



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

Human Research Ethics Committee

Annual Report 2015

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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 2015 to 31 December 2015. 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 2015 reporting period, there were 68 new applications for ethics approval, which is slightly reduced compared with the previous year, in which 80 new applications were received.

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 2015, there were eight positions on the DOH HREC which had terms expiring on 31 December 2015. These included the sitting member positions for the researcher, pastoral care member and information security representative, as well as the deputy member positions for the WA Health representative, researcher, two female laypersons and pastoral care representative. There were two resignations of deputy members, the WA Health representative and the deputy lawyer. Consequently, there was one new appointment of a deputy lawyer. The sitting researcher was also appointed to Deputy Chair, as the Deputy Chair's second term had expired. Recommendations to fill these ten positions were approved by Cabinet in September 2015.

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 2015.

Table 1 Sitting members serving on the DOH HREC in 2015

Position	<i>Incumbent</i>
Chairperson	Honorary Fellow 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 Jennifer Wall
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 2015.

Table 2 Deputy members serving on the DOH HREC in 2015

Position	<i>Incumbent</i>
WA Health representative	Dr Janine Alan (resigned in June 2015)
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 (resigned in June 2015)
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 2015, an induction workshop was not conducted.

In October 2015 an in-house training session was held for all sitting and deputy members at the Department of Health. This session was comprised of a series of presentations covering topics such as Data Linkage, Research Governance, Population Health Research Network and WA DOH data collections.

4. Meetings and executive support

The DOH HREC meets on the second Wednesday of every month. In 2015, 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 2015.

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 2015 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 2015

Total applications received in 2015	68
Approved applications	57
Withdrawn	2
In progress	9

The DOH HREC received 68 new applications during the reporting period. As shown in figure 1, of these applications, 57 were approved in 2015, 9 were still in progress by 31 December 2015 and two were withdrawn, one prior to and one following HREC review.

