



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

Human Research Ethics Committee

Annual Report 2017

Contents

| | | |
|-----|--|----|
| 1. | Background | 1 |
| 2. | Membership | 2 |
| 3. | Training | 4 |
| 4. | Meetings and executive support | 4 |
| 5. | Review of research projects | 4 |
| 6. | Annual Reports, amendments and final reports | 6 |
| | Annual Reports | 6 |
| | Amendments | 7 |
| | Final reports | 8 |
| 7. | Administrative procedures | 8 |
| 8. | Breaches, concerns and complaints | 9 |
| 9. | Major users of DOH data | 9 |
| 10. | Application of Privacy Act 1988 guidelines | 10 |
| 11. | Public awareness | 10 |
| 12. | Conclusion | 10 |
| 13. | Supporting documents | 11 |
| | Appendix A – New applications reviewed in 2017 | 12 |

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 Department of Health's (Department) 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 2017 to 31 December 2017. 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.

There has been a notable decrease in the number of new applications managed in 2017 compared with each of the preceding four years. Possible explanations for this include research funding falling due to tighter economic conditions, researchers taking some time to familiarise themselves with the Research Governance System (RGS) application system and a change to the Terms of Reference. The Terms of Reference change has meant that projects that are designed for quality assurance or evaluation projects do not necessarily require DOH HREC consideration.

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

The DOH HREC is a specialist committee that oversees the use of personal health information held by the Department. 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 the WA health system.

At the conclusion of 2017 five members' terms expired and one member resigned. Three members had terms renewed for one year and five new members were recruited for 2018. Members were renewed for a one year term only due to the State Government's review of Boards and Committees. The DOH HREC provided information for this review and in particular noted the gender representation within the committee. For 2017 there are:

- Sitting members (10 members) 3 male and 7 female
- Deputy members (11 members) 5 males and 6 females.

The staggered approach to appointing members to fixed term positions has previously 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 2017.

Table 1: Sitting members serving on the DOH HREC in 2017

| Position | <i>Incumbent</i> |
|---------------------------------|---|
| Chairperson | Dr Peter Bentley |
| WA Health representative | Ms Mary Miller (term expired December 2017) |
| Information security | Mr Gary Langham |
| Lay person | Ms Joyce Archibald (term expired December 2017) |
| Lay person | Mr Harley White (resigned June 2017) |
| Lawyer | Ms Jennifer Wall |
| Pastoral care | Reverend Jenifer Goring |
| Professional care | Ms Patricia Fowler (term expired December 2017) |
| Researcher | Dr Alison Garton (Deputy Chairperson) |
| Researcher | Dr Angela Ives |

Table 2: Deputy members serving on the DOH HREC in 2017

| Position | <i>Incumbent</i> |
|---------------------------------|---|
| WA Health representative | Mr Stephen Woods |
| Information security | Mr Shane Gallagher |
| Lay person | Dr Phillip Jacobsen (term expired 31 December 2017) |
| Lay person | Ms Kathryn Kirk |
| Lay person | Ms Yvonne Rate |
| Lawyer | Ms Nadia Saba |
| Pastoral care | Reverend Brian Carey |
| Professional care | Ms Ann McDonald |
| Researcher | Associate Professor Tom Briffa (term expired December 2017) |
| Researcher | Associate Professor Alison Reid |
| Researcher | Dr Katrina Spilsbury |

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 attend an induction workshop as well as a HREC meeting to observe the meeting processes. All members received training on the new RGS and will continue to do so.

4. Meetings and executive support

The DOH HREC meets on the second Wednesday of every month. In 2017, 11 meetings were held.

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 Department.

A quorum was met for all the meetings in 2017.

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

5. Review of research projects

The number of new applications considered by the DOH HREC in 2017 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 2017

| Total applications received in 2017 | 27 |
|-------------------------------------|----|
| Approved applications | 23 |
| Rejected | 1 |
| Withdrawn | 1 |
| In progress | 2 |

The DOH HREC received 27 new applications during the reporting period. As shown in Table 3, of these applications, 23 were approved in 2017, two were still in progress by 31 December 2017, one was rejected and one was withdrawn prior to HREC review.

