Australian Government

National Health and Medical Research Council

National Health and Medical Research Council

Report on the Activity of Human Research Ethics Committees and Certified Institutions for the period:
1 January 2015 to 31 December 2015

September 2016

Melbourne Canberra Sydney
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ORIMA RESEARCH

Background

ORIMA Research was commissioned to design and conduct the 2015 annual reporting survey on behalf of the NHMRC. The information collected provides an annual overview about the activity of HRECs during the reporting period, and is used to assess the extent to which registered HRECs and the HRECs of certified institutions meet the requirements of the *National Statement on Ethical Conduct in Human Research, 2007* (National Statement). This project was conducted in accordance with the international quality standard ISO 20252.

Contents

I. Report on the Activity of NHMRC-Registered Human Research Ethics Committees for the Period 1 January 2015 – 31 December 2015

Human Research Ethics Committees (HRECs) play a central role in the ethical oversight of research involving humans. HRECs review research proposals involving human participants to ensure that they are ethically acceptable and have been developed in accordance with relevant standards and guidelines.

The National Health and Medical Research Council (NHMRC) requests annual reports from HRECs registered with NHMRC concerning the HRECs' activities over the reporting period (a calendar year). The information that is collected in these annual reports relates to the application of specific requirements of the *National Statement on Ethical Conduct in Human Research 2007* (National Statement) including:

- the composition of the HREC;
- processes for the consideration of research proposals;
- reporting arrangements with the host institution; and
- monitoring of approved research and mechanisms for handling complaints.

The purpose of collecting the information is to gather an annual overview about the Australian HREC system. This information assists NHMRC, including the Australian Health Ethics Committee (AHEC).

The following overview of HRECs is drawn from the information provided at registration and during the reporting period from 1 January 2015 to 31 December 2015.

Any queries regarding this report can be directed to hrec.reports@nhmrc.gov.au.

A. Number of HRECs

During 2015, 215 HRECs were registered with NHMRC and 212 HRECs submitted an annual report on their activities to NHMRC (see **Table 1**). There were 217 registered HRECs in the previous (2014) reporting period, of which 216 submitted an annual report.

Table 1: Reportable HRECs by Jurisdiction

Jurisdiction	Number of HRECs
Victoria	60
New South Wales	56
Queensland	40
Western Australia	20
South Australia	18
Australian Capital Territory	13
Northern Territory	3
Tasmania	2
Total	**212**

B. HREC membership

The minimum membership of an HREC is eight members, comprising one from each core membership category described in paragraph 5.1.30 of the National Statement. This includes two individuals assigned to each of the following categories: 'persons with current research experience that is relevant to research proposals to be considered'; and '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'.

Thirteen HRECs (6%) reported that they did not meet the minimum membership requirements during the reporting period. Issues identified were:

- No layman (n=5);
- No laywoman (n=3);
- Only one member with knowledge of, and current experience in, the areas of research regularly considered by the HREC (n=4);
- No member who performs a pastoral care role in a community (n=4); and
- A total of less than eight members (n=2).

Around one-in-five HRECs (21%; n=42) indicated that during the reporting period, the HREC made decisions on research proposals when there was a vacancy[1] in one or more of the minimum membership categories. This is contrary to the requirements of the National Statement.

Additional membership

In addition to representation from the minimum membership categories, other members appointed to HRECs during the 2015 reporting period included:

- Aboriginal and Torres Strait Islander representatives;
- Academic staff;
- Clinical adviser;
- Community member;
- Consumer representative and consultant;
- Departmental, faculty and other institutional representatives;
- Deputy Chair;
- Donor (bone marrow);
- Executive staff (Chief Executive Officer, Board member, Deputy Vice Chancellor, Director);
- Ex-officio members;
- Graduates (medical and health);
- Health service representatives;
- Medical professionals (e.g. general and medical practitioners);
- Members experienced in reflecting on and analysing ethical decision-making (National Statement 5.1.32);
- Person with a disability;
- Strategic research adviser;
- Student representatives or trainees;
- Sub-committee Chairs and members;
- Support staff (executive, research or governance officers as well as other research, medical or administrative staff); and
- Members with expertise in:
    - Aboriginal and Torres Strait Islander research;
    - Bio-statistics;
    - Clinical psychology;
    - Clinical trials;
    - Data linkage;
    - Diagnostic services;

[1] A vacancy referred to not having a person appointed to the relevant minimum membership category. It did not refer to an appointed member being absent from an HREC meeting.

