



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

Department of Health Human Research Ethics Committee

Annual Report 2022

Contents

1. Background	1
2. Data collection methods	1
3. Membership	2
4. Training	3
5. Meetings and executive support	4
6. Review of research projects	4
7. Annual reports, amendments and final reports	5
Annual reports	5
Amendments	6
Final reports	7
8. Administrative procedures	8
9. Concerns, complaints, and breaches	8
10. Application of Privacy Act 1988 guidelines	9
11. Public awareness	9
12. Conclusion	9
13. Supporting documents	10
Appendix A – New applications reviewed in 2022	11

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 (the 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 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 in Australia 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 Office of Medical Research and Innovation (OMRI). 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 2022 to 31 December 2022. It includes information on its members and their expertise, the number of applications submitted to the DoH HREC and their status, the number and status of complaints and breaches reported, and the number of projects reviewed under the guidelines for Sections 95 and 95A of the *Privacy Act 1988*.

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

2. Data collection methods

Prior to 2021, data for the DoH HREC annual report was manually collected from the Ethics Executive's Officer's administrative records. In 2021, a Power BI reporting solution was developed by the Department to enable the collection of RGS data for reporting purposes. Data for this report have been collected using the Power BI Solution. This change in data collection methods has resulted in some discrepancies between the data used to prepare this annual report compared with the data presented in annual reports prior to 2021. Where data discrepancies were identified during the preparation for this report, the most accurate figures have been presented.

3. Membership

Members are appointed to fulfill specific roles as per the National Statement and the DoH HREC [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 use of large health data collections who is employed by the WA health system.

During 2022, the sitting lay male person position remained vacant with the deputy lay male person fulfilling the responsibilities of this position throughout the year. Recruitment to fill the position was completed in February 2022 and approved by Cabinet in December 2022. At the end of 2022, Cabinet approved the following updates to the membership of the DoH HREC: one new member was approved to begin in January 2023, three Members had terms renewed, two Deputy Members were appointed to a Sitting position, and one Sitting Member was appointed to a Deputy position.

The gender representation within the Committee for 2022 was as follows:

- Sitting members (nine members): four men and five women
- Deputy members (ten members): five men and five women.

The Department applies a staggered approach to appointing members to fixed term positions to ensure the continuity of experience and knowledge within the DoH HREC. Sitting members may serve only one term and deputy members may serve two consecutive terms, unless a longer term is approved by the Cabinet. 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 in 2022 with deputy members provided in **Table 2**.

Table 1: Sitting members serving on the DoH HREC in 2022

Position	<i>Incumbent</i>
Chairperson	Dr Peter Bentley
WA health system representative	Ms Ali Radomiljac
Information security	Mr Bret Watson
Lay person	Ms Kathryn Kirk
Lay person	(Vacant, recruitment process completed December 2022)
Lawyer	Ms Suzanne Hillier
Pastoral care	Rev. Graham Mabury
Professional care	Ms Natalie Fleetwood
Researcher	Dr Alison Reid
Researcher	Dr Daniel McAullay

Table 2: Deputy members serving on the DoH HREC in 2022

Position	<i>Incumbent</i>
WA health system representative	Mrs Stephania Tomlin
Information security	Mr Wil Lim
Lay person	Ms Sonia McKeiver
Lay person	Mr John McMath
Lawyer	Dr Erika Techera
Pastoral care	Dr Garth Eichhorn
Professional care	Clinical A/Prof Ann McDonald
Researcher	Prof Satvinder Dhaliwal
Researcher	A/Prof Richard Brightwell
Researcher	A/Prof Georgia Halkett

4. Training

Newly appointed sitting and deputy members are provided with induction training 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 and an HREC meeting to observe the meeting processes prior to commencing their duties. All members receive training and continuous support from the Department on using the RGS and are offered professional development opportunities as they arise. In addition to the induction workshop, training offered in 2022 included a Linkage Learning Webinar: “Information Session from the Office of the National Data Commissioner on the DATA Scheme” provided by the Population

Health Research Network (PHRN), Human Research Ethics Committee annual workshop conducted by the University of Notre Dame, and a presentation on Cloud computing and the WA Health Cloud Policy presented by the Department’s Research Governance Office.