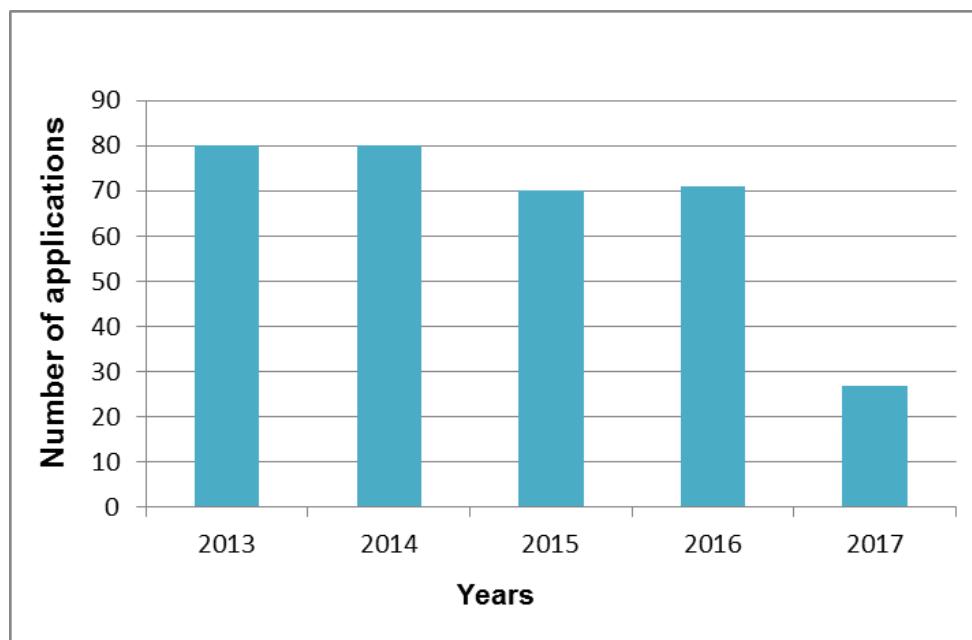
Table 4 outlines the number of reports, applications and amendment requests received from 2013 - 2017. There has been an increase in amendment requests and annual reports whilst the number of new applications has decreased.

Table 4: Number of requests received 2013- 2017

| Year | 2013 | 2014 | 2015 | 2016 | 2017 |
|--------------------|------|------|------|------|------|
| New Applications | 80 | 80 | 70 | 71 | 27 |
| Annual Reports | 66 | 47 | 120 | 83 | 96 |
| Amendment Requests | 118 | 169 | 175 | 148 | 194 |
| Final Reports | 28 | 30 | 17 | 9 | 22 |

Figure 1 shows the number of new applications considered by the DOH HREC by calendar year for the last five years.

Figure 1: Applications reviewed by DOH HREC 2013-2017



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.

Researchers are responsible for ensuring that an annual progress report, 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.

Annual Reports

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

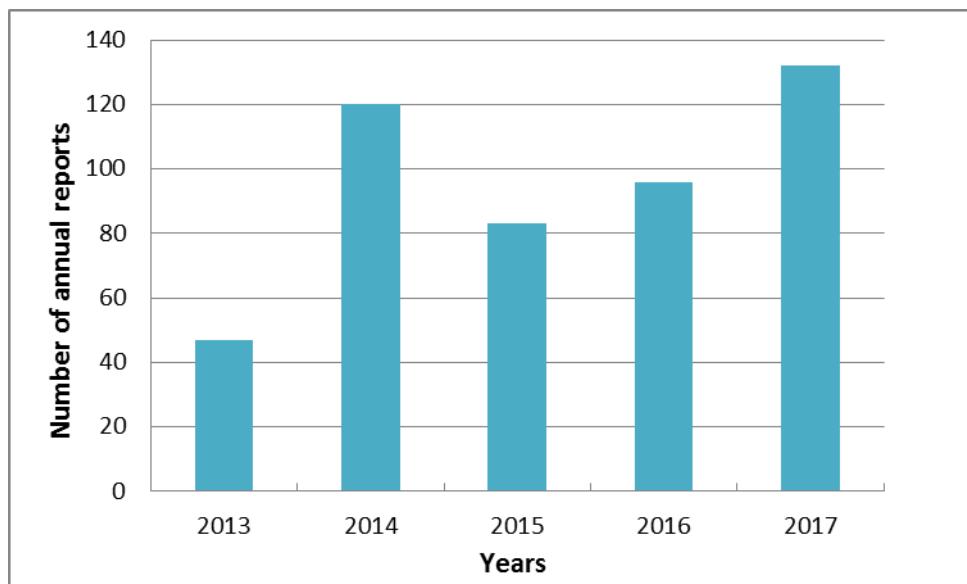
- progress to date, publication or outcome in the case of completed research
- maintenance and security of records and data
- compliance with the approved protocol
- compliance with the conditions of approval
- changes to the protocol or conduct of the research
- changes to the personnel or contact details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