Figure 1 shows the status of applications received in 2015

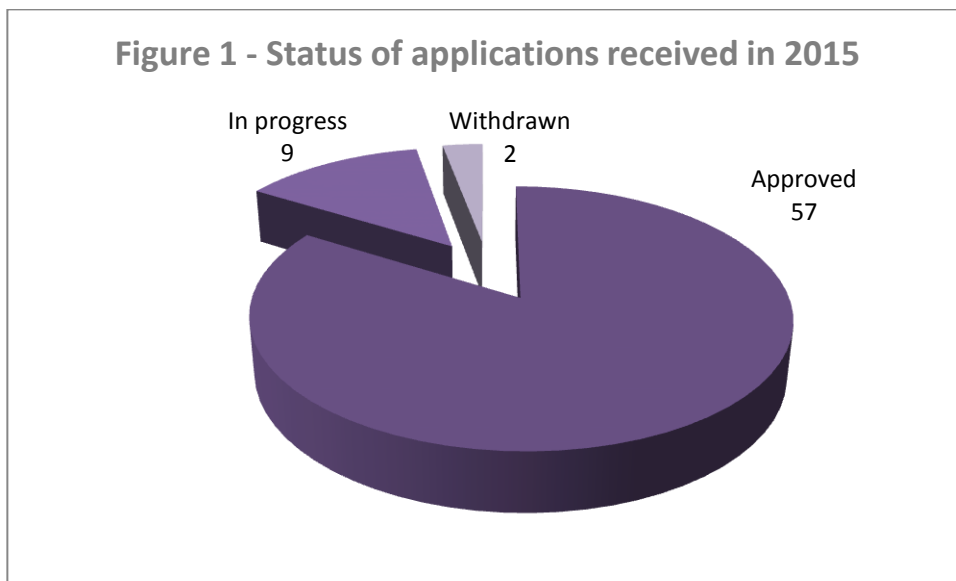
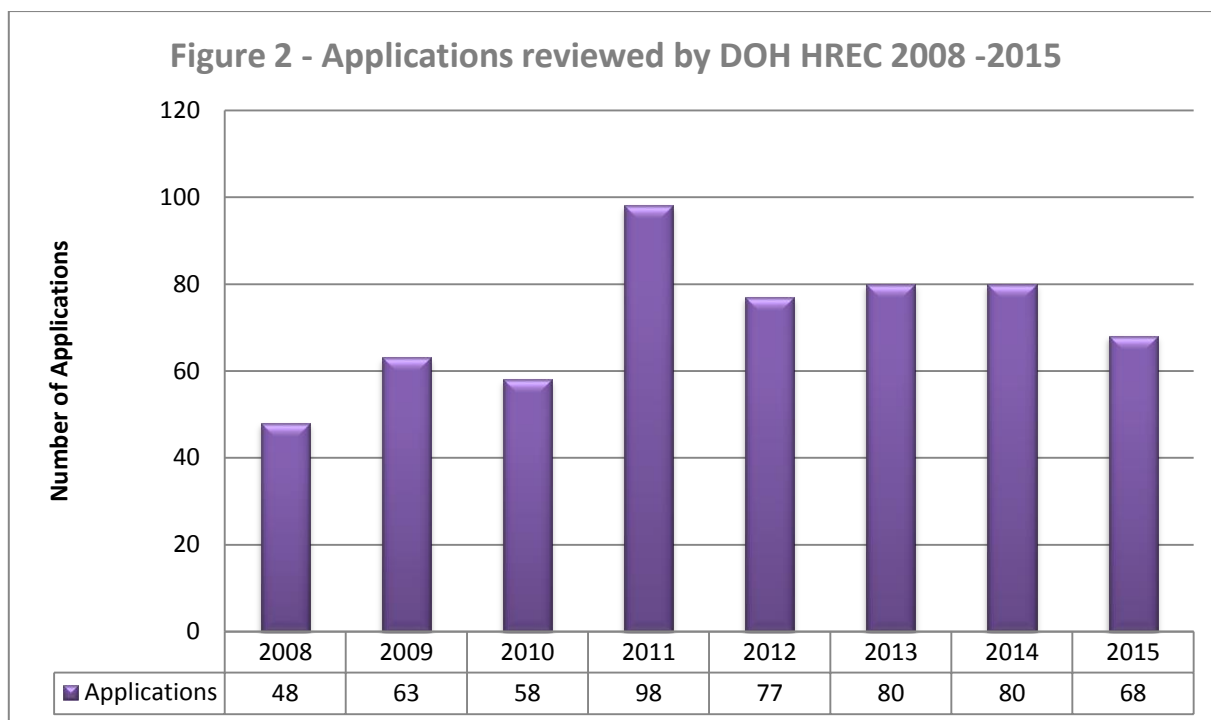


Figure 2 shows the number of new applications considered by the DOH HREC by calendar year since its inception in 2008.



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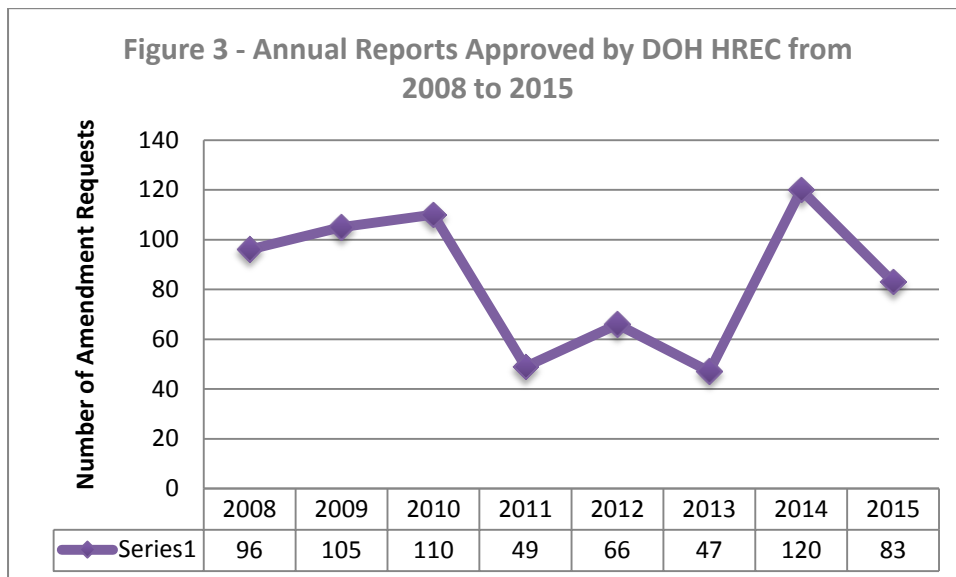
Researchers are responsible for ensuring that an annual progress report, any amendment requests and a final report are submitted to the DOH HREC in a timely manner. The templates for the required reports are accessible on the DOH HREC website.

