



Government of **Western Australia**
Department of **Health**

Human Research Ethics Committee

Annual Report 2014

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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 2007 (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 2014 to 31 December 2014. 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 2014 reporting period, there were 80 new applications for ethics approval, consistent with the previous year, in which 80 new applications were also received. This is a reflection of the continual interest and investment in health-related research in WA.

2. Memberships

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;
- at least two people with current research experience that relates to research proposals to be considered at the meetings they attend.

The Department of Health WA HREC is a specialist committee that oversees the use of personal health information held by the DOH. To ensure it has the expertise to perform this function the Terms of Reference require that the Committee also includes:

- at least one person with knowledge of and current experience in information security; and
- at least 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 2014, there were seven positions on the DOH HREC which had terms expiring on 31 December 2014. These included the member positions for the female lay person, professional care representative, researcher, WA health representative, as well as the deputy member positions for the researcher, the male layperson, and the lawyer. Recommendations to fill these seven positions were approved by Cabinet in July 2014.

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 sitting members are unable to attend meetings.

Table 1 shows the sitting members that served on the DOH HREC in 2014.

Table 1 Sitting members serving on the DOH HREC in 2014

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	Mr Alisdair Putt (until January 2014) Ms Jennifer Wall (from March 2014)
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 2014.

Table 2 Deputy members serving on the DOH HREC in 2014

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	Ms Meike Dixon
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

Newly appointed sitting and deputy members are provided with an induction that focuses on the: (i) role and scope of the DOH HREC; (ii) National Statement; (iii) information about the DOH data collections and data linkage; and (iv) legal obligations pertaining to health data. As existing members were re-elected for 2014, an induction workshop was not conducted.

4. Meetings and executive support

The DOH HREC meets on the second Wednesday of every month. In 2014, 11 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; and
- at least one third of those present being from outside the DOH.

A quorum was met for all the meetings in 2014.

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 2014 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 2014

Total applications received in 2014	80
Approved applications	62
Withdrawn	3
In progress	15

The DOH HREC received 80 new applications during the reporting period. As shown in figure 1, of these applications, 62 were approved in 2014, 15 were still in progress by 31 December 2014 and three were withdrawn.

