



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

Department of Health Human Research Ethics Committee

Annual Report 2018

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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 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 2018 to 31 December 2018. 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.

Similar to 2017, there has been a notable decrease in the number of new applications managed in 2018 compared with each of the preceding three 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 2018 seven members' terms expired and one member resigned. Two members had terms renewed, two Deputy members were promoted to Sitting member and five new members were recruited for 2019. 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 2018 there are:

- Sitting members (10 members) 4 male and 6 female
- Deputy members (11 members) 6 males and 5 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 2018.

Table 1: Sitting members serving on the DOH HREC in 2018

Position	<i>Incumbent</i>
Chairperson	Dr Peter Bentley
WA Health representative	Mr Stephen Woods
Information security	Mr Gary Langham (term expired December 2018)
Lay person	Ms Kathryn Kirk
Lay person	Mr Phillip Jacobsen
Lawyer	Ms Jennifer Wall
Pastoral care	Reverend Jenifer Goring (term expired December 2018)
Professional care	Ms Natalie Fleetwood
Researcher	Dr Alison Garton (Deputy Chairperson) (term expired December 2018)
Researcher	Dr Angela Ives (term expired December 2018)

Table 2: Deputy members serving on the DOH HREC in 2018

Position	<i>Incumbent</i>
WA Health representative	Ms Stacey Leong (Resigned March 2018)
Information security	Mr Shane Gallagher
Lay person	Mr Peter Towie
Lay person	Ms Yvonne Rate
Lay person	Mr John McMath
Lawyer	Ms Nadia Saba (term expired December 2018)
Pastoral care	Reverend Brian Carey (term expired December 2018)
Professional care	Clinical Associate Professor Ann McDonald
Researcher	Professor Satvinder Dhaliwal
Researcher	Associate Professor Alison Reid
Researcher	Dr Katrina Spilsbury (term expired December 2018)

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 2018, 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 2018.

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 2018 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 2018

Total applications received in 2018	33
Approved applications	31
Rejected	0
Withdrawn	0
In progress	2

The DOH HREC received 33 new applications during the reporting period. As shown in Table 3, of these applications, 31 were approved in 2018, two were still in progress by 31 December 2018 prior to HREC review.

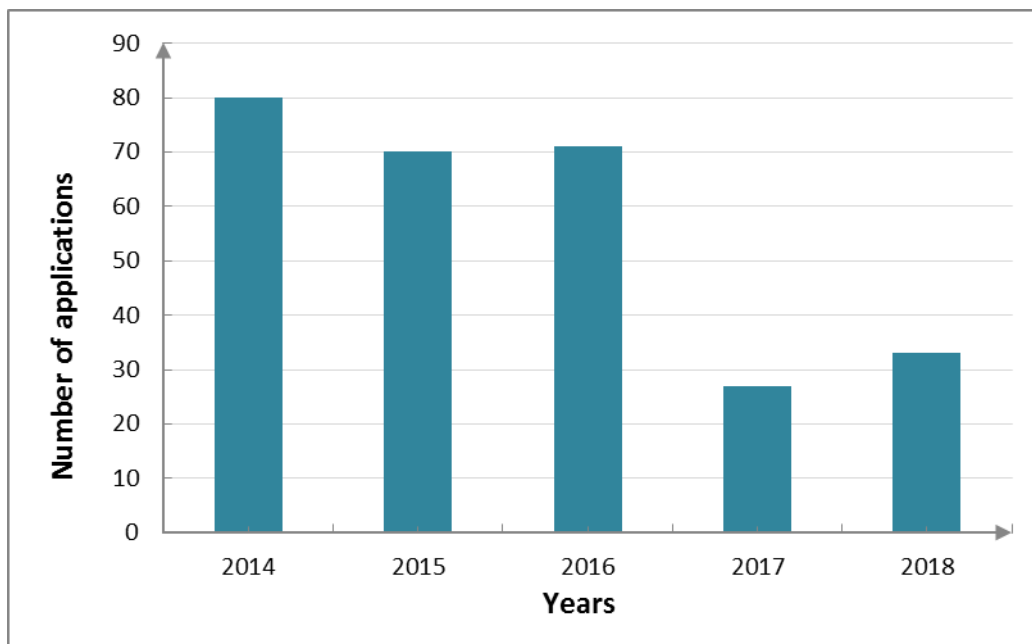
Table 4 outlines the number of reports, applications and amendment requests received from 2014 - 2018. There has been an increase in amendment requests and annual reports, and a significant increase in the number of final reports received, whilst the number of new applications is on par with 2017.