- Ethics (medical, research and bio-);
- Forensic pathology;
- Information technology;
- Medical administration;
- Moral deliberation and moral psychology;
- Nursing;
- Patient safety;
- Pharmacy;
- Psychiatry;
- Public health;
- Reproductive health;
- Sociology;
- Statistics;
- Theology;
- Tissue banks; and
- Tissue typing.

During the reporting period, just over one-quarter of HRECs (26%; n=56) indicated that an Aboriginal and/or Torres Strait Islander person was included as a member of the committee.

Institutional and non-institutional members

The National Statement 5.1.29(b) states that at least one-third of HREC members should be from outside the institution for which the HREC is reviewing research. Just under one-in-ten HRECs (8%; n=18) reported less than the desired one-third of membership from outside the institution.

Gender balance

As per paragraph 5.1.29(a) of the National Statement, as far as possible, there should be equal numbers of men and women on the HREC. While it is recognised that this may be difficult to attain, it is considered that decision making may be affected in situations where there is a significant imbalance in either direction. For this reason, NHMRC specifically considered instances in which there was at least an 80:20 gender imbalance as significant and requiring attention. Just three HRECs (1%) reported a male: female or female: male ratio of greater than or equal to 80:20.

C. Administration and general operation of the HREC

Requirements of the National Statement

Out of the 212 HRECs, 202 (95%) reported that the HREC had considered new[2] research proposals during the 2015 reporting period. All but 3 HRECs (99%; n=209) indicated that their Terms of Reference met the requirements of National Statement paragraph 5.1.27. The remaining HRECs reported that their Terms of Reference were either in draft form awaiting institutional approval, or will be revised in 2016 to comply with the requirements.

Almost all HRECs (99%; n=209) also reported that their Standard Operating Procedures met the requirements of National Statement paragraph 5.1.37. The remaining HRECs (1%; n=3) reported that:

- No meetings were held during the reporting period as no new research proposals were submitted[3]; or
- Their Standard Operating Procedures will be, or are in the process of being, revised to comply with the requirements.

All 212 HRECs indicated that records of all research proposals received and reviewed during the reporting period were kept in accordance with the requirements of National Statement paragraphs 5.2.23-5.2.27.

Reporting mechanisms

During the reporting period, all 212 HRECs indicated that there was an established reporting mechanism between the HREC and the institution(s) to which it is accountable. The most common reporting mechanism used was the provision of regular reports by the HREC to the management level[4] of the organisation(s) (75%; n=151), followed by the provision of minutes of HREC meetings to the management level[5] of the organisation(s) (55%; n=112).

Around one-in-five HRECs (19%; n=38) cited other reporting mechanisms, including:

- Regular meetings or briefings with management to provide updates and discuss any areas of concern;

[2] 'New research proposals' did not include proposals that have already been considered by the HREC during a previous reporting period. They also do not include amendments or annual reports related to approved projects.

[3] Even though no meetings were held and no research proposals were submitted, paragraph 5.1.37 of the National Statement states that an institution that establishes an HREC should ensure that the HREC establishes, implements and documents working procedures to promote good ethical review.

[4] For example, to the CEO or Board, at least annually.

[5] For example, to the CEO or Board.

- Management/executive representative attends at least one HREC meeting per annum;
- Management/executive representative is an ex-officio member;
- Executive committee established to discuss ethics and governance issues;
- Reports provided to central oversight ethics committee;
- HREC Chair provides updates and reports to management level in meetings and as required;
- Random compliance audits of HREC approved projects are conducted;
- Summary of HREC activities is submitted annually to an institutional advisory body;
- Executives are provided the file for review prior to providing institutional approval;
- Agendas, submissions, approvals and minutes are stored in a secure clearinghouse for information and through a smartsheet database directly accessible by management level; and
- Regular reports are provided to an Academic Board.

Use of the National Ethics Application Form (NEAF)

Just over four-in-five HRECs (82%; n=165) reported that they accept the use of the NEAF for some or all submissions. Of these HRECs:

- 47 HRECs (28%) require the use of the NEAF for all submissions;
- 50 HRECs (30%) require the use of the NEAF for some submissions; and
- 68 HRECs (41%) do not require the use of the NEAF for submissions.

D. HREC meetings

Among the 202 HRECs that considered new research proposals during the reporting period, 37% (n=75) reported that at least the minimum membership (as per paragraph 5.1.30 of the National Statement) was present at all meetings where a decision was made on a research proposal.

