



Government of Western Australia
Department of Health

Human Research Ethics Committee

Annual Report 2013

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1. Background

The Department of Health Human Research Ethics Committee (DOH HREC) was established in April 2008 to oversee 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 2013 to 31 December 2013. 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 2013 reporting period, there were 80 new applications for ethics approval, representing a slight increase from last year, in which 77 new applications were received. This 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.

In 2013, there were nine positions on the DOH HREC which had terms expiring on 31 December 2013. These included the member positions for the Chairperson, lawyer and male lay person, and the deputy member positions for the WA health representative, two researchers, the information security representative, the professional care representative and the lawyer. Recommendations to fill eight of these positions were approved by Cabinet in December 2013. The recruitment process for the outstanding position of deputy member lawyer is in progress.

The staggered approach to appointing members to fixed term positions comprising three-year terms has ensured the continuity of experience and knowledge within the DOH HREC. Sitting members may serve one term and deputy members may serve two 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 2013 are shown in Table 1.

Table 1 Sitting members serving on the DOH HREC in 2013

Position	<i>Incumbent</i>
Chairperson	Assistant Professor Judith Allen
WA Health representative	Ms Mary Miller
Information security	Mr Gary Langham
Lay person	Ms Joyce Archibald
Lay person	Mr Ross Monger
Lawyer	Ms Kathryn Barker
Pastoral care	Reverend Jenifer Goring
Professional care	Ms Patricia Fowler
Researcher	Dr Alison Garton
Researcher	Dr Katrina Spilsbury (Deputy chairperson)

Table 2 shows deputy members that served on the DOH HREC in 2013.

Table 2 Deputy members serving on the DOH HREC in 2013

Position	<i>Incumbent</i>
WA Health representative	Dr Janine Alan
WA Health representative	Mr Stephen Woods
Information security	Mr Shane Gallagher
Lay person	Dr Phillip Jacobsen
Lay person	Ms Kathryn Kirk
Lay person	Ms Yvonne Rate
Lawyer	Mr Alisdair Putt
Pastoral care	Reverend Brian Carey
Professional care	Mr Tim Smith
Researcher	Associate Professor Tom Briffa
Researcher	Dr Geoffrey Hammond
Researcher	Assistant Professor Angela Ives

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.

In November 2013, three members and two deputy members attended the Australasian Ethics Network Conference full-day workshop about ethics and data linkage. Participants were provided with a range of skills and knowledge to improve their ability and confidence to assess research applications proposing the use of linked data. Topics covered included:

- what is data linkage?;
- overview of data linkage in Australia;
- risks and benefits of data linkage;
- minimising and managing risk;
- considering a waiver of consent;
- legal framework and legislative requirements; and
- considerations involved in ethics review of data linkage.

This workshop was an invaluable experience for those in attendance.

4. Meetings and executive support

The DOH HREC meets on the second Wednesday of every month. In 2013, 12 meetings were held with the average meeting lasting about two hours.

A quorum for meetings of the DOH HREC exists when at least five members are physically present and include one 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.

An Ethics Executive Officer employed by the DOH provided administrative support to the DOH HREC.

5. Review of research projects

The number of new applications considered by the DOH HREC in 2013 and the status of these 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 2013

Total applications received in 2013	80
Approved applications	69
Not approved	3
In progress	8

The DOH HREC received 80 new applications during the reporting period. As shown in figure 1, of these applications, 69 were approved in 2013, eight were still in progress by 31 December 2013 and three were not approved.