Table 4: Number of requests received 2014- 2018

Year	2014	2015	2016	2017	2018
New Applications	80	70	71	27	33
Annual Reports	47	120	83	96	159
Amendment Requests	169	175	148	194	218
Final Reports	30	17	9	22	99

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 2014-2018



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

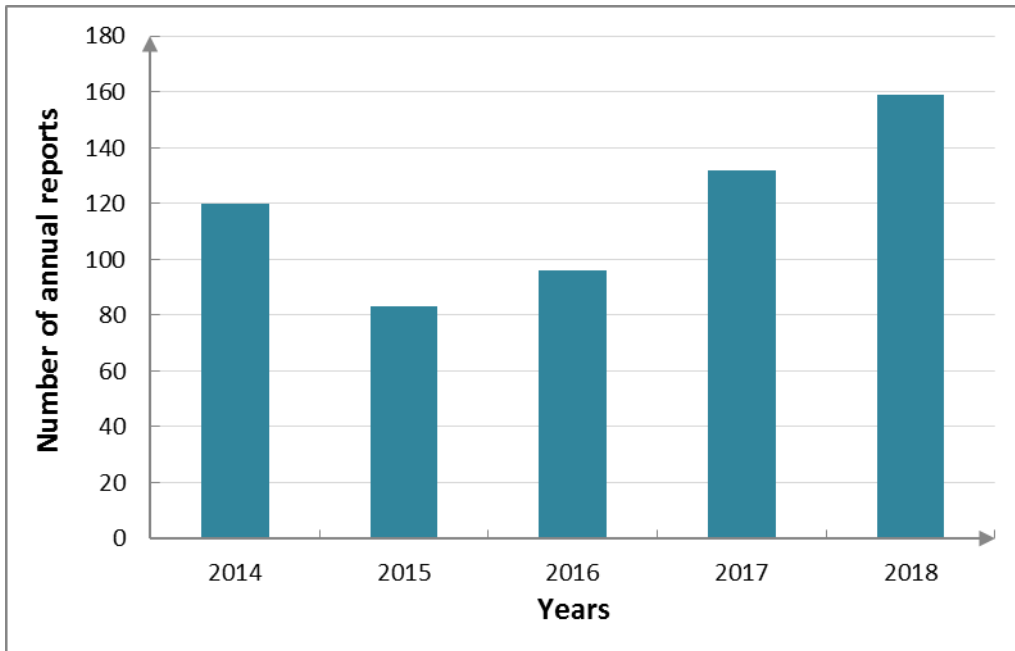
The standardised annual report requires researchers to provide the following information about the approved project:

- 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 159 annual reports were approved by the DOH HREC in 2018. As of December 2018, the RGS has implemented 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 2014 and 2018.

Figure 2: Total number of annual reports approved by DOH HREC 2014-2018

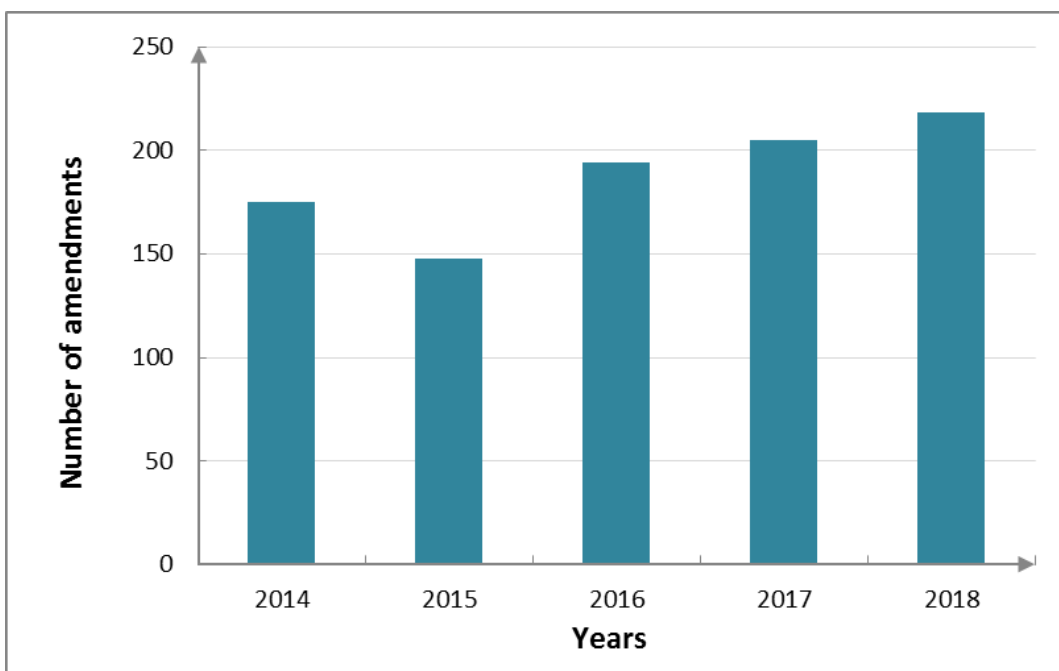


Amendments

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. Extensions were often requested to facilitate further research publications or due to delays obtaining data. A total of 218 amendment requests were approved by the DOH HREC in 2018, which is on par with amendments approved in 2017 (with 205 approved amendment requests).