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 83 annual reports were approved by the DOH HREC in 2015. The Research Development Unit, Office of the Chief Medical Officer is currently developing a new state-wide 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.

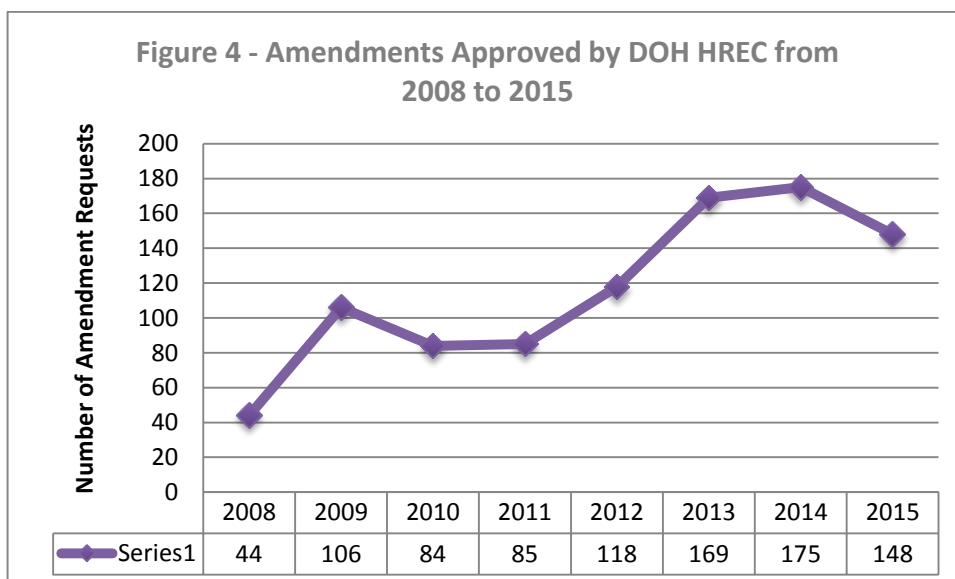
Figure 3 displays the total number of annual reports approved by DOH HREC from 2008 to 2015.



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 148 amendment requests were approved by the DOH HREC in 2015, which is a decrease from 2014 (with 175 approved amendment requests).

Figure 4 displays the total number of amendment requests approved by DOH HREC from 2008 to 2015.



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 17 final reports were submitted and approved in 2015. This was less than the 30 final reports submitted and approved in 2014. The average number of final reports submitted and approved over the last eight years is 23.

Figure 5 illustrates the total number of final reports approved by DOH HREC from 2008 to 2015.

