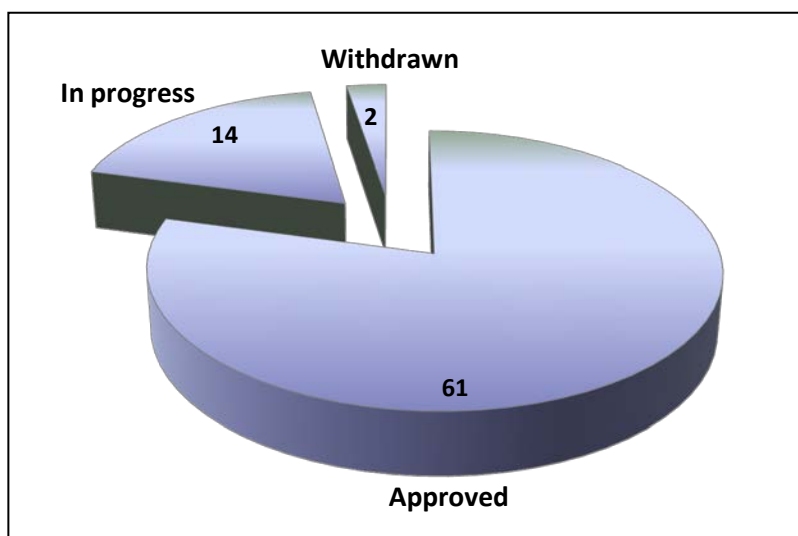
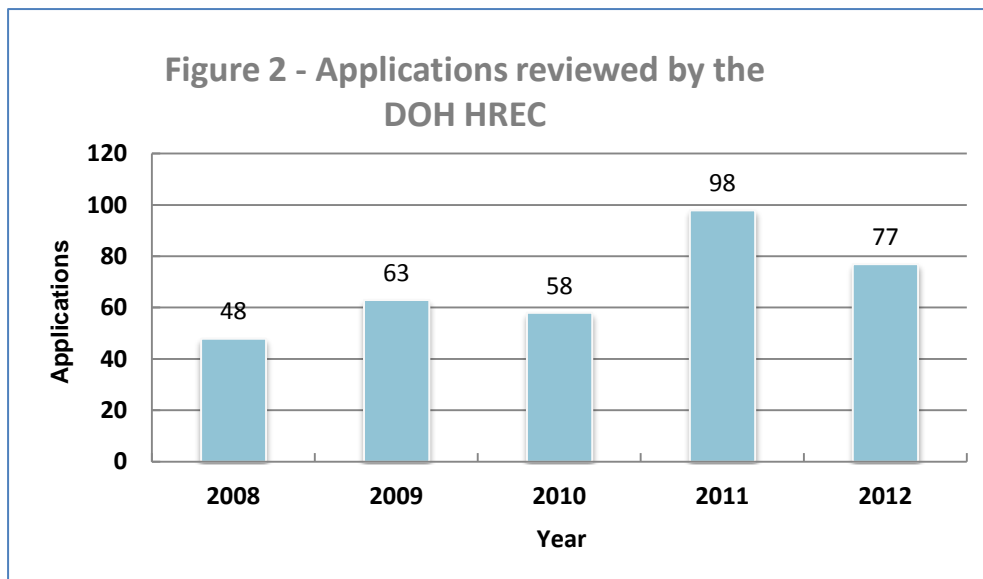


Figure 2 shows the number of new applications considered by the DOH HREC by calendar year since its inception in 2008.



The noticeable increase in new applications for the 2011 reporting period was the result of an audit of projects previously approved by the CHIC. In accordance with DOH policy, the 42 CHIC-approved projects (considered ongoing) were resubmitted to the DOH HREC. With the exception of 1 project, all these projects were granted ethics approval by the DOH HREC.

6. Annual reports, amendments and closure of projects

The DOH HREC is bound by the NHMRC guidelines to monitor the progress of all approved projects until completion. This is in accordance with chapter 5.5 of the National Statement ensuring that research conducted conforms to the approved ethical standards.

In accordance with chapter 5.5.3 of the National Statement, researchers have a significant responsibility in monitoring their research. Researchers must report any serious or unexpected adverse events or any unforeseen events that might affect the continued ethical acceptability of the project.

Researchers are responsible for ensuring that an annual progress report, any amendment requests and a final report are submitted to the DOH HREC in a timely manner.