Figure 3 shows the total number of amendment requests approved between 2014 and 2018.

Figure 3: Total number of amendment requests approved by DOH HREC 2014-2018

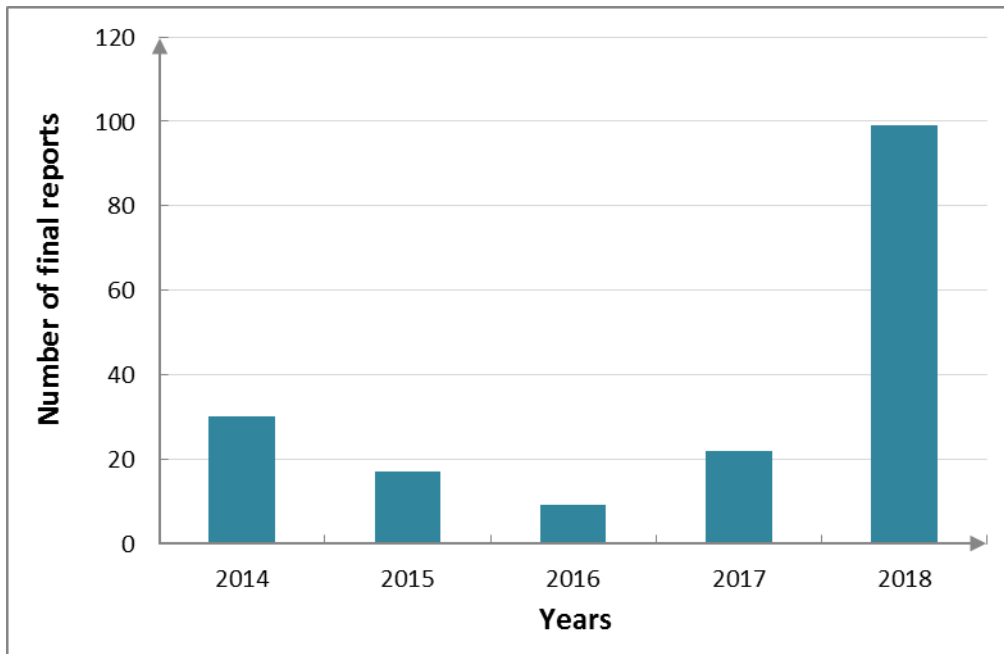


Final reports

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 99 final reports were submitted and approved in 2018. The average number of final reports submitted and approved over the last five years is 35.4. The increased number of final reports received in 2018 is attributed to the active management of audit results.

Figure 4 shows the total number of final reports approved between 2014 and 2018.

Figure 4: Total number of final reports approved by DOH HREC from 2014 - 2018



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*.

Throughout 2018 the DOH HREC Office undertook an audit of all research projects whose ethical approval was requiring closure. Researchers had a two-step process to submit a final report or request an extension of ethical approval. Researchers who failed to respond to the DOH HREC Office had their projects terminated. The audit assisted with the migration of current DOH HREC projects to the RGS.

8. Breaches, concerns and complaints

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

- concerns and complaints about the conduct of a project approved by the DOH HREC (SOP17), and
- breaches in the conduct of a project approved by the DOH HREC (SOP18)
- reporting and handling of adverse events in clinical trials (SOP19)
- the DOH HREC's review or rejection of an application (SOP26).

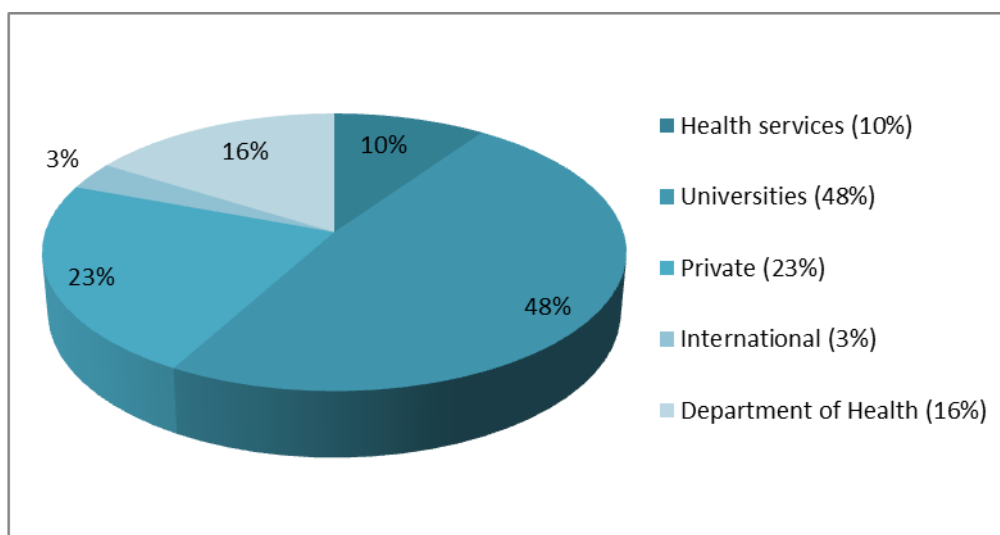
There were seven notifications of concern raised with the Committee relating to unauthorised release of data and participant consent. The Chair examined each complaint and was satisfied that no further investigations were required.