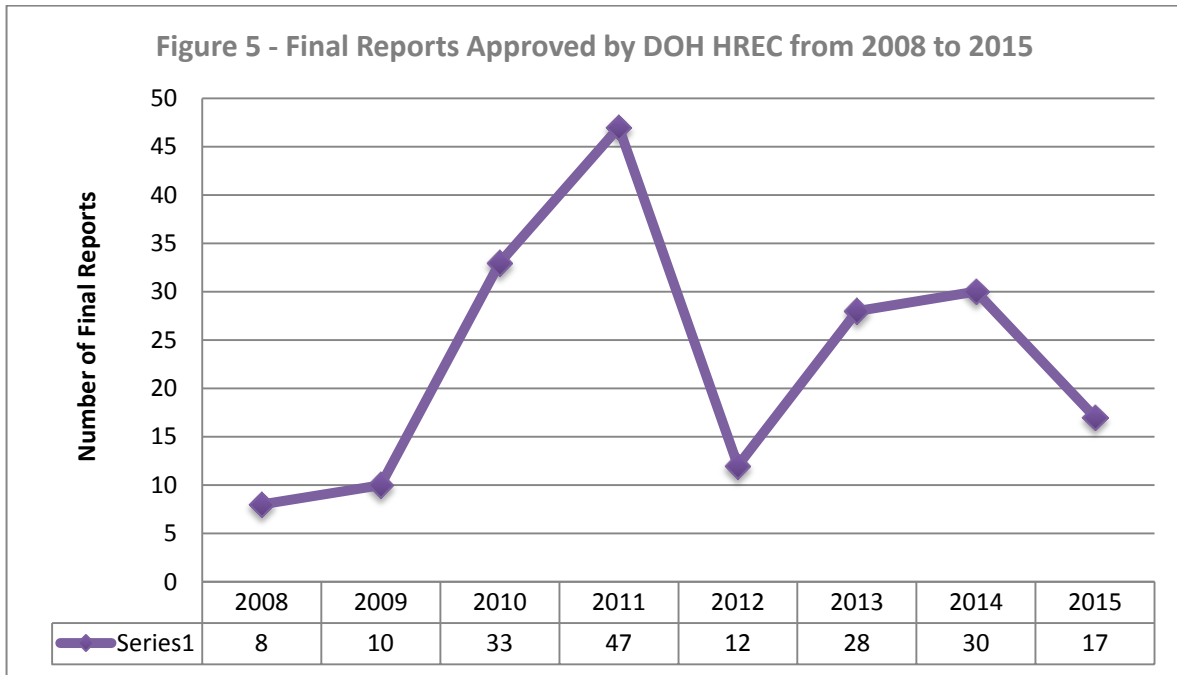
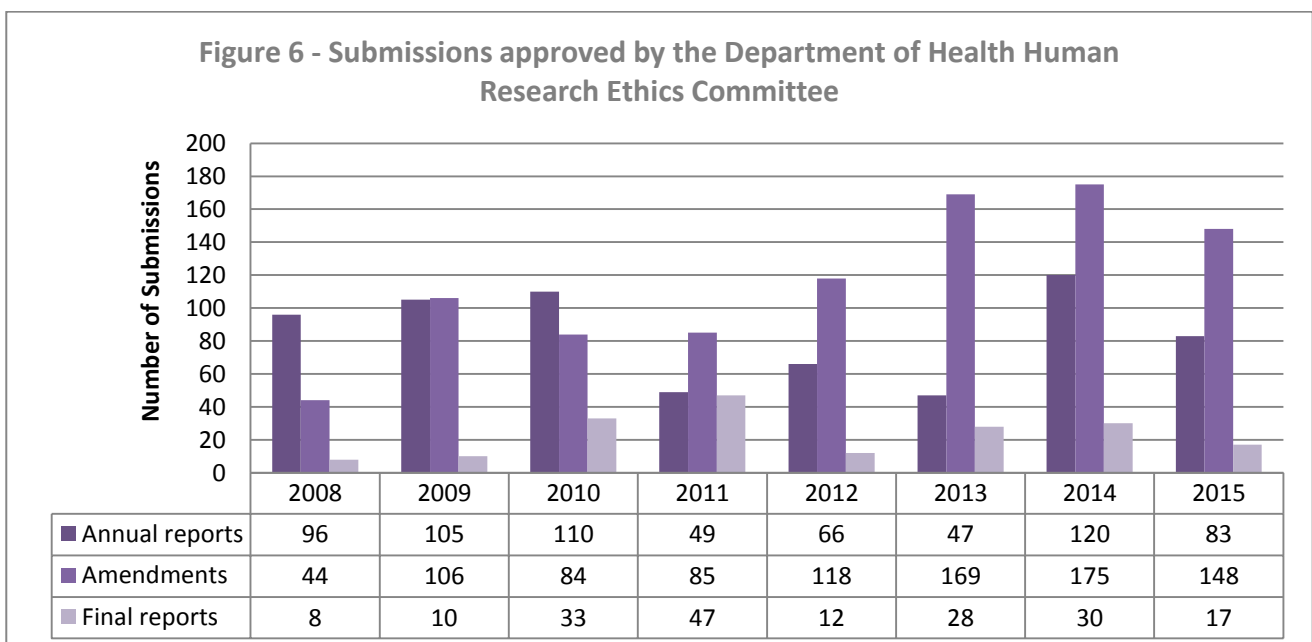


Figure 6 shows the number of final reports, amendment requests and annual reports approved by the DOH HREC by year.