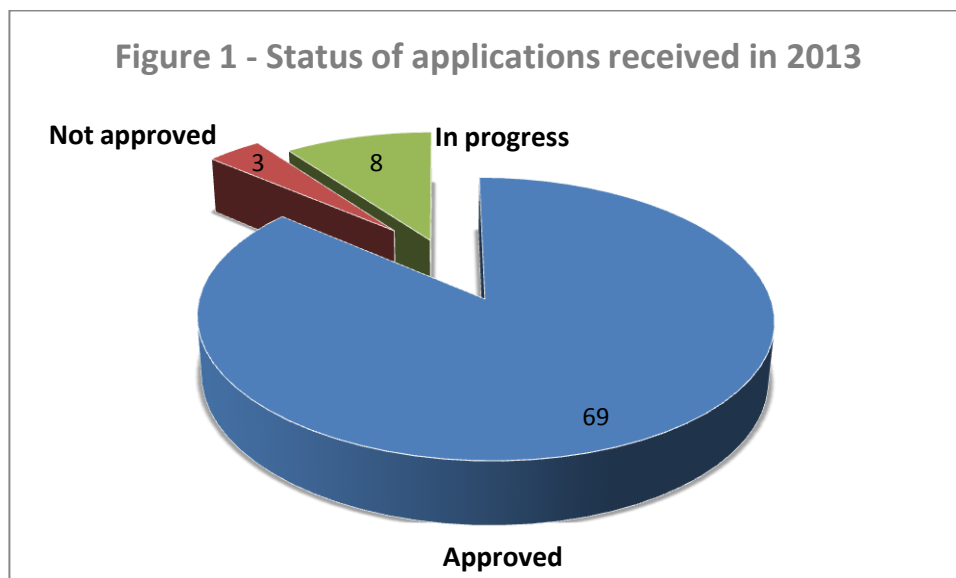
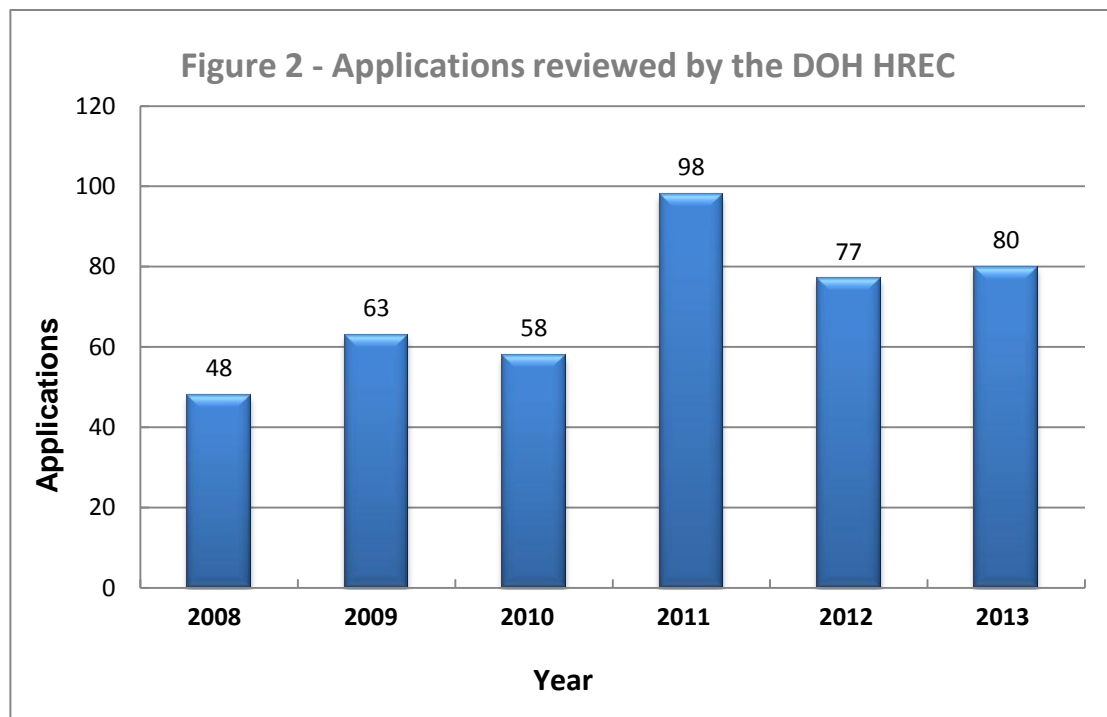


Figure 2 shows the number of new applications considered by the DOH HREC by calendar year since its inception in 2008.



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 unexpected, adverse or 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.

