



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

Human Research Ethics Committee

Annual Report 2016

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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*.

This report is presented in accordance with the reporting obligations in the DOH HREC Terms of Reference and provides a summary of the DOH HREC activities from 1 January 2016 to 31 December 2016. 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 2016 reporting period, there were 71 new applications for ethics approval, which is similar with the previous year, in which 68 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 include:

- 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.

At the conclusion of 2016 six members' terms expired. Two members had terms renewed for 3 years and four new members were recruited for 2017. At the conclusion of 2016 the long standing Chair Ms Judy Allen retired. Ms Allen has made an outstanding contribution to the Committee, the Department of Health, and both the research and general community. The Chair has been pivotal in liaising with and advising researchers on ethical issues in human research and providing leadership to policy development within the Department and the Committee.

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 DOH HREC Sitting Members with Deputy Members in Table 2 for 2016.

Table 1: Sitting members serving on the DOH HREC in 2016

Position	<i>Incumbent</i>
Chairperson	Honorary Fellow Judith Allen (term expired December 2016)
WA Health representative	Ms Mary Miller
Information security	Mr Gary Langham
Lay person	Ms Joyce Archibald
Lay person	Mr Ross Monger (term expired December 2016)
Lawyer	Ms Jennifer Wall (term renewed for 2017)
Pastoral care	Reverend Jenifer Goring
Professional care	Ms Patricia Fowler
Researcher	Dr Alison Garton (Deputy Chair)
Researcher	Dr Angela Ives (promoted to sitting member 2016)

Table 2: Deputy members serving on the DOH HREC in 2016

Position	<i>Incumbent</i>
WA Health representative	Mr Stephen Woods
Information security	Mr Shane Gallagher (term renewed for 2017)
Lay person	Dr Phillip Jacobsen
Lay person	Ms Kathryn Kirk
Lay person	Ms Yvonne Rate
Lawyer	Ms Nadia Saba
Pastoral care	Reverend Brian Carey
Professional care	Mr Tim Smith (term expired December 2016)
Researcher	Associate Professor Tom Briffa
Researcher	Dr Geoffrey Hammond (term expired December 2016)
Researcher	Dr Katrina Spilsbury (previously sitting member)

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. New members for 2017 attended an induction workshop as well as a HREC meeting to observe the process.

Members received training on the new Research Governance Service (RGS). A transition plan is in progress to implement the new system during 2017 while ensuring the Committee functions are maintained during the transition.

Two sitting members attended the Population Health Research Network Ethics and Data Linkage Workshop. This extensive training day covered core concepts of data linkage in Australia, risks management, provision of waiver of consent and the legal framework and legislative requirements.

4. Meetings and executive support

The DOH HREC meets on the second Wednesday of every month. In 2016, 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 2016.

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 2016 and the status of these applications are tabulated in Table 3. 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 2016

Total applications received in 2016	71
Approved applications	62
Rejected	1
Withdrawn	2
In progress	6

The DOH HREC received 71 new applications during the reporting period. As shown in figure 1, of these applications, 62 were approved in 2016, 6 were still in progress by 31 December 2016 and two were withdrawn following HREC review.

Figure 1 shows the status of applications received 2016.