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 was one breach received in 2015 relating to a breach in protocol. As per the TOR and SOPs an Incident Review Committee was convened and the breach investigated. Submissions were received and reviewed by all parties. Notification of the Committee's decision and the required actions was provided to all key stakeholders.

There were no concerns or complaints received.

9. Major users of DOH data

The Western Australian Universities formed the largest group of major users of DOH data for 2015, which was also the case in 2012, 2013 and 2014. The proportion of applications that were submitted by the Department of Health is slightly increased compared with previous years. The number of applications from cross-jurisdictional organisations was lower compared to the number recorded in 2012, 2013 and 2014. Researchers affiliated with cross jurisdictional organisations also comprised the lowest number of users of DOH data for 2015 which was also the case for 2014.

Health Services (including hospitals such as Sir Charles Gairdner Hospital, King Edward Memorial Hospital, Graylands Health Campus, as well as other service providers such as Lions Eye Centre and Ability Centre) submitted the same number of applications as those in the private sector, which is different to 2012, 2013 and 2014 results whereby the number of Health Service submission was higher than the submissions from the private sector. The majority of the private sector applications came from the Telethon Kids Institute which is in keeping with 2012, 2013 and 2014 results.

Figure 7 reflects the breakdown of major users of DOH data for 2015.

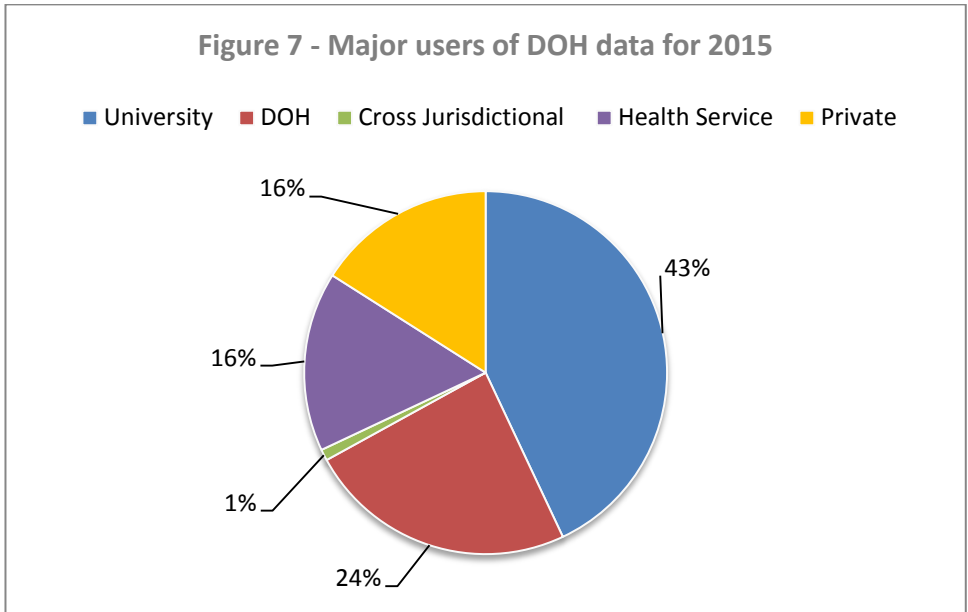
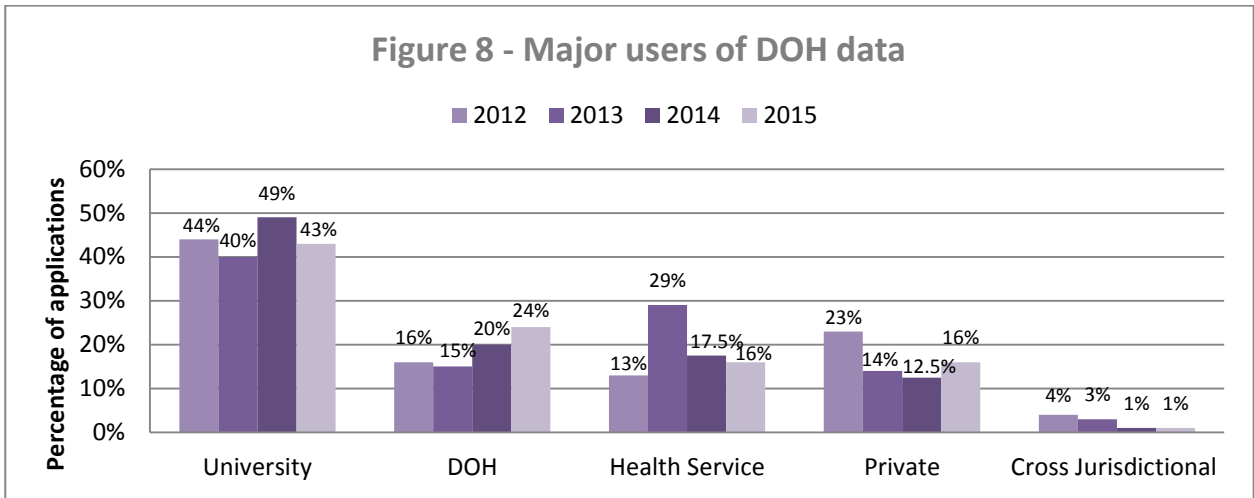