A total of 132 annual reports were approved by the DOH HREC in 2017. This was significantly higher than the previous year.

In 2018, the RGS will implement 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 2 shows the total number of annual reports approved between 2013 and 2017.

Figure 2: Total number of annual reports approved by DOH HREC 2013-2017

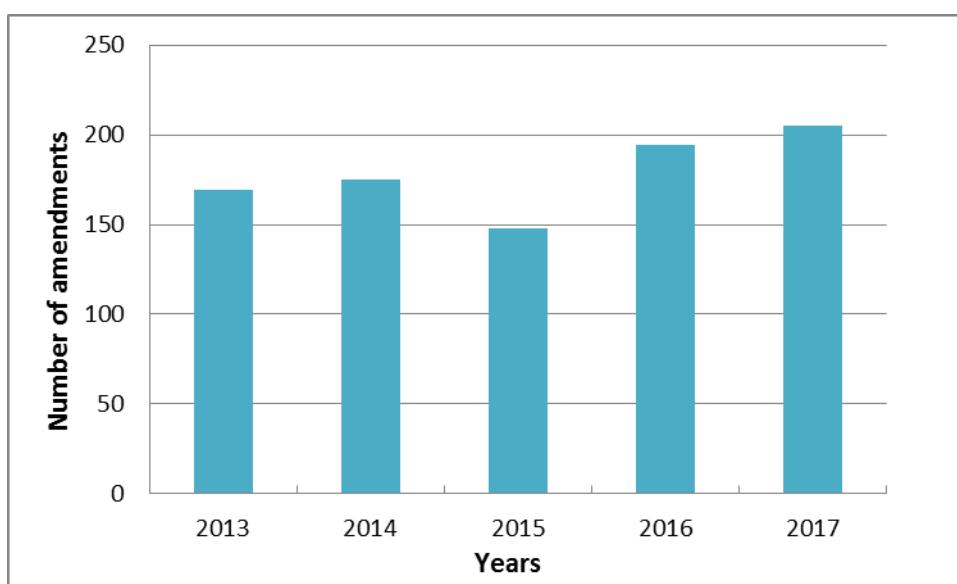


Amendments

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 205 amendment requests were approved by the DOH HREC in 2017, which is on par with amendments approved in 2016 (with 194 approved amendment requests).

Figure 3 shows the total number of amendment requests approved between 2013 and 2017.