5. Meetings and executive support

The DoH HREC meets on the second Wednesday of every month from February to December. In 2022, 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
- at least one third of those present being from outside the Department.

A quorum was met for all the meetings in 2022. An Ethics Executive Officer employed by the Department provided administrative support to the DoH HREC.

6. Review of research projects

The number of new applications considered by the DoH HREC in 2022 and the status of these applications are provided 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 2022

Total applications received in 2022*	29
Under Review	1
Approved	26
Withdrawn	1
Exempted	1

*Note: One application was received for pre-review (i.e. when feedback is sought from the HREC before a formal submission is made) at the request of the data custodians. This application has not been included here as it did not require a decision from the HREC at the time of review.

The DoH HREC reviewed 29 new applications during the reporting period. As shown in **Table 3**, of these applications, 26 were approved in 2022, one was withdrawn, one was exempted from requiring ethical approval, and one was under review awaiting additional information from the researcher as of 31 December 2022.

Table 4 outlines the number of new applications, reports, and amendment submissions received between January 2018 to December 2022. There was an increase in the number of new applications received from 2018 to 2019. In 2020, the number of new applications,

annual reports and amendment submissions decreased, which may be attributed to reduced research activity during the first year of the COVID-19 pandemic as health sector priorities were reassessed. In 2021, the number of new applications, annual reports and amendment submissions increased to similar levels as 2019, indicating the gradual recovery of research activities.

In 2022, the number of new applications received for review returned to a similar level as seen in 2020. This may be due to staff shortages experienced at the time which led to reduced capacity within the Department to conduct feasibility assessments and substantially increased the time required to prepare a submission for HREC review.

Table 4: Number of submissions reviewed 2018 to 2022

	2018	2019	2020	2021	2022
New Applications	33	39	31	40	29
Annual reports	159	153	139	143	183
Amendment Requests	218	199	181	196	188
Final Reports	99	8	8	48	31

7. Annual reports, amendments and final reports

The DoH HREC is bound by Chapter 5.5 of the National Statement to monitor the progress of all approved projects until completion.

In accordance with Chapter 5.5.3 of the National Statement, researchers must report any serious unexpected, adverse or unforeseen events that might affect the continued ethical acceptability of the project. Further, 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 integrated in the RGS system.

Annual reports

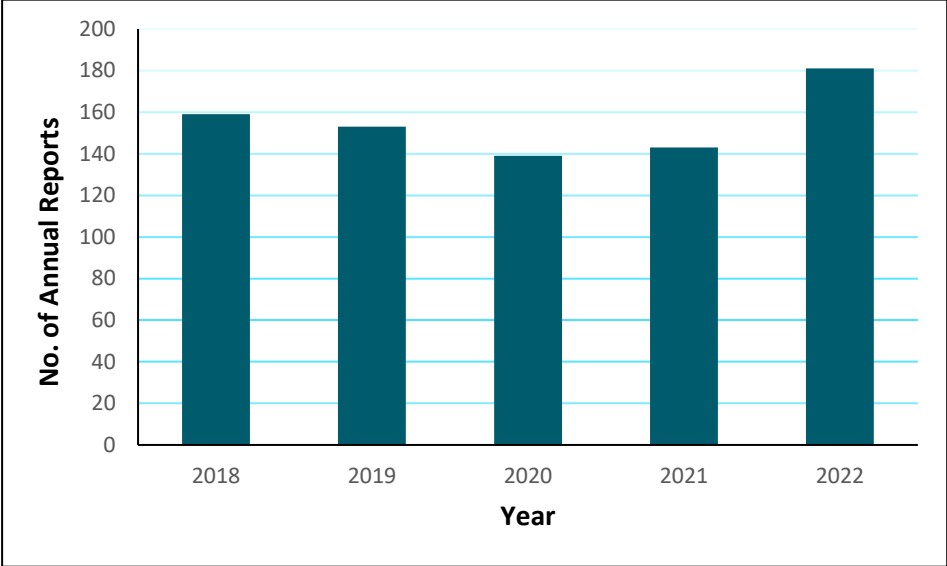
The annual report requires researchers to provide the following information about the approved project:

- 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.