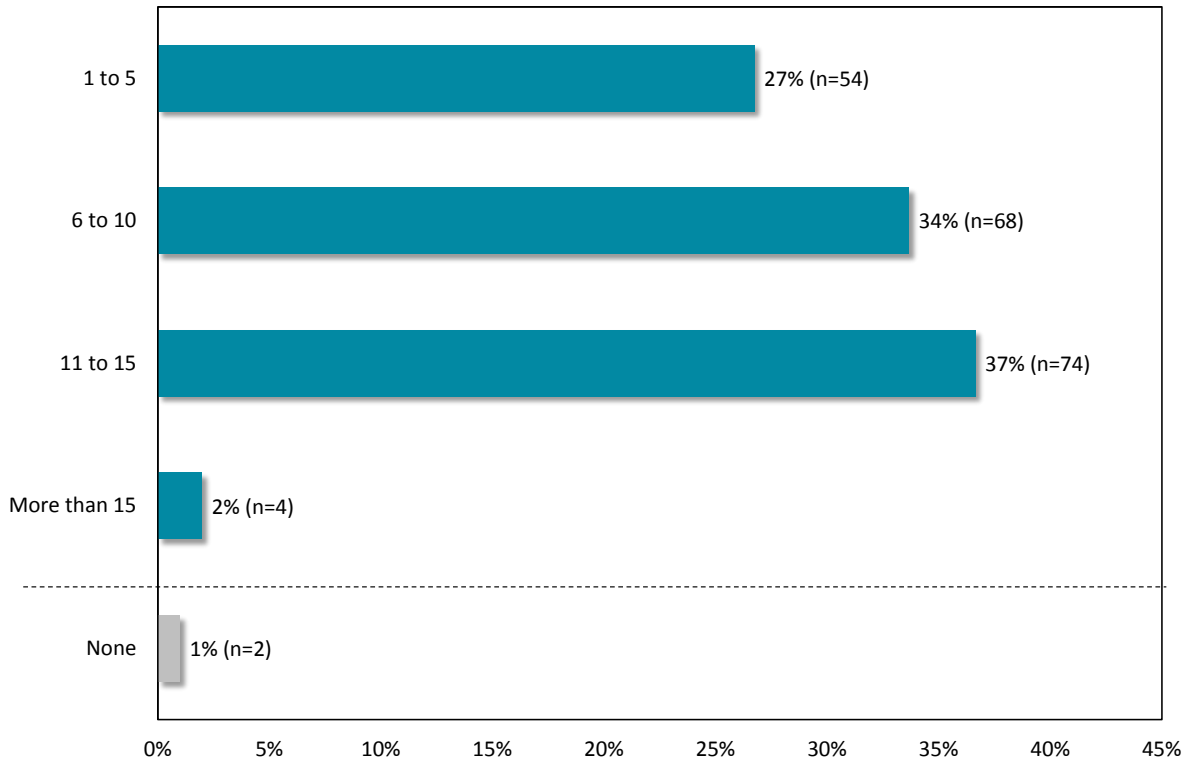
In the instances where the minimum membership was not present at all meetings, all but two HRECs (98%; n=125) reported that the Chair was satisfied, prior to a decision being reached, that the absent members who belong to the minimum membership categories received all papers, had an opportunity to contribute their views, and that these views were recorded and considered.

Number of meetings

The distribution of the number of meetings held by HRECs during the reporting period is shown in **Figure 1**.

Figure 1: Number of meetings held by HRECs in 2015

Base: HRECs that considered new research proposals during the reporting period (n=202)



The majority of HRECs (97%; n=196) reported that they had between 1 and 15 meetings during the 2015 reporting period. The maximum number of meetings held by any one HREC during the reporting period was 59 (n=1). This HREC also reported a total of 19 HREC members, with 620 new research proposals considered during the reporting period.

E. Training

During the reporting period, almost nine-in-ten HRECs (87%; n=185) indicated that the institution(s) provided opportunities to members to undertake training relevant to their work on the HREC (whether attended or not). Of these HRECs, just under nine-in-ten (86%; n=160) reported that one or more members participated in training relevant to their work on the HREC.