9. Major users of DOH data

The Universities formed the largest group of major users of DOH data for 2018, 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 2018.

Figure 5: Breakdown of major users of DOH data for 2018



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 2018, the DOH HREC applied the section 95 guidelines to three applications and the section 95A guidelines to seven 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 2018, 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 33 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 2019 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 \(2018\). Department of Health Western Australia Human Research Ethics Committee Terms of Reference. Department of Health, Perth.](#)

[Department of Health \(2018\). 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 2018

HREC #	Full project title
2018/01	Defining and Defeating Aboriginal and Torres Strait Islander Disadvantage In Breast Cancer Survival
2018/02	A review of the epidemiology, management and mortality of patients with penile cancer in Western Australia
2018/03	The WA Data Linkage System (WADLS) infrastructure project
2018/04	Impact of Rapid Access to cardiology Determined multi-modality testing among Individuals presenting with new onset Chest pain: improving quality, efficiency and cost effectiveness at Royal Perth Hospital: The RADICAL project
2018/05	Prospective study of adverse pregnancy outcomes from fetotoxic agents in the public water supply
2018/06	Heritable and environmental determinants of hospitalisation for common childhood illnesses - Study 2: association between monozygotic and dizygotic twins, their siblings and their parents in hospital admissions
2018/07	The types and causes of anticoagulant-related medication incidents across hospitals in Western Australia
2018/08	Effect of an integrated end of life primary care service on hospital use: A pilot trial
2018/09	Establishment of the Social Investment Data Resource (SIDR) to support a social investment approach for Target 120 and future projects
2018/10	Factors affecting MenACWY vaccine uptake in Western Australian 18 and 19 year olds
2018/11	Cost effectiveness of extending the Phase 3 community pulmonary rehabilitation program beyond the recommended 10 weeks
2018/12	Reproductive Outcomes for Women following a first cancer diagnosis: a Linkage Study
2018/13	Australian Institute of Health and Welfare Coordination of Health Care Study (Western Australia application)
2018/14	The safety of methoxyflurane for emergency pain relief administered by ambulance services in Western Australia
2018/15	Reducing the burden of dialysis catheter complications - a national approach
2018/16	Evaluation of the Early Psychosis Youth Services (EPYS) program: ecological analysis of health service utilisation
2018/17	Is highly-sensitive troponin testing advancing clinical practice, improving outcomes and cost-effective in the investigation and management of chest pain in the Emergency Department? (Short Title: The TropED Study)
2018/18	Histological Predictors of Squamous Cell Carcinoma Progression in High-Risk Renal Transplant Patients
2018/19	Kimberley Suicide and Self-Harm Data Project
2018/20	An assessment of late night alcohol restrictions in Queensland
2018/21	An empirical framework for assessing mortality and morbidity in people with psychotic disorders: A 7-year prospective and 10-year retrospective follow-up of 2075 participants in the Survey of High Impact Psychosis (SHIP) using linked registers
2018/22	Rare cancers in Western Australia: Incidence and survival
2018/23	Risk management of waterborne pathogens in public swimming pools and splash parks

2018/24	Follow-up of the long-term effects of a physical activity intervention on cognition, mental health, physical activity, quality of life and the utilisation of health services
2018/25	Descriptive and comparative analysis of elective orthopaedic foot surgery waiting times within the West Australian public health system
2018/26	SAFety, Effectiveness of care and Resource Use among Australian Hospitals
2018/27	The types and causes of opioid-related medication incidents across hospitals in Western Australia
2018/28	Clinical outcomes of Alternative model of Cardiac rehabilitation for Cost Effective Secondary prevention (ACCES) project
2018/39	Exploring health and justice outcomes in Aboriginal children: a follow-up study of the Western Australian Aboriginal Child
2018/30	Case-control study of the effectiveness of rotavirus vaccination during a G2P[4] rotavirus epidemic in the Northern Territory & Western Australia
2018/33	Contribution of Western Australian data to a global RSV Mortality Database (RSV GOLD-WA)

*Please note that Project 2018/31 and Project 2018/32 require additional information before the Committee will grant approval.

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