Ongoing ethics approval is dependent on researchers submitting their annual progress reports in a timely manner. **Figure 1** shows the total number of annual reports approved between 2018 and 2022.

In 2022, an increase was seen in the number of annual reports reviewed and approved compared to previous years. A total of 183 annual reports were reviewed by the DoH HREC in 2022, of which 181 were approved (2 reports still under review after additional information requested), whereas 139 to 159 annual reports were reviewed and approved in previous years. This trend may be due to active efforts from the Ethics office to follow-up on overdue progress reports during 2022.

Figure 1: Total number of annual reports approved by DoH HREC 2018 to 2022

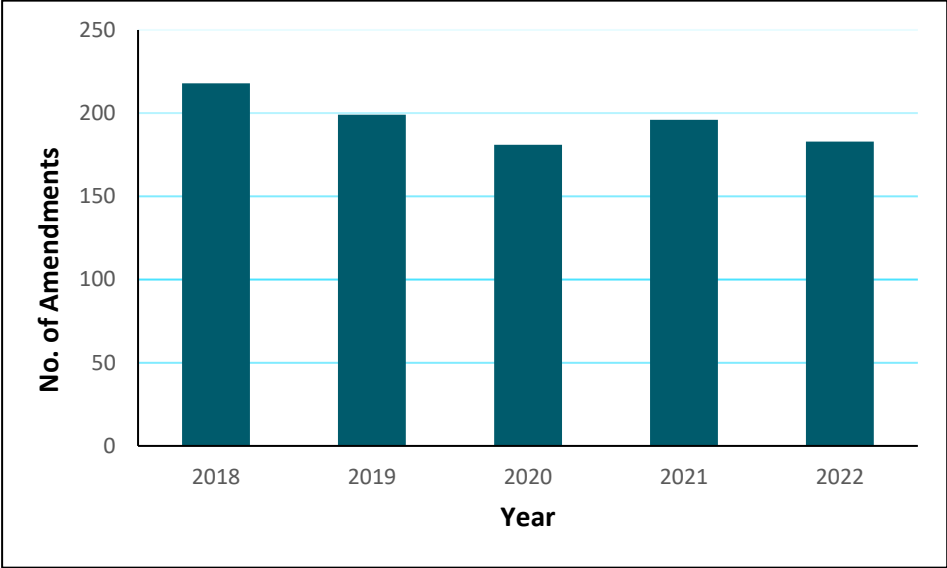


Amendments

Researchers are required to complete an amendment form when seeking to make changes to the approved research protocol. This includes changes to methodology, data required, personnel in the research team, approved data storage arrangements, and requests to extend the duration of approval for the project. Extensions to ethics approval are often requested from the DoH HREC to facilitate further research publications or due to delays obtaining data.

Figure 2 shows the total number of amendment requests approved between 2018 and 2022. A total of 183 amendment requests were approved by the DoH HREC in 2022. This was a slight decrease in number compared to most of the previous years.