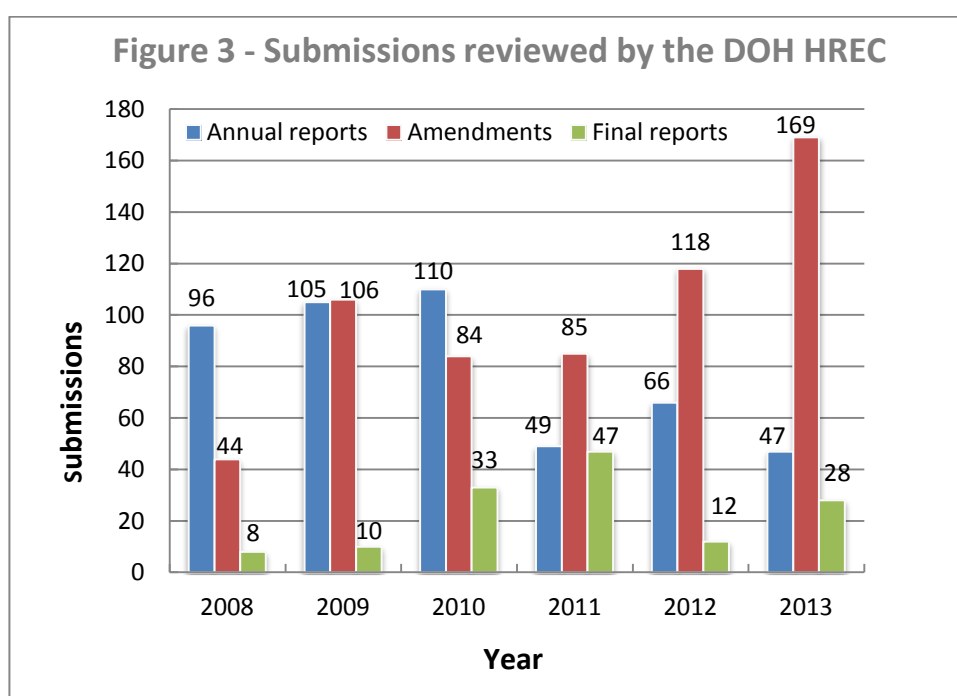
The annual progress report template is accessible to researchers on the DOH HREC website. The standardised report requires researchers to provide the following information about the approved project:

- 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 47 annual reports were approved by the DOH HREC in 2013. This was a reduction compared to the 66 annual reports received during the previous year. The database used to manage all the current projects does not have an automated system for monitoring the researchers' reporting obligations. In 2012, a review was undertaken and researchers were contacted to submit annual progress reports. A similar review was not carried out in 2013 due to time constraints. This explains why in 2012, there were a larger number of annual progress reports received than in 2013. A new database is currently being built by an external information technology provider, which will include an automated tracking system to contact researchers when they are due to submit a report. Ongoing ethics approval will be dependant on researchers submitting their reports in a timely manner.

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 169 amendment requests were approved by the DOH HREC in 2013. This figure was significantly higher than in 2012 (with 118 amendments being approved). This may have been a result of an increase in the complexity of projects with many amendments including the addition of new project team members and new data variables.

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 28 final reports were submitted and approved in 2013. This was more than double the number received in 2012 (12 final reports), though lower than the number received in 2010 (33 final reports) and 2011 (47 final reports). The new database will also ensure that the submission of final reports satisfies the researchers' reporting obligations. Figure 3 shows the number of final reports, amendment requests and annual reports submitted to the DOH HREC by year.



7. Administrative procedures

The Ethics 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 Ethics 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

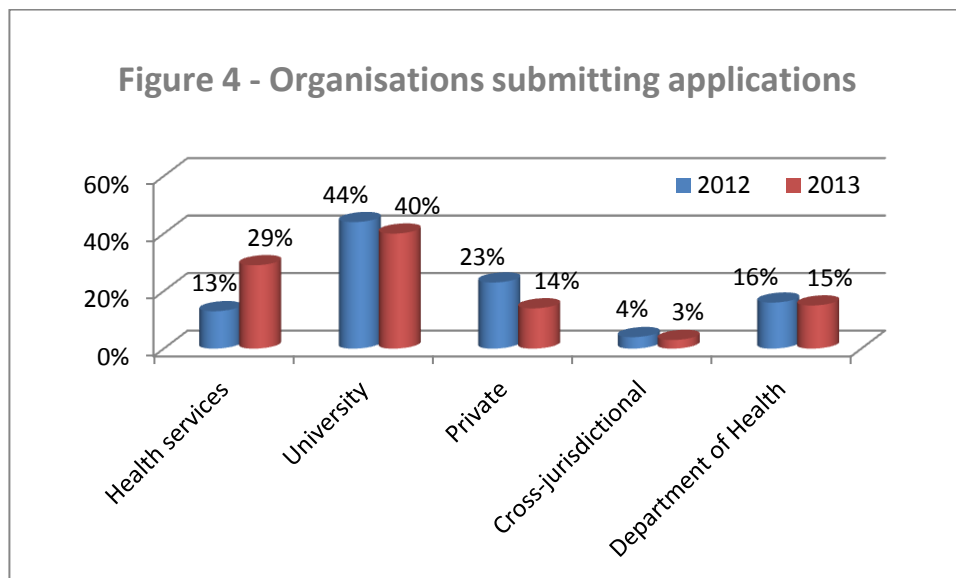
The DOH HREC SOP outlines the process for receiving, handling and responding to complaints concerning:

- 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).

