



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

Department of Health Human Research Ethics Committee

Annual Report 2021

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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 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 Research and Innovation Office (for queries, please email 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 2021 to 31 December 2021. 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 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 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. 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 allow 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 previous annual reports. 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 uses of large health data collections who is employed by the WA health system.

During 2021, the Sitting Member for Information Security resigned prior to the end of their term with the Deputy Member stepping in for the remainder of the year. At the end of 2021, six members' terms expired, three Members had terms renewed, six new members were recruited to begin in January 2022, and two Deputy Members were appointed to a Sitting position. As of January 2022, the sitting lay male person position is vacant, while recruitment is underway to fill the position. The deputy lay male person is fulfilling the responsibilities of this position in the interim.

The gender representation within the Committee for 2021 was as follows:

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

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 only one term and deputy members may serve two consecutive terms, unless 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 2021 with deputy members provided in Table 2.

Table 1: Sitting members serving on the DoH HREC in 2021

| Position | <i>Incumbent</i> |
|--|----------------------------------|
| Chairperson | Dr Peter Bentley |
| WA health system representative | Ms Ali Radomiljac |
| Information security | Mr Shane Gallagher |
| Lay person | Ms Kathryn Kirk |
| Lay person | (Vacant, recruitment in process) |
| Lawyer | Ms Suzanne Hillier |
| Pastoral care | Rev. Graham Mabury |
| Professional care | Ms Natalie Fleetwood |
| Researcher | Dr Alison Reid |
| Researcher | Dr Angela Ives |

Table 2: Deputy members serving on the DoH HREC in 2021

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

4. 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 receive training and continuous support from the DoH on using the RGS and are offered professional development opportunities as they arise. In addition to the induction workshop, training offered in 2021 included “Ethics Essentials” training provided by PRAXIS Australia and Privacy Preserving Record Linkage training provided by Curtin University.

5. Meetings and executive support

The DoH HREC meets on the second Wednesday of every month from February to December. In 2021, 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 2021.

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 2021 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 2021

| Total applications received in 2021 | 40 |
|-------------------------------------|----|
| Under Review | 7 |
| Approved | 29 |
| Not Valid | 4 |

The DoH HREC reviewed 40 new applications during the reporting period. As shown in Table 3, of these applications, 29 were approved in 2021, four were deemed not valid¹ and seven were under review by 31 December 2021, one of these having been deemed valid to progress to HREC review and the other six awaiting additional information from the researchers.

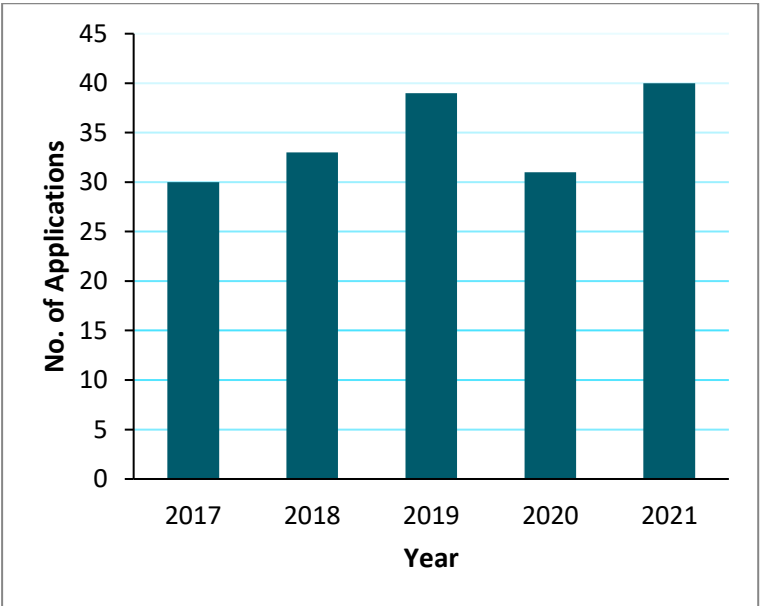
Table 4 outlines the number of reports, applications and amendment submissions received from 2017 to 2021. There was an increase in the number of new applications, annual reports and amendment submissions from 2017 to 2019. In 2020, the number of new applications, annual reports and amendment submissions decreased. Corresponding with the first year of the COVID-19 pandemic, this decrease may be attributed to reductions in research staff within the university sector and a re-direction of health sector priorities to front-line services, resulting in a reduction in research activities, including ethics submissions. In 2021, new applications, annual reports and amendment submissions increased to a similar number as 2019, indicating the gradual recovery of research activities.