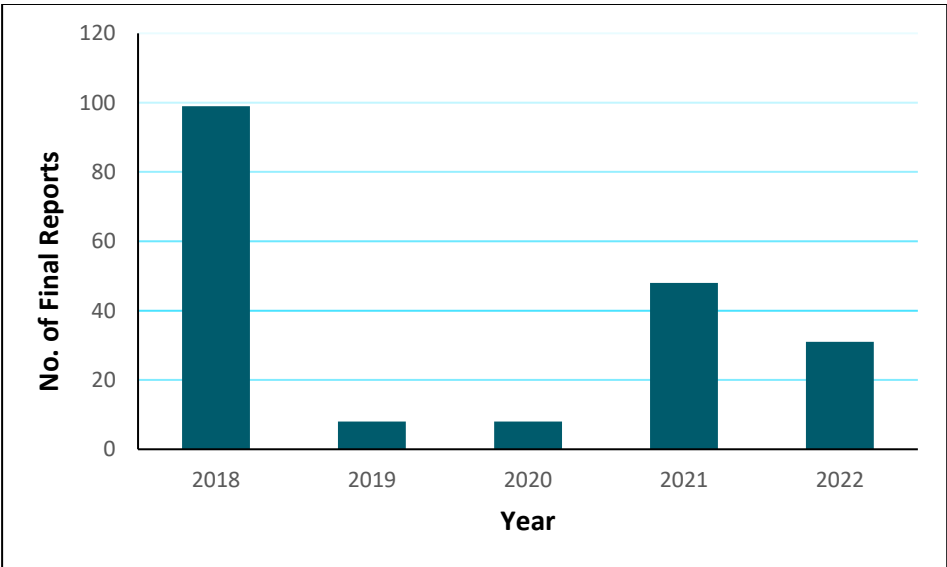
Figure 2: Total number of amendments approved by DoH HREC 2018 to 2022



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 31 final reports were approved in 2022. The average number of final reports approved over the last five years is 38.8. **Figure 3** shows the total number of final reports approved between 2018 and 2022. The high number shown in 2018 and in 2021 were the result of the HREC secretariat actively pursuing researchers to submit their final reports and a review of active projects approved prior to the advent of the RGS which identified several projects that had not completed their reporting obligations. The DoH HREC secretariat has implemented new procedures to embed active follow up of final reports at regular intervals to ensure all reporting is submitted by researchers in a timely manner. A mailout to follow-up on final reports was conducted in December for 2022, and it is anticipated that another increase in the number of final reports reviewed by the DoH HREC will be seen in 2023.

Figure 3: Total number of final reports approved by DoH HREC from 2018 to 2022



8. 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.

9. Concerns, complaints, and breaches

The DoH HREC SOP outlines the process for receiving, handling and responding to:

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

In 2021, the HREC undertook an investigation into one project on the basis of complaints about their participant recruitment method. The investigation concluded in March 2022 with all issues resolved and the HREC discussed ways to mitigate and prevent similar concerns in the future. In 2022, no new complaints about a project were received by the DoH HREC.

The Committee reviewed three projects in 2022 where a breach to the conditions of approval had taken place.

- One project involved the publication of research findings without prior approval from the data custodian. Subsequent review of the publication by a Senior Metadata Officer and the HREC found that risk of re-identification was low, so no further action was taken. The DoH HREC provides reminders in all approval letters to researchers that draft outputs should be submitted to the Research Data Services Team for review prior to publication.
- One project was non-compliant with their reporting requirements as no progress reports or other submissions were made to the HREC since 2017. The HREC determined that the project was inactive after receiving no response from the co-ordinating principal investigator following multiple attempts at contact and it was formally closed.
- One project's ethics approval had expired for more than 12 months before the researchers submitted an amendment requesting an extension to approval. In this case, the project was found to pose no confidentiality or data security issues and had not produced any outputs during the time approval had been lapsed, so reinstatement with an extension to ethics approval was granted.

10. Application of Privacy Act 1988 guidelines

Under Section 95 and Section 95A of the *Privacy Act 1988*, the DoH HREC must apply a set of guidelines to the review of research projects involving 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 Section 95 and/or Section 95a guidelines, the DoH HREC must be satisfied that it is necessary for the research to use identifiable or potentially identifiable data and, that it is impracticable to obtain consent, or that it is reasonable for the research to proceed without the consent of the individuals to whom the information relates.

In reaching a decision, the DoH HREC must also consider whether the research is in the best interests of the public and whether the likely benefits outweigh public interest in the protection of privacy.