Figure 8 displays the various organisations that submitted an application for ethics approval for the 2012, 2013, 2014 and 2015 reporting period.



10. Application of Privacy Act 1988 guidelines

There are specific situations where the Guidelines approved 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 2015, the DOH HREC applied the section 95 guidelines to three 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 2015, 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 of 68 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 2015

HREC Number	Project title
2015/01	Human capability and the progress of Indigenous people
2015/02	A comparison of the physical activity and sedentary time levels and patterns of cancer survivors and the general population
2015/03	Management of mining dusts exposure cohorts
2015/04	A multinational comparison of hospitals, ICU admissions and mortality rates amongst the very elderly
2015/05	Paediatric melanomas: Western Australia melanoma advisory service experience
2015/06	Effectiveness of quadrivalent and trivalent influenza vaccines in preventing influenza in health care workers in WA in 2015
2015/07	Factors predicting ovarian cancer: a population-based cohort study of 350,000 women followed for up to 45 years
2015/08	State-wide implementation of cervical length screening for the prevention of preterm birth
2015/09	Mining dust-related diseases in Western Australia
2015/10	Evaluation of the 'time of diagnosis protocol/service'
2015/11	Mammographic density in families with high-risk of breast cancer
2015/12	Rheumatic diseases as a risk factor for hospitalisation, emergency care use, cancer and mortality in Western Australia
2015/13	Demand and supply modelling for WA hospital services
2015/14	Evaluation of moorditj djena program
2015/15	Linked perinatal, birth, death data set project
2015/17	Maternal satisfaction with maternity services (MSMS) phase 2 (for public purposes 'Women's maternity care experiences')
2015/18	The Western Australian ocular tumour registry and biobank: Retrospective collection of demographic, clinical and pathological information as well as genetic
2015/19	Monitoring adverse events following immunisations administered in general practice using data extraction
2015/20	Neurodevelopmental and other outcomes in children with congenital heart defects in Western Australia
2015/21	In situ HER2 gene transcript detection in breast cancer tissue specimens
2015/22	A study of prolific offenders in Western Australia
2015/23	Pregnancy-related medical services utilisation and perinatal outcomes in Western Australia (WA) with a focus on recent migrants
2015/24	Utility of pathological biomarkers in predicting prognosis in breast cancer patients
2015/25	Western Australian health and pregnancy survey
2015/26	BCEES Collaborations
2015/27	Comparison of human heat stress models across Australian cities
2015/28	Hysterectomy, oophorectomy and chronic disease outcomes
2015/29	Uptake of antenatal influenza and pertussis (whooping cough) vaccination in pregnant mothers, 2015-2019
2015/30	Defying the odds': Exploring the impact of perinatal outcomes, maternal social and health outcomes and level of culturally appropriate service availability on the health of Western Australian Aboriginal infants and children
2015/31	State-wide Specialist Aboriginal Mental Health Service (SSAMHS) Evaluation 2016
2015/32	Respiratory hospitalizations in children and young people with cerebral palsy: which children and at what cost?
2015/33	Establishing integrated data for stroke to enable comprehensive monitoring of care and patient outcomes to provide evidence for clinical practice improvement
2015/34	LungScreen WA project: targeting high risk individuals for early detection of lung cancer using low dose computed tomography
2015/35	Do people with disabilities access community-based palliative care services and does this service relieve hospitals and emergency departments: a study of the needs of people with intellectual disability, multiple sclerosis and schizophrenia