The annual progress report template is accessible to researchers on the DOH HREC website. The standardised report requires researchers to provide the following information about the approved project:

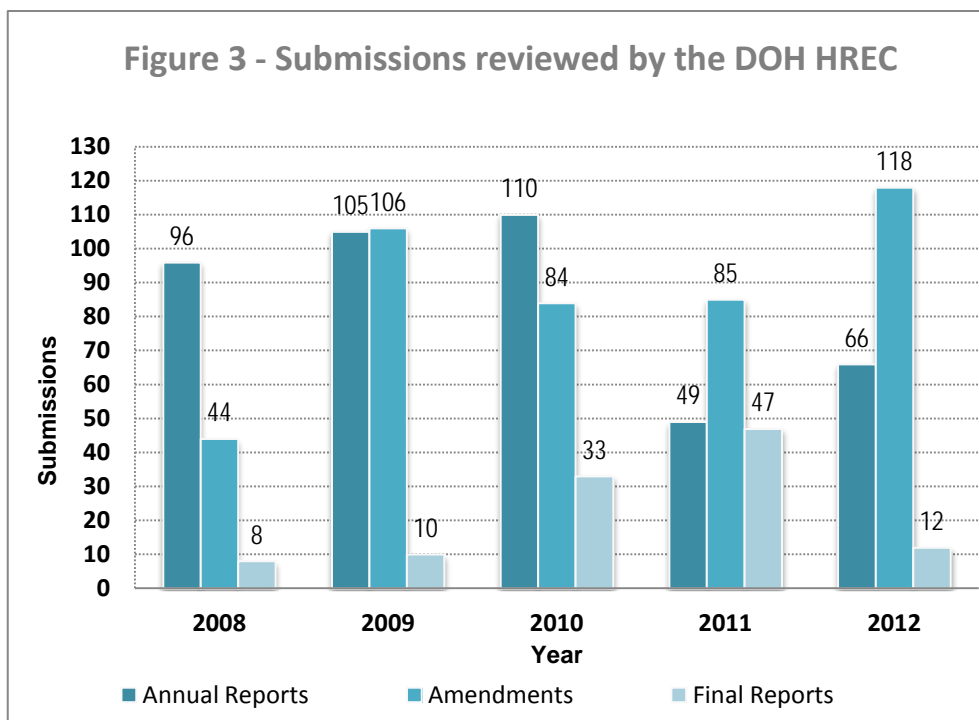
- progress to date, publication or outcome in the case of completed research;
- maintenance and security of records and data;
- compliance with the approved protocol;
- compliance with the conditions of approval;
- changes to the protocol or conduct of the research;
- changes to the personnel or contact details of the principal investigator; and
- adverse events or complaints relating to the project.

A total of 66 annual reports were approved by the DOH HREC in 2012. This was a significant increase compared to the 49 annual reports received during the previous year. This increase can be attributed to an audit carried out internally, which involved contacting researchers who had not submitted their reports on time.

The amendment request form is also accessible on the DOH HREC website. Researchers are required to complete the standard form when seeking approval for changes to the research protocol including methodology, data required, duration of the project, changes to personnel in the research team and changes to the approved data storage arrangements. A total of 118 amendment requests were approved by the DOH HREC in 2012.

A final report is required to be submitted at the completion of the research project. The report includes the outcomes of the research, a copy of the results and any publications. A total of 12 final reports were submitted and approved in 2012.

Figure 3 shows the number of final reports, amendment requests and annual reports submitted to the DOH HREC by year.



7. Administrative procedures

The Executive Officer provides administrative support for the operation of the DOH HREC and is responsible for ensuring that applications are received and processed in accordance with the Standard Operating Procedures (SOP).

The Executive Officer is also responsible for ensuring that all applications and other documentation such as agendas, minutes and correspondence are maintained in accordance with the *State Records Act 2000*.