In 2022, the DoH HREC applied the Section 95 guidelines to one application (RGS5522) and the Section 95A guidelines were applied to two applications (RGS4357 and RGS4910). All three of these applications 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 research which aims to improve the health and healthcare of the community. Accordingly, brief summaries of all research projects approved by the Committee are published quarterly on the DoH HREC website. 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

It is necessary that all human research projects are well developed, ethical and have scientific merit. In 2022, the DoH HREC discharged its responsibilities to oversee the use and disclosure of personal health information held in the Department's 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 DoH HREC worked 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. Together these groups 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. The DoH HREC aims to continue being responsive and accessible to researchers.

This report has been prepared by the Office of Medical Research and Innovation. For queries, please email OMRI@health.wa.gov.au.

13. Supporting documents

[Department of Health \(2021\). 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 \(2014\). 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 2022

#	PRN	Project Title
1	RGS 5221	Implementing a Statewide Population-Based Cancer Staging Approach into the WA Cancer Registry
2	RGS 5223	Long-term outcomes of severe trauma patients after using retrievable vena cava filters to prevent pulmonary embolism (PE)
3	RGS 5276	Adverse event reports of anaphylaxis after Comirnaty and Vaxzevria COVID-19 vaccinations, Western Australia, 22 February to 30 June 2021
4	RGS 4357	Data Linkage of Patients Undergoing Laparoscopic Sleeve Gastrectomy in Western Australia
5	RGS 5131	End of pilot evaluation of the WA Public Health Officer Training Program (WAPHOTP)
6	RGS 5364	Phase 2: Diagnosing Innovation: A Human-Centred Design Approach to Cultivate Innovation in the Western Australian Health System
7	RGS 5389	The Ovarian Cancer Prognosis and Lifestyle (OPAL) Study [Data Linkage]
8	RGS 4586	Investigation of cancer aggregation patterns in Western Australia
9	RGS 4621	Does pneumococcal vaccination protect against cardiovascular disease? A randomised placebo-controlled double blind trial.
10	RGS 5317	Food Insecurity and Food Stress in Western Australia
11	RGS 5335	Determining the speed of registration of COVID_19 clinical trials compared to non-COVID_19 clinical trials
12	RGS 5378	Health Service Utilisation and Health Outcomes among Refugees in Western Australia: A Retrospective Cross-Sectional Analysis (2007 to 2021)
13	RGS 5409	Using data linkage to integrate primary and secondary data across the continuum of care to support population health planning and clinical management of chronic disease in Western Australia
14	RGS 5471	Exploring Western Australian community and healthcare professional's perceptions regarding the links between climate change and health
15	RGS 5494	The Busselton Family Heart Study: Investigations into the relationship between lipid metabolism and health outcomes
16	RGS 5522	Vaccine effectiveness of COVID-19 vaccines in Western Australia
17	RGS 4983	Ovarian cancer: investigating variation in care and survival, aetiology and risk factors to improve outcomes in Australia via national data linkage. The OVARIAN Study.
18	RGS 5216	Birthing on Country Connected to country Birthing on Country On Country we Grow
19	RGS 5306	Review of prescribing practices, authorisations for and harms due to Schedule 8 Opioids in Western Australia
20	RGS 5477	Nutrition Monitoring Survey Series (Nutrition Monitoring Survey 2022)
21	RGS 5490	Improving diet quality of patients living with obesity: A randomised controlled trial to build effective dietetic service delivery using technology in a primary health care setting
22	RGS 5203	ICBP-COVID19: Assessing the COVID-19 impact on cancer in the International Cancer Benchmarking Partnership
23	RGS 5516	Assessing the risk of Long COVID in Western Australia
24	RGS 5673	Quantifying health service utilisation, mortality and temporal trends in people with mental illness or suicidal behaviour in Western Australia

25	RGS 5690	Mental health disorders among individuals with craniofacial anomalies in Western Australia – A population-based retrospective data linkage study
26	RGS 5123	Closing the Gap for Aboriginal Head and Neck Cancer Outcomes
27	RGS 3517	Evaluation of the Research Translation Projects Program
28	RGS 4910	Evaluation of the Early Years Initiative: Child Outcomes Sub-study
29	RGS 5809	Enabling greater stability, usability, and migration readiness of the Research Governance Service (RGS)

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