In 2013, there were two complaints received in relation to one project. In both cases, the DOH HREC reviewed the way that these complaints were dealt with by the research team. The DOH HREC concluded that both complaints were managed appropriately and that no further action was required.

9. Major users of DOH data

Figure 4 displays the various organisations that submitted an application for ethics approval for the 2013 reporting period. Researchers affiliated with Western Australian University departments formed the largest group, which was also the case in 2012. The proportion of applications that were submitted by the Department of Health and cross-jurisdictional organisations remained the same. However, more researchers in the various Health Services (including Sir Charles Gairdner Hospital, Fremantle Hospital, Royal Perth Hospital, King Edward Memorial Hospital and Princess Margaret Hospital) submitted applications than those in the private sector. Similar to 2012, the bulk of the private sector applications came from the Telethon Institute for Child Health Research.



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 2013, the DOH HREC applied the section 95 guidelines to 5 applications and the section 95A guidelines to 4 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 2013 and project summaries for approved proposals are available at www.health.wa.gov.au/healthdata/HREC/proposals.cfm.

12. Conclusion

In 2013, 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 69 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 (2012a). *Department of Health Western Australia Human Research Ethics Committee Terms of Reference*. Department of Health, Perth.

Department of Health (2012b). *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 2013

Project	Project title
2013/01	Health policy makers' perceptions of the development and implementation of compulsory public health measures
2013/02	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.
2013/03	Long term outcomes of recombinant growth hormone therapy
2013/04	The utilisation of medications during pregnancy and the associated health outcomes
2013/05	Validating and enhancing population-based data linkage for infectious diseases research
2013/06	Defining appropriate use of troponin testing for diagnosis of acute coronary syndromes in primary care
2013/07	The cost of injury in Western Australia: an overview of total and health system costs
2013/08	Multidrug resistant tuberculosis in Western Australia
2013/09	Decreasing depression during the menopausal transition: a pilot study
2013/10	Assessing health outcomes for residents of supported accommodation services
2013/11	Validation of pertussis (whooping cough) vaccination uptake in mothers of newborns
2013/12	The accurate measurement of physical activity and sedentary time among non-Hodgkin lymphoma survivors study
2013/13	The accurate measurement of physical activity and sedentary time among breast cancer survivors study
2013/16	Predicting the impact of current obesity and diabetes trends on future prevalence of cardiovascular disease in Australia
2013/17	Successful ageing in older men – thriving not just surviving in the health in men study
2013/18	The social cost of smoking in Western Australia in 2009/10 and the social benefits of future reductions in smoking prevalence
2013/19	Data linkage of new Community Health Information System (CDIS) with DOH mortality data to identify deceased community health clients
2013/20	Evaluating equitable management of acute coronary syndrome across regional Western Australia
2013/21	Analysis of services used and the costs of caring for people living with HIV/AIDS (PLWHA) in WA
2013/22	Which are the most effective strategies for engaging with clinicians before and during the implementation of E-health initiatives?
2013/23	Missing voices: communication difficulties after stroke and traumatic brain injury in Indigenous Australians - linked data component
2013/24	An integrated national assessment of cervical cancer prevention, incidence and survival for Australian Aboriginal and Torres Strait Islander women: a data linkage study
2013/25	The long term consequence of IVF on the offspring – a prospective cohort study using the Raine cohort as comparator – initial contact leading to recruitment
2013/26	Health outcomes for older Indigenous Australians: a 5 year follow up study
2013/27	Enhanced mortality database for estimating Indigenous life expectancy
2013/28	Analysis of WA emergency department demand
2013/29	Does methadone maintenance treatment increase the risk of significant health problems in an older cohort?
2013/30	Colonoscopic surveillance for colorectal cancer in Lynch syndrome mutation carriers