Figure 1 shows the status of applications received in 2014

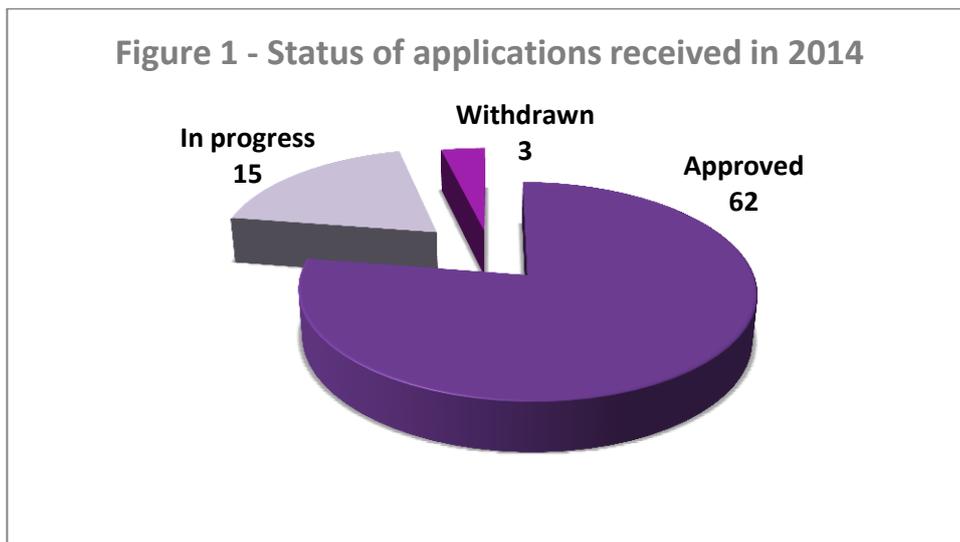
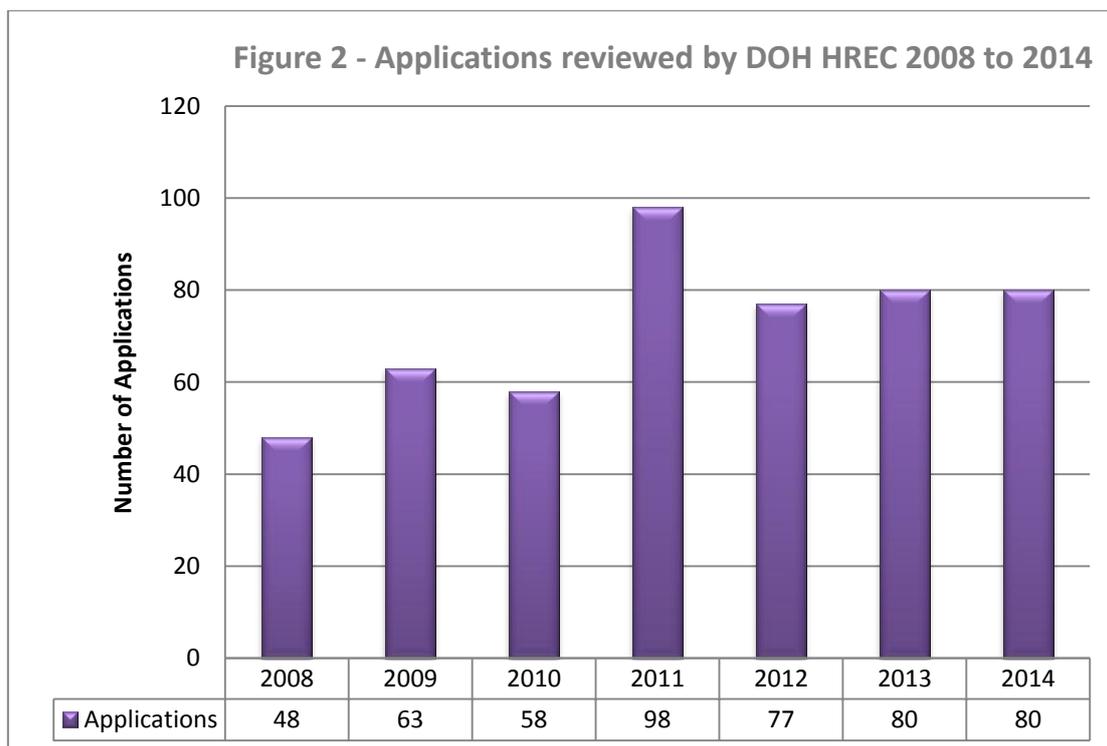


Figure 2 shows the number of new applications considered by the DOH HREC by calendar year since its inception in 2008.



6. Annual reports, amendments and final reports

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.

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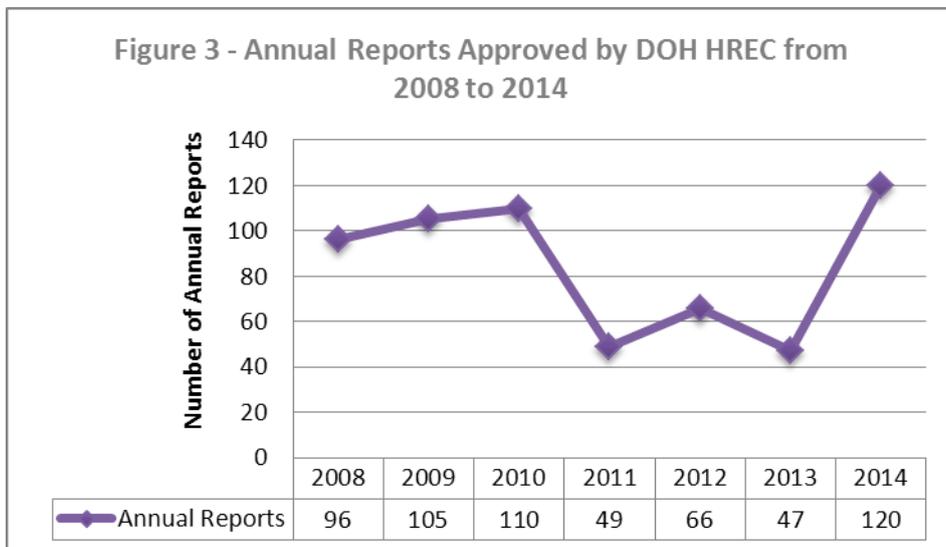
Researchers are responsible for ensuring that an annual progress report, any amendment requests and a final report are submitted to the DOH HREC in a timely manner. The templates for the required reports are accessible on the DOH HREC website.