Table 4: Number of submissions received 2017 to 2021

| Year | 2017 | 2018 | 2019 | 2020 | 2021 |
|--------------------|------|------|------|------|------|
| New Applications | 30 | 33 | 39 | 31 | 40 |
| Annual reports | 96 | 159 | 153 | 139 | 143 |
| Amendment Requests | 194 | 218 | 199 | 181 | 196 |
| Final Reports | 22 | 99 | 8 | 8 | 48 |

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

Figure 1: New applications reviewed by DoH HREC 2017 to 2021



¹ “Not valid” applications included three applications that were submitted to the DoH HREC in error by selecting the incorrect HREC on RGS, and one application that was withdrawn prior to DoH HREC review.

7. Annual reports, amendments and final reports

The DoH HREC is bound by 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 RGS.

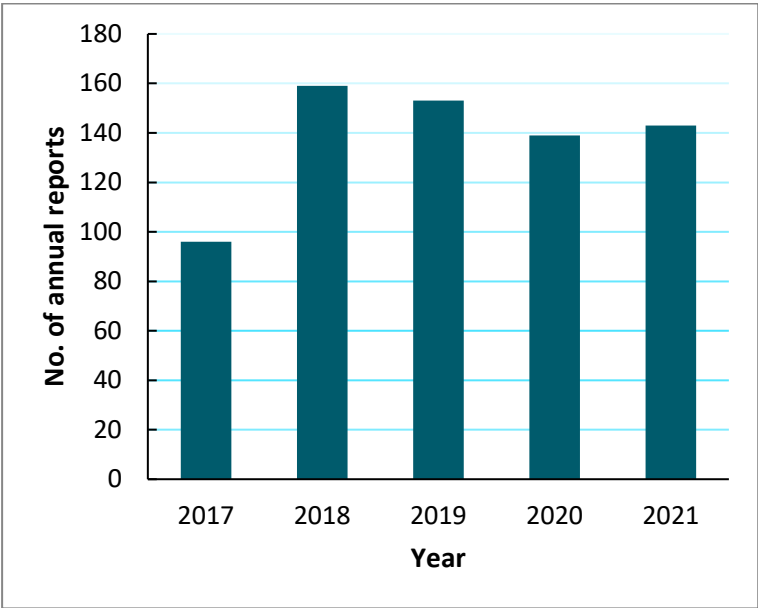
Annual reports

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 143 annual reports were approved by the DoH HREC in 2021. 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 2017 and 2021.

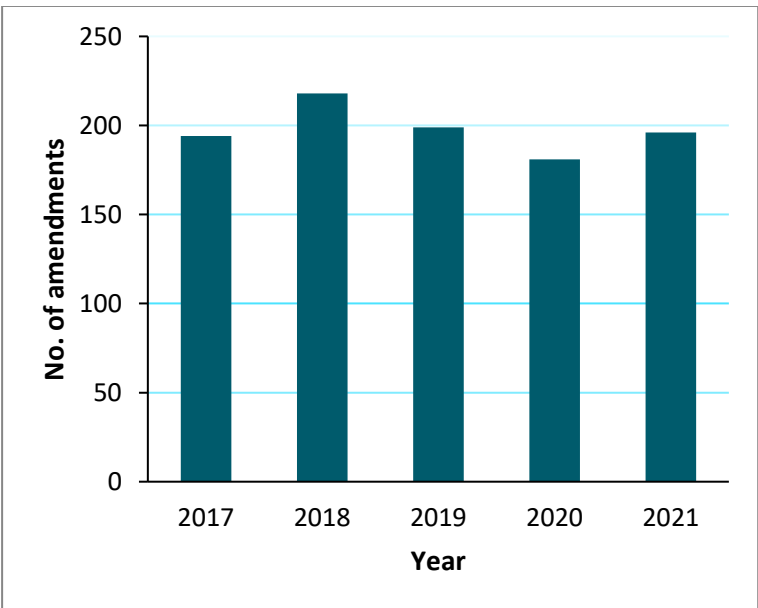
Figure 2: Total number of annual reports approved by DoH HREC 2017 to 2021



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 196 amendment requests were approved by the DoH HREC in 2021. Figure 3 shows the total number of amendment requests approved between 2017 and 2021.