Figure 1: Status of applications received in 2016

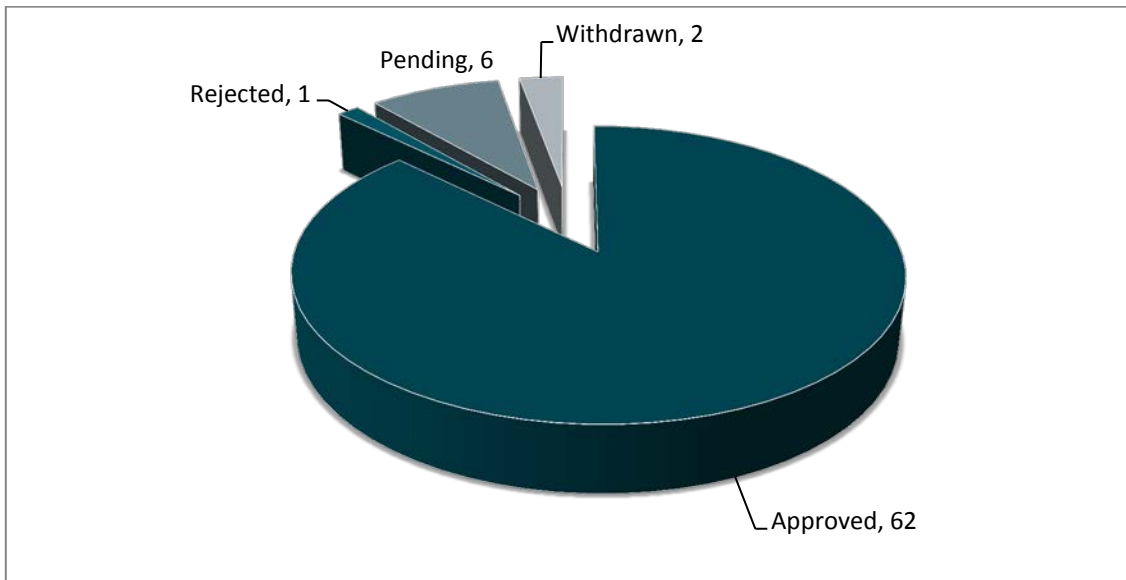
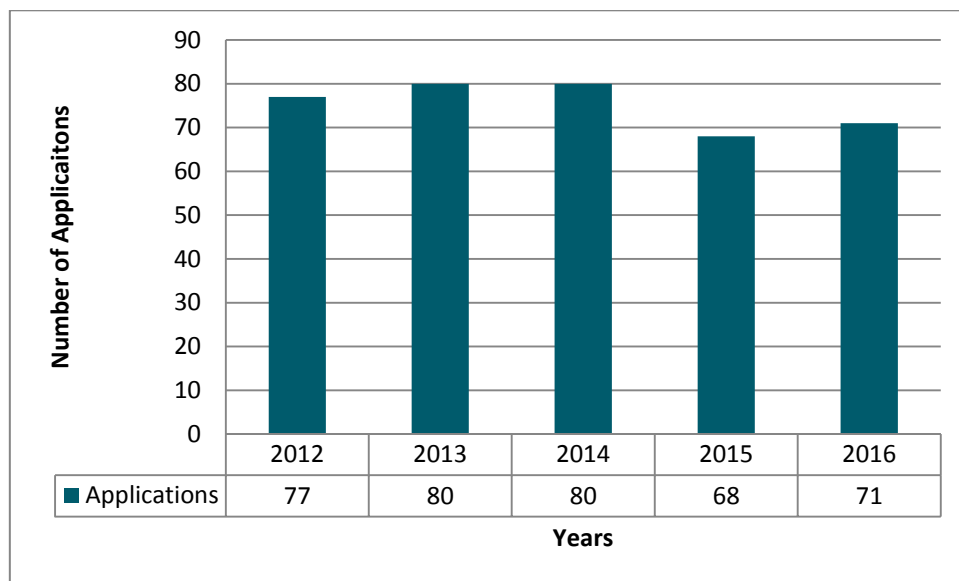


Figure 2 shows the number of new applications considered by the DOH HREC by calendar year for the last 5 years.

Figure 2: Applications reviewed by DOH HREC 2012-2016.



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.

Annual Reports

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.

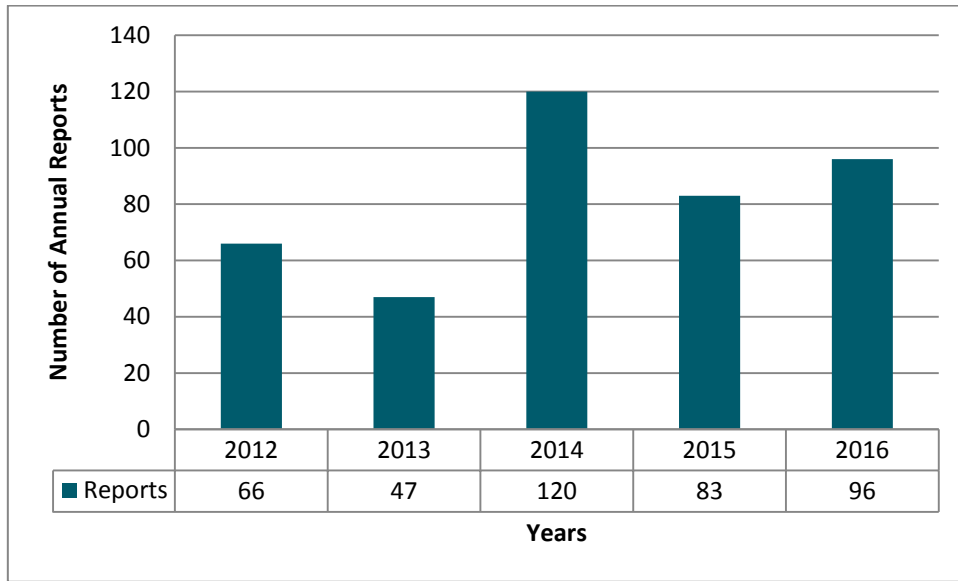
The standardised annual report requires researchers to provide the following information about the approved project:

- 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 96 annual reports were approved by the DOH HREC in 2016. The Research Development Unit, Office of the Chief Medical Officer, is currently implementing the new state-wide database, the Research Governance Service (RGS), 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 shows the total number of annual reports approved between 2012 and 2016.

Figure 3: Total number of annual reports approved by DOH HREC 2012-2016.

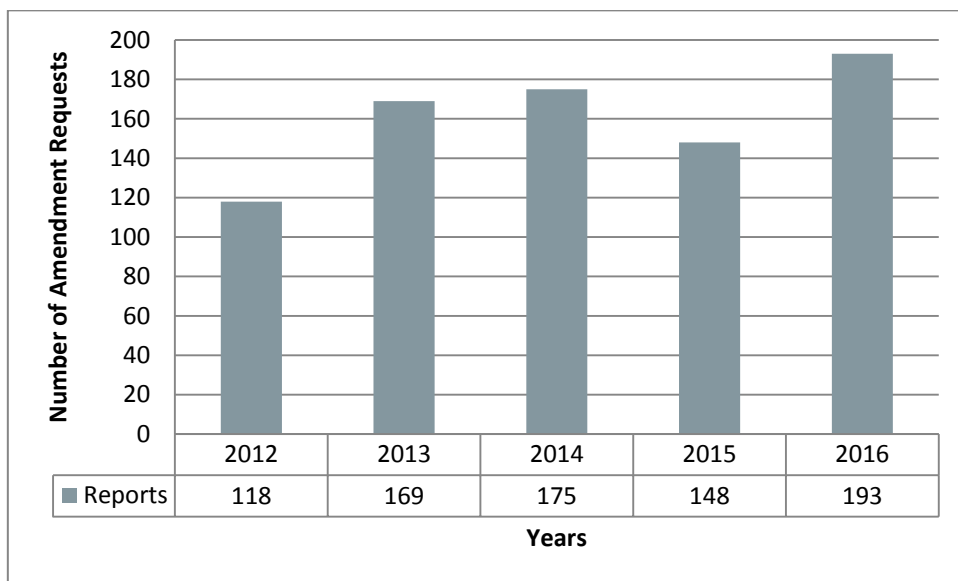


Amendments

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 193 amendment requests were approved by the DOH HREC in 2016, which is an increase from 2015 (with 148 approved amendment requests).

Figure 4 shows the total number of amendment requests approved between 2012 and 2016.

Figure 4: Total number of amendment requests approved by DOH HREC 2012-2016.