The standardised annual 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 120 annual reports were approved by the DOH HREC in 2014. This is the highest number of annual reports submitted in a year since DOH HREC inception in 2008. This is also a significant increase compared to the 47 annual reports received during the previous year. In 2014 an audit of overdue annual reports was undertaken by DOH internally, whereby researchers were prompted to submit their overdue annual reports. This explains why there were a larger number of annual reports received compared to previous years. The Research Development Unit, Office of the Chief Medical Officer is currently developing a new statewide database, which will include an automated tracking system to contact researchers when they are due to submit a report. Ongoing ethics approval will be dependent on researchers submitting their reports in a timely manner.

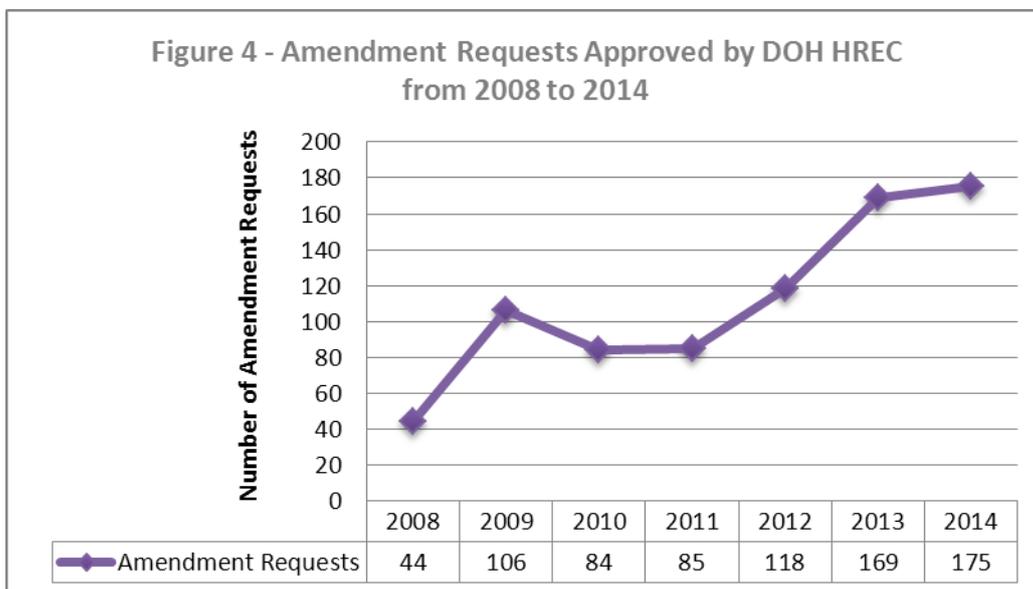
Figure 3 displays the total number of annual reports approved by DOH HREC from 2008 to 2014.



Amendments

Researchers are required to complete the standard amendment request 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 175 amendment requests were approved by the DOH HREC in 2014, which is the highest number of amendment requests approved since HREC has been operational. This is a slight increase from 2013 (with 169 approved amendment requests). This may be attributed to the increased amount of approved annual reports that may have highlighted the need for amendments to researchers or due to an increase in the complexity and longer duration of projects.

Figure 4 displays the total number of amendment requests approved by DOH HREC from 2008 to 2014.



Final Reports

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 30 final reports were submitted and approved in 2014. This was slightly more than the 28 final reports submitted and approved in 2013. The average number of final reports submitted and approved over the last seven years is 24, thus both the 2013 and 2014 totals are above average.

Figure 5 illustrates the total number of final reports approved by DOH HREC from 2008 to 2014.