8. Breaches, concerns and complaints

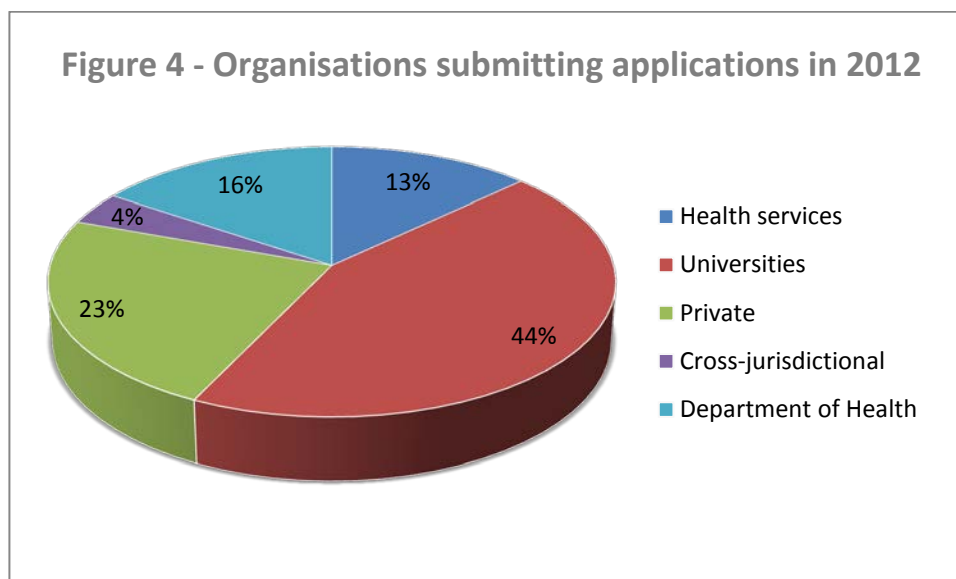
The DOH HREC SOP outlines the process for receiving, handling and responding to complaints concerning:

- reporting and handling of adverse events in clinical trials (SOP17);
- breaches in the conduct of a project approved by the DOH HREC (SOP18);
- concerns and complaints about the conduct of a project approved by the DOH HREC (SOP19); and
- the DOH HREC's review or rejection of an application (SOP20).

Concerns were raised over potential breaches for 2 projects. However, in both cases the matters were resolved successfully.

9. Major users of DOH data

Figure 4 displays the various organisations that submitted an application for ethics approval for the 2012 reporting period. Researchers affiliated with Western Australian university departments formed the largest group, followed by researchers from the private sector. With regard to the private sector, the majority of requests came from the 'Telethon Institute for Child Health Research'.



The Department of Health submitted 16% of the applications, health services (including Sir Charles Gairdner Hospital, Fremantle Hospital, Royal Perth Hospital, Princess Margaret Hospital, King Edward Memorial Hospital and Kimberley Population Unit) submitted 13% of the applications and cross-jurisdictional projects only accounted for 4% of the total number of applications submitted.

10. Application of *Privacy Act 1988* guidelines

There are specific situations where the Guidelines under Section 95 of the *Privacy Act 1988* (section 95 guidelines) and the Guidelines approved under Section 95A of the *Privacy Act 1988* (section 95A guidelines) need to be applied to research projects. Specifically, these guidelines apply to disclosure of personal health information from Commonwealth agencies or the private sector.

If personal health information is required from a Commonwealth agency and used for research purposes without the consent of the individual, then section 95 guidelines are relevant.

If personal health information is required from an organisation in the private sector without the consent of the individual and any of the following uses applies, then section 95A guidelines are relevant:

- research relevant to public health or to public safety; and/or
- the compilation or analysis of statistics; and/or
- the conduct of the management, funding or monitoring of a health service.

In considering the guidelines, the DOH HREC must consider whether it is necessary for the research to use identified or potentially identifiable data and whether it is reasonable for the research to proceed without the consent of the individuals to whom the information relates to.

In reaching a decision, the DOH HREC considers whether the public interest in the research and the likely benefits outweigh the public interest in privacy.

In 2012 the DOH HREC applied the section 95 guidelines to 4 applications and the section 95A guidelines to 8 applications which were granted ethics approval.

11. Public awareness

The DOH HREC takes the view that it is important that members of the public are aware of the ways in which personal health information collected by DOH WA is used for the public benefit. Accordingly the DOH HREC has initiated the quarterly publication on the DOH HREC website of brief summaries of all research projects approved by the Committee. Publication of the summaries commenced in 2012. Project summaries for approved proposals are available at www.health.wa.gov.au/healthdata/HREC/proposals.

12. Conclusion

In 2012, the DOH HREC discharged its responsibilities to oversee the use and disclosure of personal health information held in the DOH data collections. The combined skills and expertise of the Committee members and deputy members were applied to the ethical review and approval of 61 new projects.

Members of the Committee observed that the quality of applications has significantly improved in recent years. The Committee operates in tandem with the review of applications conducted by data managers to ensure that applications are well developed, that privacy and security are properly protected and that the interests of individuals are respected.