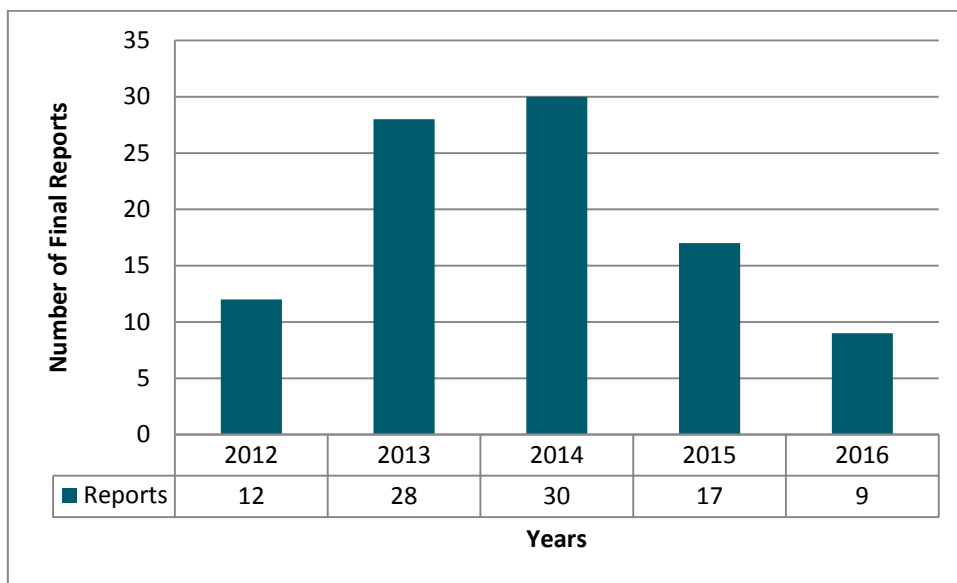


Final reports

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 9 final reports were submitted and approved in 2016. This was less than previous years. The average number of final reports submitted and approved over the last 5 years is 19.2. During 2016 researchers were asking for an extension to project timelines rather than closing projects. These extensions were often requested to facilitate further research publications or due to delays obtaining data.

Figure 5 shows the total number of final reports approved between 2012 and 2016.

Figure 5: Total number of final reports approved by DOH HREC from 2012 - 2016.



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).

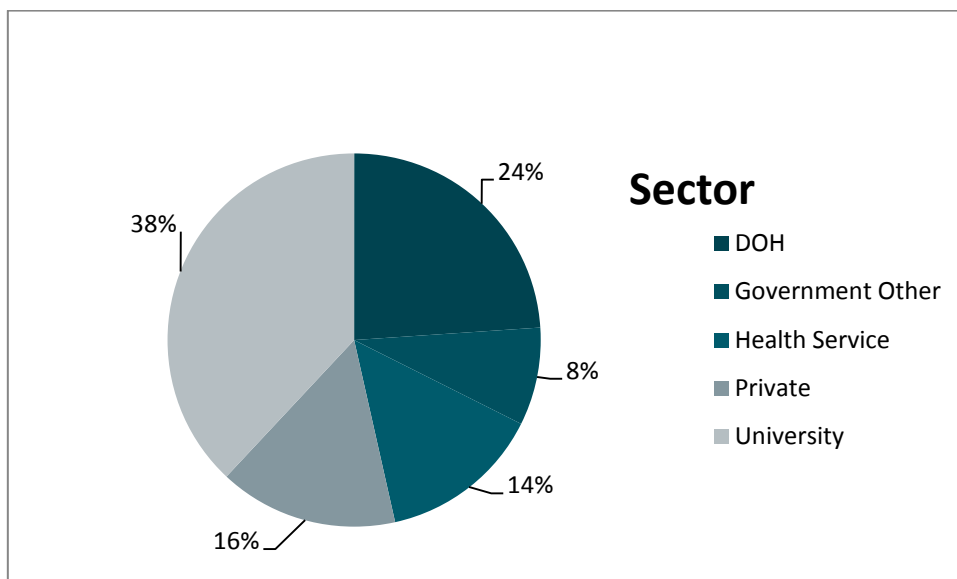
There were three notifications of concern raised with the Committee in regard to research publications and confidentiality of data. The Chair examined each complaint and was satisfied that no further investigations were required.

9. Major users of DOH data

The Universities formed the largest group of major users of DOH data for 2016, which was also the case in 2012, 2013, 2014 and 2015. The Department of Health was responsible for almost a quarter of all applications. Health Services submitted a similar number of applications as those in the private sector, which is the same as 2015 (data not shown). The majority of the private sector applications came from the Telethon Kids Institute. Other Government agencies include both State and Commonwealth agencies including the Mental Health Commission and Australian Institute of Health and Welfare.

Figure 6 shows the breakdown of major users of DOH data for 2016.

Figure 6: Breakdown of major users of DOH data for 2016.



