



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

# Department of Health Human Research Ethics Committee

**Annual Report 2020**

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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 and scientific standards of human research
- protect the welfare, rights and dignity of individuals, as well as the privacy and confidentiality of their personal health information (including health information) 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 2018 (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 was prepared by the Research and Innovation Office (for queries, please email [RIO.DOH@health.wa.gov.au](mailto:RIO.DOH@health.wa.gov.au)). It 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 2020 to 31 December 2020. 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.

The Research Governance Service (RGS) is a centralised IT system that was adopted by WA Health in 2017. Its purpose is to enable the completion, submission, administration, tracking and reporting of research projects through their life cycle including ethics approval, site authorisation, monitoring and publications. The RGS is a mandatory system for all researchers, project members, site administrators, Human Research Ethics Committees and Research Governance Offices. Accordingly, the RGS has become fundamental in managing applications for ethical and governance approval.

## 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.

During 2020, one member's term expired, five members had terms renewed and two new members were recruited to begin in March 2020 and January 2021. Two Sitting Members resigned unexpectedly in October 2020, which resulted in new recommendations being submitted to Cabinet at the end of the year, and these had not been approved by 31 December 2020.

The DoH HREC noted the gender representation within the Committee. For 2020 there were:

- Sitting members (ten members): four males and six females
- Deputy members (nine members): six males and three 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. 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 2020.

**Table 1: Sitting members serving on the DoH HREC in 2020**

<b>Position</b>	<b><i>Incumbent</i></b>
<b>Chairperson</b>	Dr Peter Bentley
<b>WA health system representative</b>	Mr Stephen Woods
<b>Information security</b>	Mr Shane Gallagher
<b>Lay person</b>	Ms Kathryn Kirk
<b>Lay person</b>	Mr Phillip Jacobsen
<b>Lawyer</b>	Ms Suzanne Hillier
<b>Pastoral care</b>	Prof Colleen Hayward
<b>Professional care</b>	Ms Natalie Fleetwood
<b>Researcher</b>	Dr Alison Reid
<b>Researcher</b>	Dr Angela Ives

**Table 2: Deputy members serving on the DoH HREC in 2020**

<b>Position</b>	<b><i>Incumbent</i></b>
<b>WA health system representative</b>	Mr Richard Gillett
<b>Information security</b>	Mr Bret Watson
<b>Lay person</b>	Ms Sonia McKeiver
<b>Lay person</b>	Mr John McMath
<b>Lawyer</b>	Ms Nadia Saba
<b>Pastoral care</b>	Rev Graham Mabury
<b>Professional care</b>	Clinical Associate Professor Ann McDonald
<b>Researcher</b>	Professor Satvinder Dhaliwal
<b>Researcher</b>	Associate Professor Richard Brightwell

### 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 an HREC meeting to observe the meeting processes. All members received training on the RGS and will continue to do so.

### 4. Meetings and executive support

The DoH HREC meets on the second Wednesday of every month. In 2020, 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 2020.

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 2020 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 2020**

<b>Total applications received in 2020</b>	<b>31</b>
Approved applications	28
Rejected	0
Withdrawn	1
In progress	2

The DoH HREC reviewed 31 new applications during the reporting period. As shown in Table 3, of these applications, 28 were approved in 2020, one was withdrawn and two were still in progress by 31 December 2020.

Table 4 outlines the number of reports, applications and amendment requests received from 2015 to 2020. There was a decrease in the number of new applications, annual reports amendment requests and final reports. The overall reduction in the number of submissions is likely to be attributed to the impact of COVID-19. Universities have reduced the number of staff employed to do research and those working in the health sector may have had their focus redirected to front-line services. In addition, the need for some to work from home while managing family commitments, may have also resulted in a reduction in work outputs, including ethics submissions.