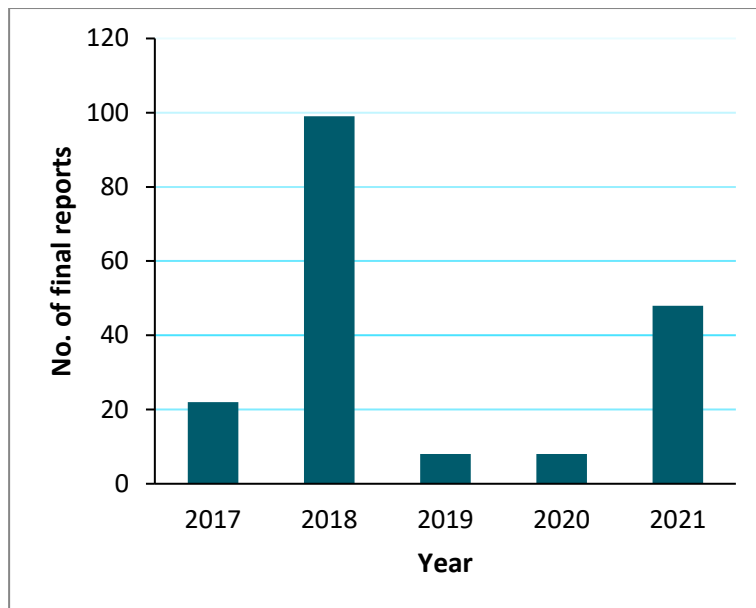
Figure 3: Total number of amendments approved by DoH HREC 2017 to 2021



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 2021. 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 2017 and 2021. The high number shown in 2018 and in 2021 were the result of the HREC secretariat actively pursuing researchers to submit their final reports. 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.

Figure 4: Total number of final reports approved by DoH HREC from 2017 to 2021



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. 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)
- 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 2021, the Committee reviewed four projects whose ethics approval expired more than 12 months before submitting an amendment requesting an extension to HREC for approval. The HREC considered the various reasons these projects expired and decided that each project should be reviewed on a case by case basis. The Committee agreed that an investigation was needed to identify the implications of a breach to ethics approval, and if this would also be considered a data breach due to data being accessed without a current ethics approval. As of February 2022, discussions are in progress with the relevant data custodians to determine the extent of any data breach.

In 2021, the HREC commenced investigations into several queries and complaints that had been received by the DoH and researchers in relation to one research project. In December 2021, the Committee requested further information and clarification from the project research team and the DoH. While the queries and complaints have been resolved, the HREC's investigation into the research project is ongoing. The DoH Research and Innovation office is also managing the complaints received by the DoH according to the [WA Health Complaints Management Policy](#).

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 2021, the DoH HREC applied the section 95 guidelines to two applications (RGS4268 and RGS4055). The section 95A guidelines were applied to one application (RGS3741). Two of these applications were granted ethics approval. One application was withdrawn (RGS4055).

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, 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

In 2021, 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 40 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 \(2021\). 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 2021