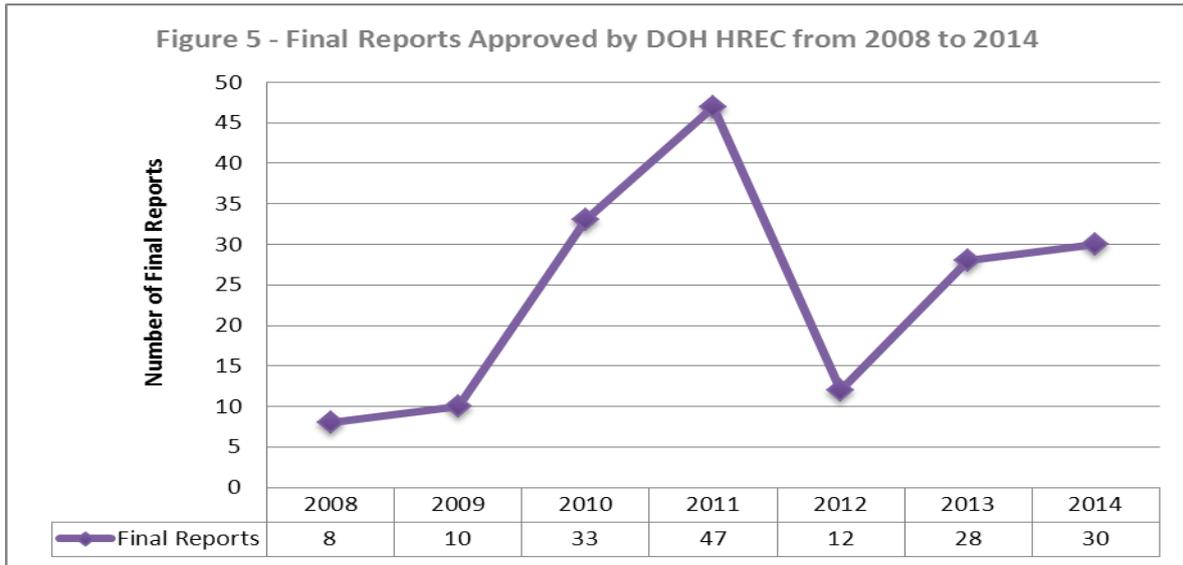
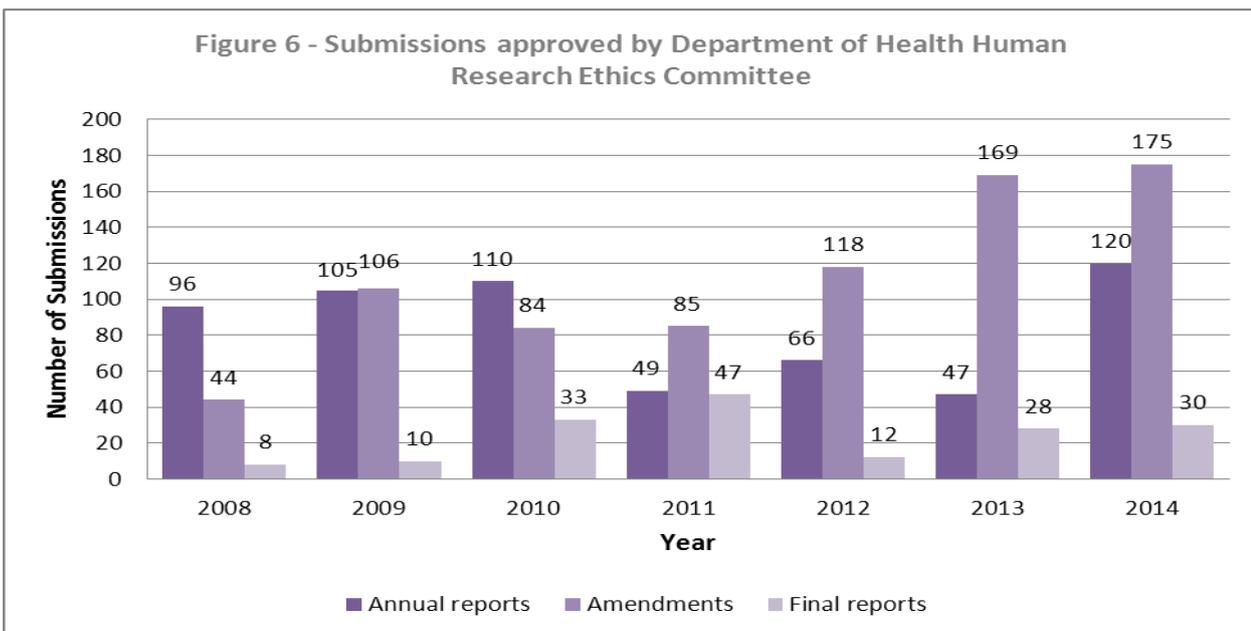


Figure 6 shows the number of final reports, amendment requests and annual reports approved by the DOH HREC by year.



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).

There were no breaches, concerns or complaints received in 2014.