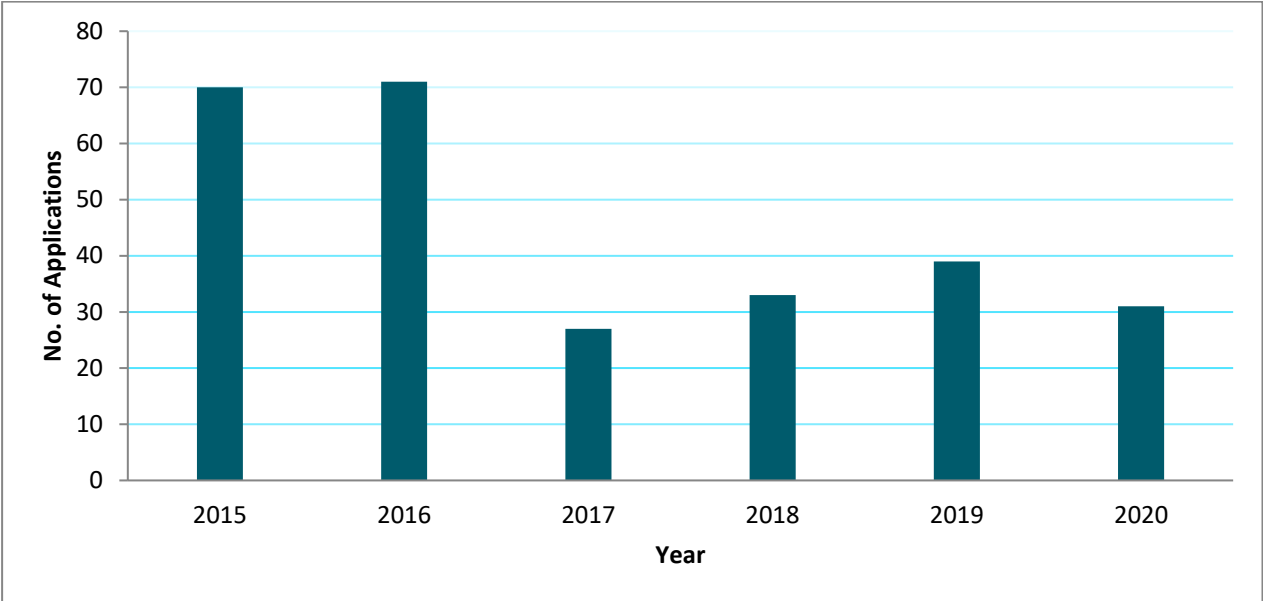
There was a noticeable decline in the number of new ethics applications in 2017 compared to the previous two years. Two potential contributing factors have been identified: 1) the introduction of RGS and 2) a reduction in funding allocated to research in 2017. Since then, there has been a gradual increase in the number of submissions, even during the COVID-19 pandemic (compared to 2017).

**Table 4: Number of requests received 2015 to 2020**

Year	2015	2016	2017	2018	2019	2020
New Applications	70	71	27	33	39	31
Annual reports	120	83	96	159	163	139
Amendment Requests	175	148	194	218	204	191
Final Reports	17	9	22	99	15	10

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

**Figure 1: Applications reviewed by DoH HREC 2015 to 2020**



## 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 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 in the Research Governance Service.

### Annual reports

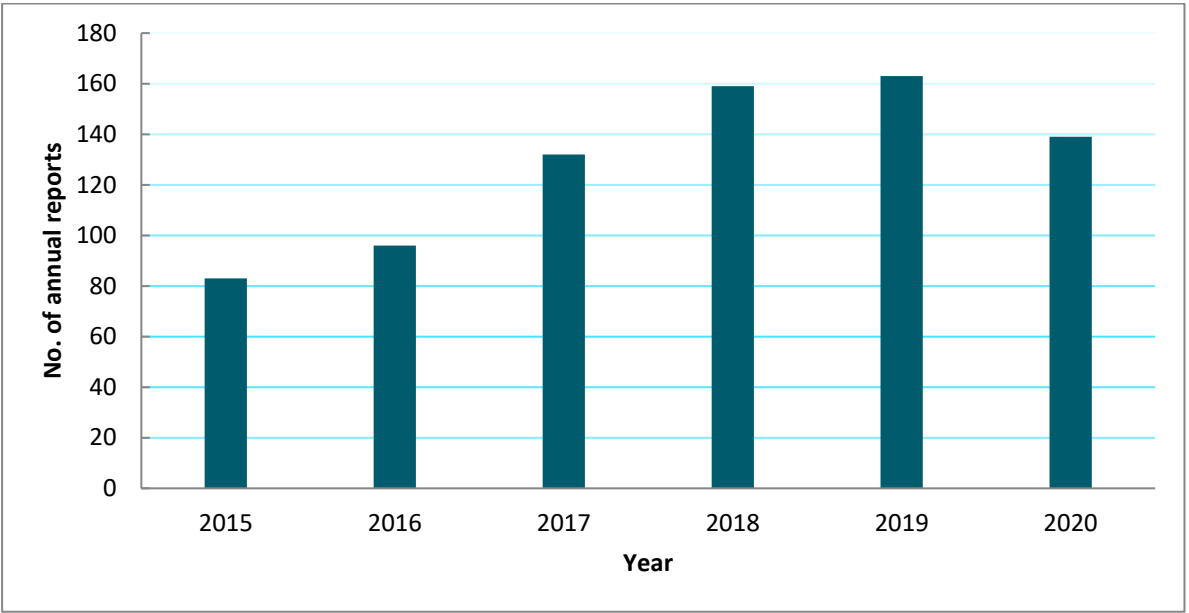
The standardised annual report requires researchers to provide the following information about the approved project:

- 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 139 annual reports were approved by the DoH HREC in 2020. In December 2019, the RGS implemented an automated tracking system to contact researchers when they were due to submit a report. Ongoing ethics approval is dependent on researchers submitting their reports in a timely manner. Figure 2 shows the total number of annual reports approved between 2015 and 2020.



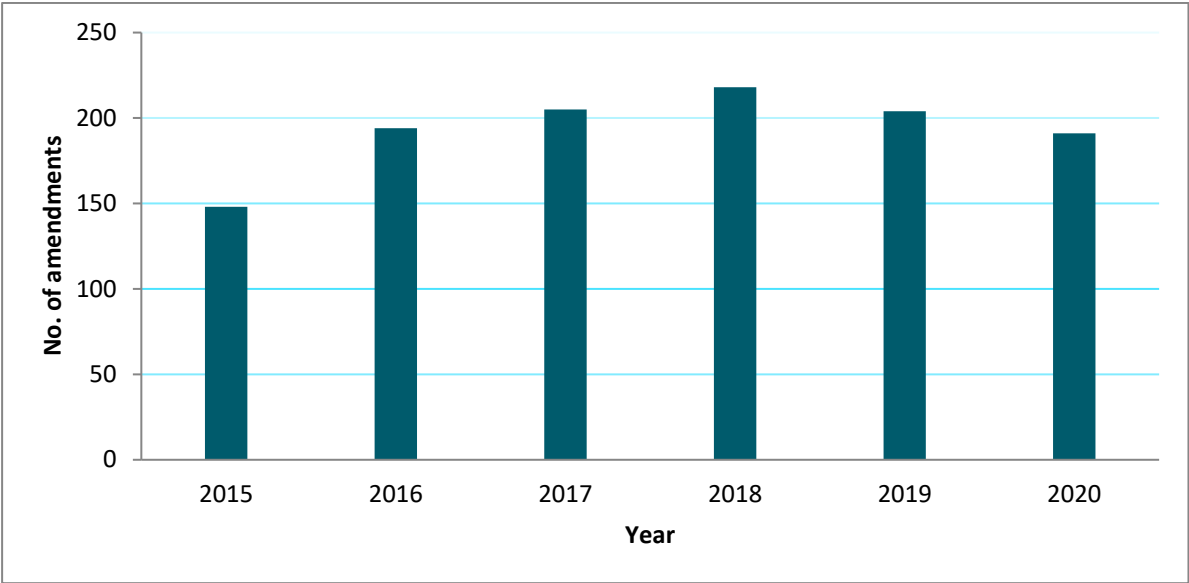
**Figure 2: Total number of annual reports approved by DoH HREC 2015 to 2020**



**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 191 amendment requests were approved by the DoH HREC in 2020. Figure 3 shows the total number of amendment requests approved between 2015 and 2020.