2013/31	Body mass index and risk of mortality
2013/32	Diabetes, obesity and liver disease-related mortality
2013/33	Understanding an Aboriginal child's journey through paediatric ambulatory care in Western Australia
2013/34	National alcohol indicators project
2013/35	Using data linkage to study the burden and impact of <i>Clostridium difficile</i> infection in Western Australia
2013/36	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
2013/37	Long-term follow-up of Murray Valley Encephalitis survivors in Western Australia
2013/38	Pharmacotherapy for smoking cessation during pregnancy and the inter-pregnancy period
2013/39	Follow-up and active surveillance of trivalent influenza vaccine to mums (FASTMum)
2013/40	Determinants and demographics of hospital and Silver Chain resource usage amongst WA cancer patients, and how that has changed over time.
2013/41	Infrastructure linkage - WA hospital pharmacy data
2013/42	Dementia and hospitalisations due to an injury: a population based study
2013/43	Trend analysis of the physical activity patterns of the Australian adult population from 1997 to 2012
2013/44	Western Australian register for developmental anomalies
2013/45	Data linkage of WA health and wellbeing surveillance system
2013/46	Infrastructure linkage of aged care datasets: home and community care and aged care assessment program
2013/47	Identifying genetic risk factors for cardiovascular disease in extended pedigrees in the Busselton health study
2013/48	Risk of osteoporotic and minimal-trauma re-fracture and costs related to incident osteoporotic fractures
2013/49	FluMum: A prospective cohort study of mother infant pairs assessing the effectiveness of maternal influenza vaccination in prevention of influenza in early infancy
2013/50	Closing the gap on Indigenous birth registration
2013/51	The role of tumour biology in influencing outcomes for Indigenous Australians diagnosed with breast cancer.
2013/52	A retrospective observational study of two types of pharmacotherapy treatment for opiate dependence in Western Australia.
2013/53	Assessment of the impact of the National bowel cancer screening program on the stage at diagnosis of colorectal cancer in WA
2013/54	A prospective evaluation of the impact of the nurse practitioner role on emergency department serviced outcomes (Parts A & B)
2013/55	Extending the ANZDATA registry by linking to administrative datasets
2013/56	WA colorectal research group
2013/57	Can cognitive bias modification prevent depression?
2013/58	Use of the seasonal influenza vaccination canning tool module to monitor vaccine uptake and vaccine effectiveness in Western Australia
2013/59	Upper gastrointestinal incidence and cancer nurse coordinator involvement in WA, July 2011- June 2012
2013/60	National survey of high impact psychosis

2013/61	Estimating the completeness of case ascertainment of the Western Australian children's diabetes database by linkage to the hospital morbidity data system
2013/62	CONCORD-2 Global surveillance of cancer survival
2013/63	Pneumococcal meningitis in Western Australian children 1990-2013: clinical course, resource use, outcome, epidemiology, microbiology and the effect of widespread vaccination.
2013/64	Influenza vaccination uptake in pregnant women in Western Australia.
2013/65	Childhood developmental pathways to educational achievement in Western Australia: a multilevel data linkage study
2013/66	Pathways of children in contact with multiple government agencies in Western Australia
2013/67	Investigating rising demand for emergency healthcare by older age groups
2013/68	Today's lung cancer risk in WA miners: using the power of linked data
2013/69	Neural tube defect incidence: has mandatory folic acid fortification of bread making flour reduced the incidence of neural tube defects in Australia?
2013/71	Influenza vaccination in pregnant women: a cohort study to assess vaccine uptake, effectiveness and impact on birth outcomes in Western Australia
2013/72	Modelling linked population data to understand outcomes for children of incarcerated mothers and the role of the prison environment to reduce negative social and economic impacts
2013/73	St John Ambulance: infrastructure linkage
2013/74	Retrospective establishment of a clinical eating disorder cohort database
2013/75	The relationship between diet and educational outcomes in a cohort of Western Australian children
2013/76	Evaluation of the Aboriginal Maternity Group Practice Program (AMGPP) in the South Metropolitan Health Service
2013/77	Life expectancy in cerebral palsy to the sixth decade
2013/78	Rare and emerging subtypes of under-researched cancers epidemiology studies (RESOURCES Program)
2013/79	National familial hypercholesterolemia registry
2013/80	A randomised controlled trial testing the efficacy and cost benefit of cognitive behavioural therapy on the health outcomes of chronic obstructive pulmonary disease patterns
2013/81	WA diversion program - adult court diversion program evaluation - recidivist analysis
2013/83	Modelling predictors of hospital demand to improve clinical service planning, intervention evaluation and performance management
2013/84	Evaluation of the southern inland health initiative navigator program

☆ *Please note that project numbers 2013/14, 2013/15, 2013/70 and 2013/82 are missing from the above table. Projects 2013/14 and 2013/15 were reviewed by the DOH HREC, but then assessed to be outside the scope of the Committee. Projects 2013/70 and 2013/82 were found to be incomplete and will consequently be fully reviewed in 2014.*



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