9. Major users of DOH data

The Western Australian University departments formed the largest group of major users of DOH data for 2014, which was also the case in 2012 and 2013. The proportion of applications that were submitted by the Department of Health increased slightly from previous years. The number of applications from cross-jurisdictional organisations was lower compared to the number recorded in 2012 and 2013. Researchers affiliated with cross jurisdictional organisations also comprised the lowest number of users of DOH data for 2014.

Health Services (including hospitals such as Sir Charles Gairdner Hospital, Fremantle Hospital, Royal Perth Hospital and Princess Margaret Hospital, as well as other service providers such as Silver Chain Group and Cancer Council) submitted a higher number of applications than those in the private sector, which is consistent with 2012 and 2013 results. However, the total number of applications submitted by Health Services and private organisations has reduced compared with 2013 figures. The majority of the private sector applications came from the Telethon Institute for Child Health Research which is in keeping with 2012 and 2013 results.

Figure 7 reflects the breakdown of major users of DOH data for 2014.

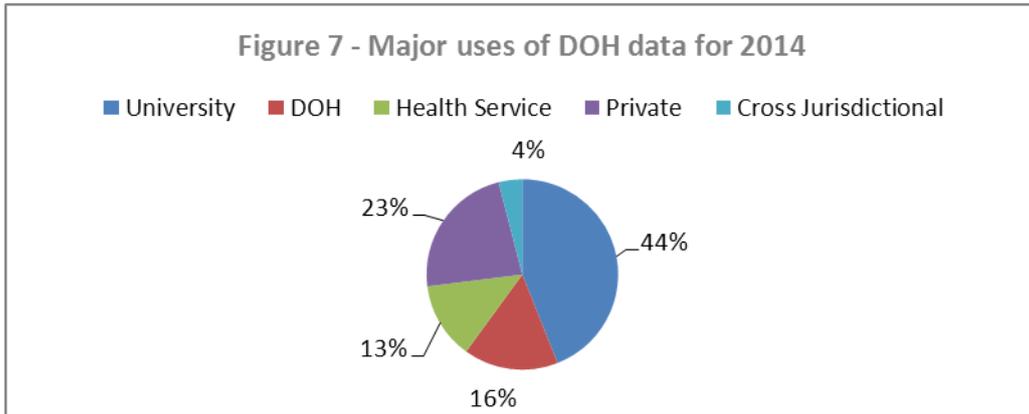
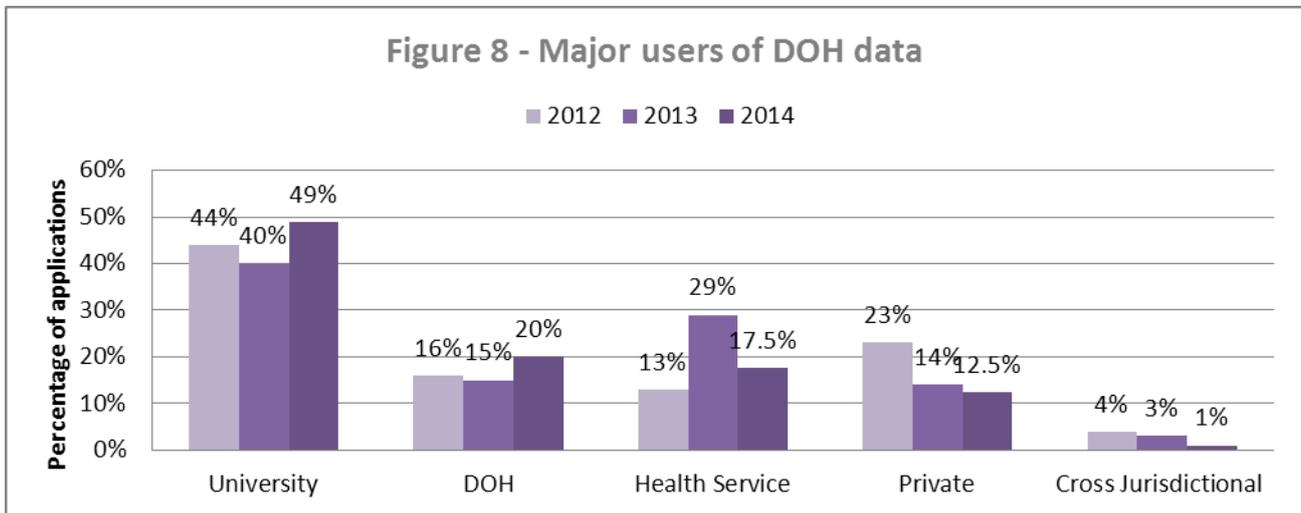


Figure 8 displays the various organisations that submitted an application for ethics approval for the 2012, 2013 and 2014 reporting period.