HREC Number	Project Title
2015/36	Prenatal origins and health outcomes of male reproductive congenital anomalies diagnosed at birth and testicular cancer in adulthood
2015/37	Examining performance indicator data to enable improvements to the performance monitoring and evaluation within the WA public health system
2015/38	Evaluating the use and effectiveness of passive immunisation in reducing RSV-associated morbidity in high risk infants
2015/39	Genetic analysis of complex disease
2015/40	Genetic profiling of carcinomas of unknown primary (CUP)
2015/41	Eye injuries and their causes
2015/42	Oral health care for mental health consumers
2015/43	Uptake of antenatal influenza and pertussis (whooping cough) vaccination in pregnant Aboriginal mothers and its association with influenza vaccination of their children
2015/44	Heatwave related health service demands in WA - Identify vulnerable populations
2015/45	An investigation of research outputs from data linkage projects in Western Australia
2015/46	An investigation into the use of WA data collections in linked data projects, 1995 – 2014 and how this compares with other data linkage centres
2015/47	Australian longitudinal study on women's health
2015/48	Treatment and prevention of depression among older Western Australian adults living in regional and remote areas – The MIRROR pilot study: Randomised controlled trials of behavioural activation
2015/49	Risk of osteoporotic and minimal-trauma re-fracture and costs related to incident osteoporotic fractures in Western Australia: a 10 year snapshot using the WA Hospital Morbidity Data System
2015/50	HER2 expression in upper GIT precancerous lesions and adenocarcinoma and its correlation with morphological subtypes, progression and prognosis
2015/51	A measure of Australian women's private health care maternity experiences
2015/52	WA Register of Developmental Anomalies – Cerebral Palsy: Contribution of data to Australian Cerebral Palsy Register
2015/53	Child Development Information System (CDIS)
2015/54	Does pneumococcal vaccination protect against cardiovascular disease? A randomised placebo-controlled double blind trial
2015/55	Transitions of care at discharge for paediatric patients: Communication practice
2015/56	Enhancing the accuracy of heart disease risk assessment in Indigenous Australians
2015/57	Rheumatoid Arthritis as a risk factor for hospitalisation, emergency care use, cancer and mortality in Western Australia
2015/58	The effectiveness of pre-travel health advice on illness rates in Western Australians returning from Bali, Indonesia
2015/59	INSPIRED (WA): Investigating services provided in the residential care environments for dementia in Western Australia
2015/60	Independent review of upper gastrointestinal surgical procedures at public health services in WA
2015/61	Routine data linkage between St John of God Subiaco Hospital Gynaecological Cancer Registry and WA Cancer Registry
2015/62	Increasing population health by making better funding decisions: estimation of the cost-effectiveness threshold for the Australian health system
2015/63	Supporting people with mental illness on release from prison- developing and evaluating a pilot multi-agency case management approach
2015/64	ACT Asbestos health study: Data linkage study on the risk of mesothelioma and other cancers
2015/65	Recent changes in IVF clinical practice: data linkage to investigate their impact on fetal growth, birth defects and cerebral palsy
2015/66	Health, education and employment outcomes in survivors a childhood cancer: A data linkage study

2015/67	Improving primary care for Aboriginal mothers and babies in the Kimberley region of Western Australia: a population and region based cluster randomised trial driven by local health service providers
2015/68	ECU-DOH policy and practice brief reports of the health and wellbeing of Western Australians aged 60 years and older

*Please note that project numbers 2015/17 is missing from the above table as this project was withdrawn and consequently was not reviewed by HREC. Project 2015/61 was reviewed by HREC however was withdrawn subsequent to the review.



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