Figure 3: Total number of amendment requests approved by DOH HREC 2013-2017

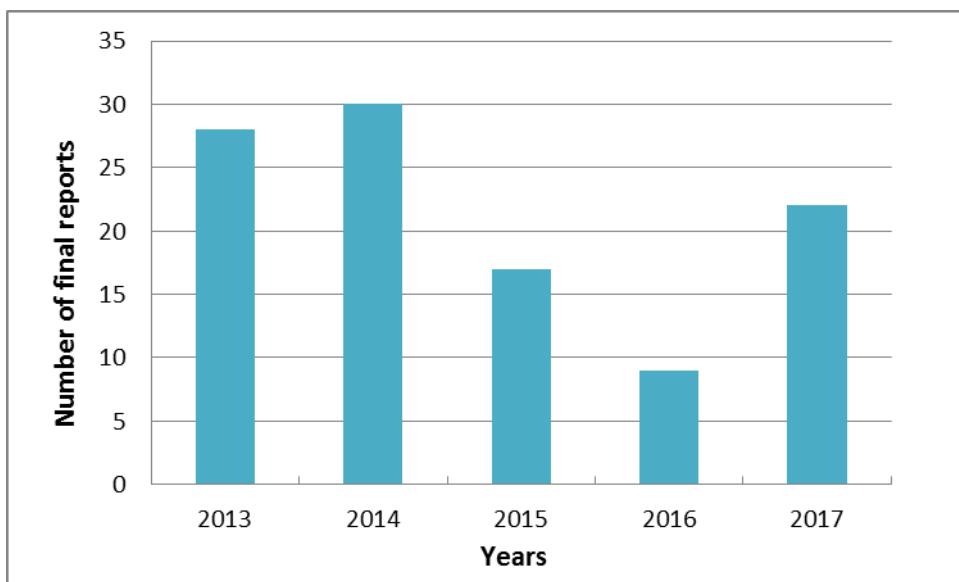


Final reports

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 22 final reports were submitted and approved in 2017. The average number of final reports submitted and approved over the last five years is 21.2. During 2017 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 4 shows the total number of final reports approved between 2013 and 2017.

Figure 4: Total number of final reports approved by DOH HREC from 2013 - 2017



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 2017 relating to a breach in protocol. As per the Terms of Reference and SOPs an Incident Review Committee was convened and the breach is currently under investigation. Submissions were received and reviewed by all parties. Notification of the Committee's decision and the required actions will be provided to all key stakeholders.

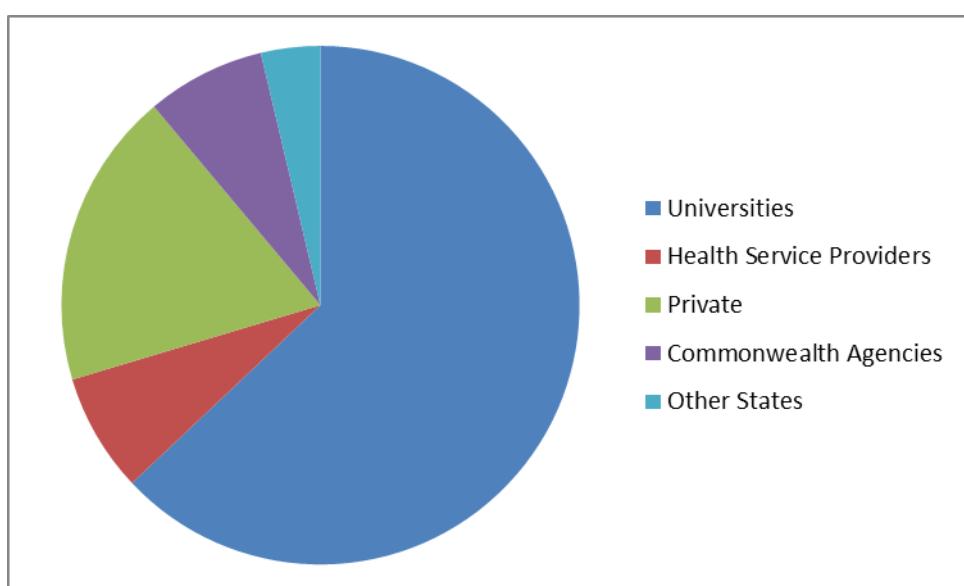
There were eight notifications of concern raised with the Committee relating to research publications, unauthorised release of data and participant consent. The Chair examined each complaint and was satisfied that no further investigations were required.

9. Major users of DOH data

The Universities formed the largest group of major users of DOH data for 2017, which was also the case in previous years. There were similar numbers of applications submitted by Health Service Providers and Commonwealth agencies. Majority of the private sector applications came from the Telethon Kids Institute.

Figure 5 shows the breakdown of major users of the Department's data for 2017.