13. Supporting documents

Department of Health (2009). *Information about your health data*. Department of Health, Perth.

Department of Health (2011a). *Department of Health Western Australia Human Research Ethics Committee Terms of Reference*. Department of Health, Perth.

Department of Health (2011b). *Department of Health Western Australia Human Research Ethics Committee Standard Operating Procedures*. Department of Health, Perth.

National Health and Medical Research Council (2000). *Guidelines approved under Section 95 of the Privacy Act 1988*. Commonwealth of Australia. Canberra.

National Health and Medical Research Council (2001). *Guidelines approved under Section 95A of the Privacy Act 1988*. Commonwealth of Australia. Canberra.

National Health and Medical Research Council (2007). *National Statement on Ethical Conduct in Human Research*. Australian Government. Canberra.

Appendix A – New applications reviewed in 2012

Project	Project title
2012/01	Studies of hospital morbidity and the association between morbidity and mortality in Western Australia indigenous and non-indigenous children born between 1980 and 2005, inclusive.
2012/02	Maternal prenatal stress exposure and risk of infectious disease hospital admissions for offspring in childhood and early adolescence
2012/03	Patterns and trends in deaths attributed to birth defects in WA children born 1980 - 2001 by race and location
2012/04*	Life limiting conditions in children and young people in Western Australia: prevalence and survival
2012/05	Cross jurisdictional data linkage project
2012/06	A cohort study to measure the effectiveness of pertussis vaccination of parents of newborns
2012/07	Epidemiology of rotavirus infection and effect of rotavirus vaccination in Western Australia (July 2006 - June 2013)
2012/08	The WA family connections genealogical project
2012/09	The burden of atrial fibrillation
2012/10	Media portrayal of illicit drug users: influences on public perception and impact on injecting drug users
2012/11	Retrospective audit of success rates of pleurodesis in malignant pleural effusions due to mesothelioma in Western Australia
2012/12	Investigation to determine the degree of bladder cancer stage migration by examination of histopathology reports held by the WA Cancer Registry (WACR) for the periods (1982-1986)
2012/13	Partnership intervention trial to redress treatment delay and improve outcomes in rural cancer patients: implementation/evaluation phase
2012/14	The psychological factors that inhibit or facilitate motorist's effective responding to emergency vehicle encounters
2012/15	Western Australia Notifiable Infectious Disease Database (WANIDD): infrastructure linkage
2012/16	Hepascore2-a simple method of determining severity of liver fibrosis in chronic hepatitis C liver disease
2012/17	Mothers who die: a national population study of mothers dying in pregnancy and up to 42 days after birth - data linkage

2012/18	Mothers who die: a national population study of mother dying in pregnancy and up to 42 days after birth
2012/19*	Does methadone maintenance treatment increase the risk for diabetes, cancer, osteoporosis, mental illness and cardiac problems in an older cohort?
2012/20	Long term follow up of the FIELD (fenofibrate intervention and event lowering in diabetes) cohort study
2012/21	Utilisation of intensive care services in bariatric surgery
2012/22	Evaluation of the MMEEx cancer module stage ii: validation of MMEEx data
2012/23	An investigation of the antenatal determinants and morbidity outcomes of intellectual disability and autism
2012/24	Evaluation of morbidity and mortality associated with home birth in Western Australia
2012/25	Body mass index as a predictor of long-term outcomes after adult cardiac surgery
2012/26	Consumer copayments for prescription medicines: impact on access and health outcomes
2012/27	Population-based trends and health outcomes after burn injury hospitalisation in Western Australia
2012/28	Case-control studies of the cerebral palsies in term and preterm infants in Western Australia 1980-1995 (CCCP): the aetiological role of birth defects
2012/29	Morbidity and mortality outcomes in women following treatment with Assisted Reproductive Technology (ART) in Western Australia
2012/30	Estimating the prevalence of cardiovascular disease, chronic kidney disease and diabetes and incidence of acute coronary syndrome and end-stage kidney disease in NSW and WA, using linked hospital and deaths data
2012/31	Evaluating the effect of blood transfusion on morbidity and mortality from acute upper gastrointestinal haemorrhage
2012/32*	Evaluation of the uptake of hepatitis B vaccination among sexual and household contacts of patients notified with hepatitis B
2012/33	Influenza vaccination uptake in pregnant women in Western Australia
2012/34	Management of penile cancer
2012/35	Accurate measurement of physical activity and sedentary time among colon cancer survivors (the ACCEL study)
2012/36	The Australian perinatal mental health reforms: using population data to evaluate their impact on service utilisation and related cost effectiveness
2012/37	Public health approach to child abuse and neglect: antecedents and outcomes