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 2016, the DOH HREC applied the section 95 guidelines to two applications and the section 95A guidelines to eight 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 2016, 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 71 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 2016

HREC #	Full project title
2016/01	Methicillin-resistant Staphylococcus aureus: Its Clinical Significance and Implication on the Western Australian Health System
2016/02	Western Australian Family Cancer Study – Genetic epidemiology of colorectal cancer [Stort title: The WA Family Cancer Study]
2016/03	The impact of a nurse-supported, community-based heart failure management service on self-management behaviour and psychosocial outcomes. [Short title: Nurse-supported heart failure management]
2016/04	Linking data from three national cancer screening programs
2016/05	The association between maternal ultraviolet radiation exposure and serum 25(OH)D levels during pregnancy and subsequent risk of Type 1 diabetes mellitus in offspring.
2016/07	Evaluating the creation of small area synthetic estimates of health outcome prevalence from the Western Australian Health and Wellbeing Surveillance System. [Short title: Small area synthetic estimates of health outcome prevalence]
2016/08	Analysing key performance indicator data to enable performance monitoring and evaluation within the WA public health system. [Short title: Improving the effectiveness of key performance monitoring for Annual Reports]
2016/09	Development of serum models that can accurately predict clinical outcomes in chronic liver disease
2016/10	Quantifying the Burden of Systemic Sclerosis in Australia: From Data Linkages to Patient-Reported Outcomes
2016/12	The epidemiology of Maternal Mortality And Morbidity in WA, 2001-2014.
2016/13	Primary Care Type Emergency Department Presentations – definition and cost-effective design [Short title: Primary Care Type Emergency Department Presentations]
2016/14	Alcohol-related harm in WA reduced through cost-effective initiatives
2016/15	Driving health care efficiencies and patient care outcomes by improving communication across acute and primary transitions of care. Phase 1 - Developing unplanned readmissions risk models for elderly and mental health patients.
2016/16	Reducing inequality in the developmental vulnerability of Australian children: Role of the neighbourhood environment.
2016/17	Western Australian component of the South Australia and Northern Territory Stroke Study (initial phase) (SAINTSS1)
2016/18	A randomised controlled trial to evaluate the effectiveness of SMS immunisation reminders in general practice [Short title: Evaluation of SMS reminders for immunisation]
2016/19	Describing microcephaly in Western Australia: baseline data in response to Zika Virus concerns. [Short title: Epidemiology of microcephaly in WA]
2016/20	The impact of community palliative care on hospital use and place of death among non-cancer decedents [Short title: impact of community palliative care on non-cancer decedents]
2016/21	Brightwater Care Group Infrastructure Linkage
2016/22	Living with Acute Coronary Syndrome: what happens to people in the early years after discharge from hospital with a coronary event in Australia.
2016/23	Is the incidence of heart attack still decreasing in Australia? Developing more reliable methods for monitoring trends in myocardial infarction and monitoring trends in myocardial infarction and coronary heart disease (AUS-MOCHA) [SHORT TITLE: Developing more reliable methods for
2016/24	Rheumatic disease conditions as risk factors for hospitalisation, emergency care use, cancer and mortality in Western Australia from 1980 to 2012.