Figure 5: Breakdown of major users of DOH data for 2017



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 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 2017, the DOH HREC applied the section 95 guidelines to five applications and the section 95A guidelines to five applications which all 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 the Department, 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

http://ww2.health.wa.gov.au/Articles/A_E/Department-of-Health-Human-Research-Ethics-Committee

12. Conclusion

In 2017, the DOH HREC discharged its responsibilities to oversee the use and disclosure of personal health information held in the Department data collections. The combined skills and expertise of the Committee members and deputy members were applied to the ethical review of 27 new projects.

The Committee works closely with data managers, Data Linkage Branch, and more recently with Research Governance Unit, to ensure that applications are well developed, that privacy and security are properly protected and that the interests of individuals are respected.

The Committee looks forward to the fully implemented RGS in 2018 and developing a close and constructive relationship with the Research Governance Unit. This will ensure that as well as providing robust ethical review we work cooperatively and efficiently. The Committee intends to ensure ongoing responsiveness and accessibility to researchers.

13. Supporting documents

[Department of Health \(2017\). Department of Health Western Australia Human Research Ethics Committee Terms of Reference. Department of Health, Perth.](#)

[Department of Health \(2017\). 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 2017

| HREC # | Full project title |
|---------|---|
| 2017/02 | Gynaecological Cancer in Western Australia: A Program of Research [Short Title: Gynaecological Cancer in WA] |
| 2017/03 | A ten-year evaluation of community treatment orders on mental health and forensic outcomes |
| 2017/04 | Establishment of Prostate Cancer Outcomes Registry Australia and New Zealand in Western Australia |
| 2017/05 | Effects of HPV vaccination on the development of cervical abnormalities for Aboriginal women: A Western Australian study |
| 2017/06 | Enhanced Indigenous Mortality Data Collection |
| 2017/07 | Probabilistic linkage using privacy preserved linkage variables |
| 2017/08 | Government Data Custodians and Decision-Making: Release of Personal Information for Research [Short title: Government Data Custodians and Decision-Making] |
| 2017/09 | Royal Flying Doctor Services Data Linkage Project |
| 2017/10 | WARDA participation in an international project: The Comprehensive CA-CP Study: Combining congenital anomaly (CA) and cerebral palsy (CP) data for a comprehensive investigation into opportunities for prevention [Short Title: The Comprehensive CA-CP Study] |
| 2017/11 | Is risk-based licensing an effective intervention for reducing alcohol-related harms |
| 2017/12 | Long-term outcomes after bariatric surgery in Western Australia 2007 – 2016. |
| 2017/13 | Secondary falls prevention in older people presenting to the emergency department with a fall: A multi-centre randomised controlled trial of efficacy, cost-effectiveness and acceptability of the RESPOND program |
| 2017/14 | Spatio-temporal Analysis of Asthma Hospitalisation in the metro areas of Western Australia. |
| 2017/15 | Ribotyping analysis of repeated infections of Clostridium difficile for the Western Australian population |
| 2017/16 | HPV Partnership Project 1: Factors associated with non-initiation and non-completion of school-based HPV vaccination |
| 2017/19 | Knowledge user capacity to engage with Evidence Based Decision Making practices: Exploring employer perceptions during the course of recruitment |
| 2017/20 | The Injury Comorbidity Index Study |
| 2017/21 | Western Australian Child Development Atlas |
| 2017/22 | Early Menopause: Implementation research using the experiences and perspectives of women and health professionals to translate evidence into practice (Alternative Title: Long-term consequences of early menopause.) |
| 2017/23 | Mathematical Modelling to Inform National Seasonal Influenza Vaccination Policy |
| 2017/24 | The D-Health Trial: Data Linkage |
| 2017/25 | Surveillance of disease outcomes and management of people diagnosed with hepatitis B or hepatitis C virus infection in Western Australia: A population-based linkage study |
| 2017/26 | Monitoring the impact of the Western Australian Preterm Birth Prevention Initiative on preterm births |

*Please note that Project 2017/17 was withdrawn before being reviewed by the DOH HREC. Project 2017/01 and Project 2017/27 require additional information before the Committee will grant approval. Project 2017/18 was not approved.

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