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 the review of research projects. Specifically, these guidelines apply to disclosure of personal health information from Commonwealth agencies or the private sector.

The Guidelines under Section 95 of the Privacy Act 1988 apply to medical research which involves the use of personal health information held by a Commonwealth agency without the consent of the individual.

The Guidelines approved under Section 95A of the Privacy Act 1988 apply 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:

- 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 be satisfied that it is necessary for the research to use identified or potentially identifiable data and, that it is impracticable to obtain consent (s95A Guidelines), or that it is reasonable for the research to proceed without the consent of the individuals to whom the information relates (s95 Guidelines).

In reaching a decision, the DOH HREC must also consider whether the public interest in the research and the likely benefits outweigh the public interest in privacy. In 2014, the DOH HREC applied the section 95 guidelines to seven applications and the section 95A guidelines to five 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, 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 and project summaries for approved proposals are available at www.health.wa.gov.au/healthdata/HREC/proposals.cfm.

12. Conclusion

In 2014, 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 80 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 2014

HREC Number	Project Title
2014/01	Identifying genetic risk factors for mammographic density in extended pedigrees in the Busselton health study
2014/02	Acute rheumatic fever increase in Western Australia
2014/03	The Australian rare diseases survey
2014/04	Compliance of post radiation therapy head and neck cancer patients with caries preventative protocols
2014/05	An exploratory study of participants' experiences and views of altruistic surrogacy
2014/06	The impact of using sampling methods to minimise disclosure risk in studies using linked administrative data
2014/07	Follow-up and active surveillance of trivalent influenza vaccine in mums (FASTMum)
2014/08	Validation and impact of the four hour rule in the emergency department: a large data linkage study
2014/09	Incidence and burden of childhood injury in Australia
2014/10	A prevalence study on parents with intellectual disability and their children in Western Australia
2014/11	Long-term use and cost-effectiveness of secondary prevention medications for heart disease in Western Australian seniors
2014/12	Western Australian safety and quality point prevalence survey 2014
2014/13	Anaemia in Western Australian children: incidence in Aboriginal and non-Aboriginal populations across the state
2014/14	An audit of the outcomes of Western Australian patients undergoing peritonectomy (+/-heated intra-peritoneal chemotherapy - HIPEC).
2014/16	Predicting emergency department demand in Western Australia
2014/17	The epidemiology, risk factors and economic costs of severe bacterial lower limb cellulitis in Western Australia
2014/18	Morphology and molecular profiling of interval colorectal cancers: is procedural quality or altered biology responsible?
2014/19	Health seeking behaviours and knowledge of infectious disease risks in Western Australian travellers to Asia
2014/20	An international collaboration for autism registry epidemiology: multinational investigations of autism risk factors and trends (MINERvA)
2014/21	An investigation of parental mental health among the Aboriginal population in Western Australia, and its impact on children's outcomes
2014/22	The pathogen specific burden of hospitalisation for enteric and blood stream infection in children and young people in Western Australia
2014/23	Mortality after first-ever seizure
2014/24	Intellectual disability exploring answers (IDEA) database: infrastructure linkage
2014/25	Population-level relevance of risk factors for cancer
2014/26	An evaluation of out of pocket costs associated with treatment for people diagnosed with cancer in four rural health regions of Western Australia
2014/27	Are total hip and knee replacements associated with an increased cancer risk? A nationwide cohort study
2014/28	Personal alarms - expectations and outcomes
2014/29	Patterns of care for adolescents and young adults with cancer
2014/30	Risks and benefits of breast cancer screening: BreastScreen WA cohort study of overdiagnosis and breast cancer mortality
2014/31	Pregnancy associated breast cancer in the Western Australian population: how does time from conception to breast cancer diagnosis affect survival?
2014/32	Survival from uveal melanoma in Western Australia 1981-2005
2014/33	10 year outcomes of an emergency department delivered brief intervention with adolescent alcohol and other substance users