2016/25	WARDA-CP participation in an international collaborative project: An exploration of cerebral palsy in higher order multiples [SHORT TITLE: WARDA-CP participation in a collaborative study of CP in multiples]
2016/26	Improving access to primary care for Aboriginal babies in Western Australia [SHORT TITLE: Improving access to primary care for Aboriginal babies]
2016/27	The impact of first and second eye cataract surgery on crash risk
2016/28	Evaluating the effect of providing tailored patient education for older people at hospital discharge in addition to usual care on rates of falls after hospital discharge compared to providing a social intervention in addition to usual care – a randomised controlled trial [SHORT TITLE: Tailored Patient Education for Preventing Falls after Hospital Discharge]
2016/29	Baseline for monitoring the burden of rheumatic heart disease in Australian jurisdictions: Western Australian component [SHORT TITLE: Burden of rheumatic heart disease in Western Australia]
2016/30	Cleft lip and palate - a comparative psychosocial perspective
2016/31	Families impacted by cancer in Western Australia: a profile to support healthy child development
2016/32	Does gastrostomy improve the lives of children with severe disability and their families [Short title: Gastrostomy in severe disability]
2016/33	The association of sleep apnoea with long-term health outcomes in Western Australian adults [SHORT TITLE: Association of sleep apnoea with long-term health outcomes]
2016/34	New indicator “Western Australia Emergency Access Target (WEAT) Percentage of Emergency Department (ED) Attendances that are re-attendances less than or equal to 48 hours of the previous attendance” using encrypted linkage keys. [SHORT TITLE: Encrypted linkage keys to accurately calculate ED re-attendances]
2016/35	Hospitalisation and mortality due to cirrhosis in Western Australia [SHORT TITLE: Burden of liver cirrhosis in Western Australia]
2016/36	Cubes of Cancer Activity (CoCA)
2016/37	Identification of markers for diagnosis and prognosis of cancer
2016/38	Non Admitted Patient Activity and Wait List Data Collection Infrastructure Linkage
2016/39	Healthdirect Australia Telehealth and E-Health Syndromic Surveillance System
2016/40	The interaction of masculinity and exercise in prostate cancer
2016/42	The Epidemiology of Perinatal and Infant Mortality in WA, 1994-2013
2016/43	The care coordination experiences of people living with rare diseases in Western Australia
2016/44	Evaluating the Undiagnosed Diseases Program, Western Australia (UDP-WA): Perspectives from parents/caregivers
2016/45	Long term treatment outcomes in early psychosis specialist services
2016/46	Alcohol use during aquatic activities; perspectives from Western Australian School Leavers [Short Title: Alcohol use, school Leavers and aquatic activities]
2016/47	Observing Recurrent Incidence of Adverse Outcomes following Hospitalisations (ORION) [Short Title: ORION]
2016/48	Characteristics and outcomes of Brightwater Care Group clients with an Acquired Brain Injury
2016/49	Influence of physical activity, obesity and smoking on survival after a prostate cancer diagnosis [SHORT TITLE: Lifestyle factors associated with prostate cancer survival]

2016/50	Implementation of evidence based guidelines for the management of atrial fibrillation (AF) via an electronic clinical governance management system [SHORT TITLE: Management of AF]
2016/51	Inter-pregnancy interval, obstetric/morbidity history and adverse pregnancy outcomes [SHORT TITLE: Obstetric history and adverse outcomes]
2016/52	Western Australian Burden of Disease Study [SHORT TITLE: WA Burden of Disease Study]
2016/53	IMPROVE - Investigating Medication re-Purposing to Reduce risk of OVarian cancer and Extend survival
2016/55	Alcohol related harm in young people
2016/56	Pertussis Vaccination in pregnant women: a cohort study to evaluate vaccine safety and effectiveness in Western Australia
2016/57	Association between rates of opioid prescribing and opioid-related deaths in Western Australia
2016/58	Use of eye care services in Western Australia
2016/59	A Comprehensive Approach to International Cancer Survival Benchmarking
2016/60	Using linked population data to investigate the impact of intimate partner violence on children's outcomes
2016/61	Does continuity of primary care reduce demand on emergency department presentations and hospital admissions? [SHORT TITLE: Continuity of primary care]
2016/62	Occupational Injury Surveillance using the Royal Perth Hospital State Trauma Registry [SHORT TITLE: Occupational surveillance based on RPHSTR]
2016/63	Parenthood in Patients Receiving Dialysis or Kidney Transplantation: A National Study of Perinatal Risks and Outcomes Through Population Record Linkage
2016/64	Multi-country investigation of influenza vaccine effectiveness in preventing hospitalisation and other adverse outcomes associated with influenza among pregnant women [SHORT TITLE: Influenza vaccine effectiveness in pregnant women]
2016/65	Evaluation of the Medibank Health Solutions Integrated Healthcare Service Model of Care Initiative [SHORT TITLE: Medibank Integrated Healthcare Evaluation]
2016/66	Renal Demand Modelling Project
2016/67	Evaluating New Mental Health Initiatives
2016/68	Evaluation of the Older Adult Program
2016/69	Evaluation of a Prevention and Recovery Care (PARC) Model for Patients with Mental Illness
2016/70	Establishment of a linked data repository for epidemiological analyses
2016/71	The Busselton Diabetes Study: A study of diabetes in a rural Australian setting
2016/72	Transfer of Epidemiological Information to the Western Australian Coronial Suicide Information System (WACISIS).

*Please note that project numbers 2016/06 and 2016/11 were withdrawn before being reviewed by HREC. Project 2016/41 and 2016/54 were reviewed by HREC, but withdrawn subsequent to the review. Project 2016/73 was rejected.

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