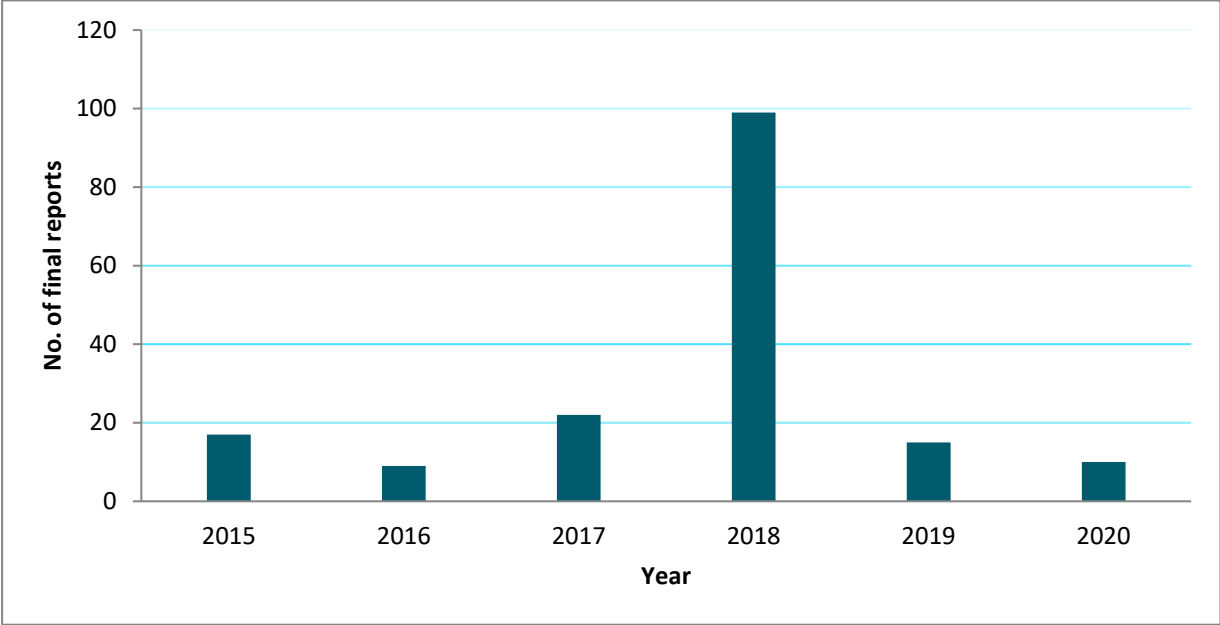
**Figure 3: Total number of amendments approved by DoH HREC 2015 to 2020**



### 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 10 final reports were approved in 2020. The average number of final reports approved over the last five years is 31. Figure 4 shows the total number of final reports approved between 2015 and 2020. The high number shown in 2018 was a result of actively pursuing researchers to submit their final reports after an audit had been carried out, which showed that many researchers had not fulfilled their reporting requirements. It is acknowledged that in 2019 and 2020 there was a significant reduction in the number of final reports submitted. In 2021, a process will be implemented where researchers are contacted if the expected completion date or ethics approval date of their project has lapsed to request that they submit a final report for their project, where this has not occurred.

**Figure 4: Total number of final reports approved by DoH HREC from 2015 to 2020**



### 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*. Additionally, the Ethics Executive Officer provides support and guidance for researchers applying for ethics approval and acts as a point of liaison between the DoH HREC and researchers.

## 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).

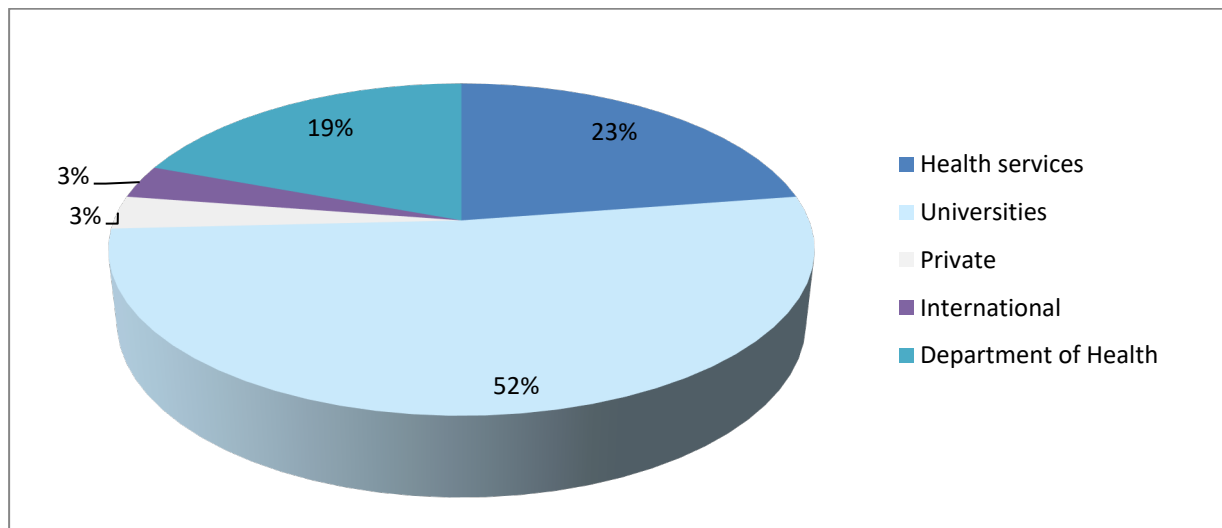
In 2020, there was one notification of concern raised with the Committee relating to unauthorised release of data. The Chair examined this complaint and was satisfied that no further investigation was required.