| # | PRN | Project Title |
|----|----------|--|
| 1 | RGS 4846 | AURORA – AUstralian Registry and biObank of thoRACic cancers |
| 2 | RGS 4844 | Australian Longitudinal Study on Women's Health Data Linkage Project |
| 3 | RGS 5164 | AusVaxSafety national enhanced adverse events following immunisation (AEFI) and adverse events of special interest (AESI) surveillance and follow-up |
| 4 | RGS 3183 | Cancer Patient Experience Survey |
| 5 | RGS 4770 | Cancer Risk aftEr medicAlly assisTed rEproduction |
| 6 | RGS 4675 | Characterising the epidemiology of RSV and other respiratory infections through record linkage: clinical burden, outcomes, risk factors and impacts of interventions |
| 7 | RGS 4589 | Conceptualising Artificial Intelligence Readiness (AIR) for Businesses |
| 8 | RGS 4328 | Congenital Heart Alliance of Australia and New Zealand (CHAANZ) Congenital Heart Disease Registry |
| 9 | RGS 4357 | Data linkage of patients undergoing Laparoscopic Sleeve Gastrectomy in Western Australia |
| 10 | RGS 4623 | Diagnosing Innovation: A Human-Centred Design Approach to Cultivate Innovation in the Western Australian Health System |
| 11 | RGS4813 | Digital health readiness of graduate allied health staff in country Western Australia |
| 12 | RGS 4505 | Do major spinal and hip surgeries improve the lives of children with severe disability and their families? |
| 13 | RGS 4709 | Elderly Trauma Outcome Predictor (ETOP) Study |
| 14 | RGS 4810 | EpiNet Case Control Study of SUDEP |
| 15 | RGS 3451 | Establishment of a Western Australian Congenital Heart Disease database to evaluate trends in the incidence of congenital heart disease in Western Australia |
| 16 | RGS 5134 | Evaluating the impact of immunisation requirements for enrolment (No Jab No Play) |
| 17 | RGS 4579 | Evaluation of Four New Urgent Care Centres – A Federal Initiative to Expand Urgent Medical Care Options |
| 18 | RGS 4359 | First 600 COVID-19 CASES in Western Australia: Public Health Response Effectiveness of Contact Tracing & Restrictions in WA |
| 19 | RGS 5054 | Geospatial assessment of the effect of climate change on health in Aboriginal people in the Kimberley, WA – past, present and future |
| 20 | RGS 4939 | Health Information-flow Quality Determinacy |
| 21 | RGS 3202 | Health service utilisation and long-term outcomes from Kawasaki disease, using the Western Australian Linked Data |

| | | |
|----|----------|--|
| 22 | RGS 4564 | Health service utilisation and preventable mortality in justice-involved young people: A national, retrospective data linkage study |
| 23 | RGS 5159 | Implementing a statewide population-based cancer staging approach into the WA Cancer Registry: A qualitative process evaluation |
| 24 | RGS 4150 | Incidence and costs of injury in Western Australia: 2020 |
| 25 | RGS 4586 | Investigation of cancer trends and aggregation patterns in Western Australia |
| 26 | RGS 4161 | Longitudinal study of prognostic biomarkers for melanoma |
| 27 | RGS 5223 | Long-term outcomes of severe trauma patients after using retrievable vena cava filters to prevent pulmonary embolism (PE) |
| 28 | RGS 4252 | Multimorbidity in Busselton Baby Boomers |
| 29 | RGS 5148 | Obstetric, sociodemographic, and environmental risks of adverse perinatal and early childhood outcomes in Australia |
| 30 | RGS 5186 | Perceptions of the scope of practice of the enrolled nurse and advanced skill enrolled nurse |
| 31 | RGS 4297 | Prevalence, prognosis and management of autoimmune encephalitis in Australia: a national data-linkage approach. |
| 32 | RGS 3764 | Privacy Preserving Record Linkage for Western Australian Birth Defects and Australian Pharmaceutical Benefits Scheme Claims Data |
| 33 | RGS 4462 | Risk assessment of Legionella pneumophila in cooling towers in Western Australia |
| 34 | RGS 148 | Single Troponin Accelerated Triage of Chest Pain Study |
| 35 | RGS 4469 | STaR-Link: National Collection of Cancer Data on Stage, Treatment and Recurrence (STaR) – Phase 2 data linkage |
| 36 | RGS 4711 | The effect of maternal age and ethnicity on pregnancy complications, length of labour, and mode of birth |
| 37 | RGS 4435 | The impact of the COVID-19 pandemic on emergency department presentations, hospitalisations, all-cause mortality and cancer notifications in Western Australia |
| 38 | RGS 3752 | Transitioning from out-of-home care: a longitudinal population-based study |
| 39 | RGS 1183 | Understanding the incidence, prevalence and rates of progression of chronic kidney disease in Western Australia |
| 40 | RGS 4782 | Using data analytics and economic modelling to support population health planning and clinical management of mental health patients |
| 41 | RGS 4086 | West Australian heart Valve Study (WAVES) |
| 42 | RGS 4890 | Whole genome sequencing in high risk breast cancer patients |

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