HREC Number	Project Title
2014/34	Investigating vaccine safety via cross-jurisdictional data linkage of the Australian Childhood Immunisation Register with hospital morbidity data (Western Australian component)
2014/35	Effect of formal multidisciplinary discussion on the management and survival of people newly diagnosed with colorectal cancer
2014/36	Hospitalisations for oral/dental reasons in children in Western Australia
2014/37	Improving the detection of disadvantaged Australians at high risk of cardiovascular disease
2014/38	Liver cancer stem cells increase the risk of hepatocellular carcinoma
2014/39	National mental health costing study
2014/40	Incidence and case fatality in myocardial infarction: trends and risk factors
2014/44	An assessment of bicycle helmet legislation on cyclist head injuries in Western Australia
2014/45	Fourth study of mortality and cancer incidence in aircraft maintenance personnel
2014/46	Assessing the efficacy and cost-effectiveness of targeted advance care planning interventions among patients with severe respiratory disease in a tertiary hospital and in a rural setting
2014/47	Descriptive analysis of community-associated methicillin-resistant <i>Staphylococcus aureus</i> and its burden on health services in the Kimberley, Western Australia.
2014/48	The cost-effectiveness of sustaining tenancies of formerly homeless clients with high needs
2014/49	Telehealth remote monitoring for people with multiple chronic conditions
2014/50	Mammographic density as a predictor of breast cancer risk and mortality in Western Australian Aboriginal women
2014/51	A population-based case-control study investigating risk factors and patterns of health care use in Alzheimer's disease and dementia
2014/52	Self-perceived work readiness of recent graduates employed by WA Health
2014/53	Modelling the public health and safety impacts of liquor licensing changes on communities: enhancing evidence-based liquor licensing decisions
2014/54	Time trends and risk factors for cancer incidence in people with HIV in Australia: a data linkage study
2014/55	The real and changing atherothrombotic disease burden and secondary prevention
2014/56	A study to investigate the ratio of breslow thickness to skin thickness as a prognostic factor in patients with malignant melanoma
2014/57	Birthplace in Australia: a population based cohort study
2014/58	Heritable and environmental determinants of hospitalisation for common childhood illnesses - study 1: association between non-twin siblings in hospital admissions
2014/59	The breast cancer employment and environment study umbrella project
2014/60	The breast cancer employment and environment study: BCAC sub-project
2014/61	Cleft lip and palate – a comparative psychosocial perspective 634QP
2014/62	Pterygia and skin cancer in Western Australia
2014/63	Investigating the impact of liquor superstores in WA
2014/64	Impact of neuropsychological evaluation on hospital presentations, admission rates and length of stay and in a sample of general medical patients
2014/65	Leading change in the turbulent and complex public health sector - a case study of an Australian public health system
2014/66	Validation of influenza data as measured by the seasonal influenza vaccine
2014/67	Survey of antenatal influenza vaccination uptake in 2014, and the association between maternal antenatal influenza vaccination uptake and childhood immunisation status at 2, 4, 6 and 12 months
2014/68	What influences the outcomes for patients undergoing upper gastro-intestinal surgery as treatment for cancer?
2014/69	Analysis of the implementation of breast cancer multi-disciplinary team decisions
2014/70	Evaluation of the healthier workplace WA project – healthy worker module
2014/71	Cervical screening register of Western Australian infrastructure project linkage
2014/72	Atrioventricular septal defects in children and fetuses: a 20 year review

HREC Number	Project Title
2014/73	Health care workers as athletes: can mental toughness characteristics and overtraining behaviours identified in athletes be applied to health care workers
2014/74	Determining the burden and costs of pressure injuries treated in Western Australia, 2007-2013
2014/75	Using information in a mammogram to predict preventable chronic diseases other than breast cancer
2014/76	The effects of rapid weight loss on mammographic density, a strong predictor of breast cancer risk
2014/77	Royal Australian College of Medical Administrators' graduates preparedness for their roles
2014/78	Implementing an outreach support program for family carers of older people discharged from an acute medical assessment unit: cost consequences for the Western Australian health care system
2014/79	Evaluation of the impact of a patient-focussed brochure on participation in the National Bowel Cancer Screening Program in Western Australia
2014/80	Developing a model of care for the long term follow-up of childhood cancer survivors
2014/81	Oral health service planning

*Please note that project numbers 2014/15, 2014/41, 2014/42 and 2014/43 are missing from the above table. Project number 2014/15, 2014/41 and 2014/43 were withdrawn and project number 2014/42 was rejected by data custodians and consequently was not reviewed by HREC.



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