## 9. Users of the Department of Health's data for research

Applications for data for research from the Department's data collections and registers in 2020, came from Universities (52%), Health services (23%), private sector (3%), Department of Health (19%) and overseas (3%).

Figure 5 shows the breakdown by users of the Department's research data for 2020. As usual, the largest users of DoH data for research were the universities and health services.

**Figure 5: Breakdown by users of DoH data for research in 2020**



## 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 2020, the DoH HREC applied the section 95 guidelines to two applications (RGS0000004268 and RGS0000004055). The section 95A guidelines were applied to one application (RGS0000003741). Two of these applications were granted ethics approval. One application was withdrawn (RGS0000004055).

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

## 12. Conclusion

In 2020, 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 31 new projects.

The Committee works closely with data custodians, the Research Data Services team and the Research Ethics and Governance Services team to ensure that researchers comply with the National Statement on Ethical Conduct in Human Research. Together they ensure that the welfare, rights and dignity of individuals are taken into consideration and that the privacy and confidentiality of any personal information requested, is protected. It is necessary that all human research projects are well developed, ethical and have scientific merit. The Committee aims to continue being responsive and accessible 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 2020

#	PRN	Title
1	RGS0000003462	Using total population data to produce policy-relevant evidence to increase access to services for Aboriginal children with intellectual disability / autism spectrum disorder in Western Australia
2	RGS0000003376	Australian hepatitis B and hepatitis C duplicate notifications linkage project
3	RGS0000003496	Indigenous Child Removals Western Australia
4	RGS0000003307	Substance Use Disorder Aeromedical Retrievals in Western Australia
5	RGS0000003741	Anaphylaxis characteristics and epidemiology in Western Australia (ACE-WA) Study
6	RGS0000003508	Exploring choice of care for urgent but non-life-threatening conditions
7	RGS0000003700	Impact of initiatives aimed at increasing adolescent HPV vaccination coverage – an evaluation in Western Australia
8	RGS0000003834	Estimating the incidence and cost of communicable illness in WA travellers returning from Indonesia
9	RGS0000003846	Age of diagnosis of congenital anomalies in Western Australia
10	RGS0000003959	PathWest laboratory medicine diagnostic stewardship during COVID-19 epidemic
11	RGS0000003836	What is the impact of the National Bowel Cancer Screening Program on colorectal cancer outcomes for people over the age of 50 with severe mental illness?
12	RGS0000003631	Improving Dementia Statistics
13	RGS0000003200	Exploration of radiological pancreatic and renal density as a risk factor for subsequent cancer development
14	RGS0000003966	Assessing the risk of tuberculosis among all migrants to Australia
15	RGS0000001352	Is it safe to drive after common upper limb trauma? Identifying factors that increase the risk of motor vehicle accident after wrist fractures and upper limb burns.
16	RGS0000003507	Improving joint replacement outcomes in Australia.
17	RGS0000004055	Donovanosis in Australia assessment of elimination
18	RGS0000004036	Cancer and mortality among Queensland Coal Mine Workers
19	RGS0000004163	Minimally invasive approach to manage early childhood caries in Aboriginal pre-schoolers.
20	RGS0000003686	Services provided and outcomes for patients suspected of experiencing a heart attack or stroke and transported by the Royal Flying Doctor Services (RFDS) to hospitals across Western Australia.

21	RGS0000004065	Relative survival from cancer in kidney transplant recipients and people with end-stage kidney disease in Australia and New Zealand (the ReSKiTE study)
22	RGS0000003930	Improving physical health and quality of life and reducing cognitive decline and the rate of falls for people with mild cognitive impairment: a randomised controlled trial
23	RGS0000004268	National Suicide Prevention Trial Evaluation: Implementation and Effectiveness
24	RGS0000004249	The National Support for Child and Youth Mental Health Program Overarching Evaluation (CHYME): Integrated Data Analysis
25	RGS0000004284	Follow-up after curative treatment for colorectal cancer
26	RGS0000004371	Understanding and responding to the cost and health impact of short-term health staffing in remote and rural Aboriginal and Torres Strait Islander community controlled health services
27	RGS0000004419	Predicting the future post-stroke- contributing factors and age differences for readmission
28	RGS0000004252	Multimorbidity in the Busselton Healthy Ageing Study (BHAS)
29	RGS0000004435	The impact of the COVID-19 pandemic on emergency department presentations, hospitalisations, all-cause mortality and cancer notifications in Western Australia
30	RGS0000004462	Risk assessment of Legionella pneumophila in cooling towers in Western Australia
31	RGS0000004445	Nutrition Monitoring Survey Series

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