2012/38	Analysis of differences in bowel cancer outcomes between NBCSP participants and non-NBCSP participants in Australia
2012/39	A population-based study on the effect of childhood onset type 1 diabetes on school performance
2012/40	The epidemiology of moderate and serious injury among Western Australian cyclists
2012/41	Calculating injury severity scores from hospital, trauma and death records in WA
2012/42	Estimation of the annual prevalence, burden of disease, health service utilisation and survival of patients diagnosed with cancer in Western Australia
2012/43	Epidemiology of oesophageal atresia in Western Australia
2012/44	Australian early development index: (AEDI): infrastructure linkage
2012/45	Effectiveness of rotavirus vaccination in Western Australia: a case-control study
2012/46	Health watch, the Australian institute of petroleum health surveillance program
2012/47	Evaluation of COAG aboriginal health liaison officer program in south metropolitan health services (SMHS)
2012/48	Validating 3m outcome quality indicators as a potential tool to enhance quality of care in the Australian hospital setting – a collaborative study
2012/49	Evaluation of the trends and outcomes for women screened for an diagnosed with precursor lesions or cervical carcinoma: a Western Australian perspective utilising data linkage
2012/50	Mortality among juvenile offenders in Western Australia: a retrospective population-based cohort study
2012/51	Detailed multivariate analysis of factors influencing the occurrences and outcome of road crashes and injuries using linked hospital, roads, death, insurance, trauma and licensing data
2012/52	Survival, hospitalisations and school achievement for children born with cleft lip and palate in Western Australia, from 1980 to 2010
2012/53	Exposure to perinatal inflammation and risk of hospitalisation with infection in childhood in extremely premature infants
2012/54	Epidemiology of anaphylaxis in Western Australia (EPAWA)
2012/55	Trends in hepatocellular carcinoma in Western Australia from 1983 to 2010
2012/56	Identifying opportunities for preventing respiratory infections in children through integrating population-based health and laboratory data
2012/57	Outcomes of <i>Staphylococcus Aureus</i> bacteraemia: methicillin-resistant vs methicillin-susceptible organisms

2012/58	Qskin sun and health study
2012/59	The incidence of cardiovascular disease and the distribution of risk factors for cardiovascular disease among people with psychosis in Western Australia 1970-2011
2012/60	Evaluation of a complex intervention to increase uptake in school HPV vaccination program
2012/61	Developing and validating a job exposure matrix to assess occupational exposures to endocrine disrupting chemicals (EDCs) in relation to birth outcomes
2012/62	Colonoscopy services and outcomes in Western Australia (WA). Population-based studies using linked WA data
2012/63	Mortality and morbidity in opiate dependent patients and their offspring following treatment with methadone, buprenorphine or implant naltrexone
2012/64	Cause of mortality in people with rheumatic heart disease in the Kimberley 1990-2010
2012/65	Investigating school dental records for Raine children
2012/66	The effect of prophylactic, risk reducing prophylactic surgery on survival among patients with a history of breast cancer
2012/67	Effectiveness of rotavirus vaccine in preventing rotavirus and non-rotavirus acute gastroenteritis (AGE) hospitalisations in WA
2012/68	Merkel cell carcinoma in Western Australia: the significance of polyomavirus and p63 status
2012/69	Partnership intervention trial to redress treatment delay and improve outcomes in rural cancer patients (the 'IRCO trial'): evaluation phase - tranche I
2012/70	The Western Australian pregnancy cohort (Raine) study
2012/71	Linkage of monitoring of drugs of dependence data collection
2012/72	Australian firefighters' health study
2012/73	The impact of chlamydia infection on reproductive health in women – WA data linkage study
2012/74	Exploring the impact of rare diseases on the Western Australian health system
2012/75	Linkage of the Australian Childhood Immunisation Register (ACIR) and state based registers to evaluate and inform Australia's immunisation program
2012/76	Use of emergency departments by vulnerable groups at the end of life
2012/77	An investigation of the development pathways to hospitalised deliberate self-harm (DSH) behaviours among young people: a birth cohort study using cross-jurisdictional linked data in Western Australia

***Please note that projects 2012/19 and 2012/32 were withdrawn. Project 2012/04 was discontinued.**



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