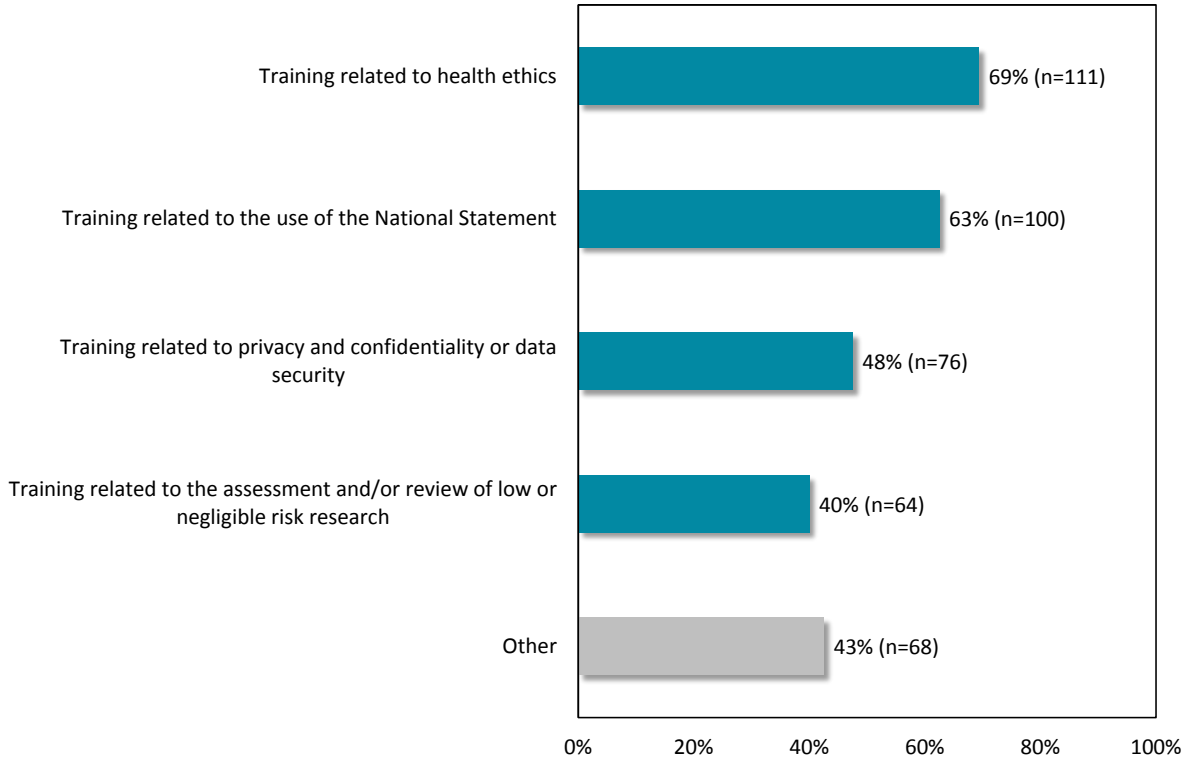
Types of training

As shown in **Figure 2**, the most common type of training that HREC members participated in was related to health ethics (69%; n=111), followed by training related to:

- Use of the National Statement (63%; n=100);
- Privacy and confidentiality or data security (48%; n=76); and
- The assessment and/or review of low or negligible risk research (40%; n=64).

Figure 2: Types of training undertaken by HREC members

Base: HRECs that indicated that at least one committee member participated in training relevant to their work on the HREC during the reporting period, multiple responses accepted (n=160)



Just over two-in-five HRECs (43%; n=68) also reported other types of training that HREC members participated in, including:

- General ethics courses, workshops, and seminars, such as:
  - Australasian Association of Bioethics and Health Law (AABHL) Conference;
  - Australasian Ethics Network (AEN) Conference;

  - Good Clinical Practice (GCP) training;
  - Intensive Bioethics Course;
  - PRAXIS Online Ethics Training Course;
  - PRAXIS Intensive Research Ethics Course; and
  - Training sessions conducted by a state or territory government health department.
- Training tailored to address a range of topics specific to the areas of research regularly considered by the HREC.
- Training related to:
  - Autonomy vs vulnerability;
  - Conduct of clinical trials;
  - Consent and data sharing issues;
  - Data linkage;
  - Genomics research;
  - Guardianship;
  - Open data;
  - Philosophy of ethics;
  - Privacy legislation;
  - Quality assurance;
  - Radiation safety;
  - Research conducted in sleep labs;
  - Research in changing contexts;
  - Research in prisons;
  - Research involving unequal relationships;
  - Research merit and integrity;
  - Research methodologies;
  - Research with Aboriginal and Torres Strait Islander Peoples;
  - Research with children and young people/ research in schools;
  - Social media;
  - Statistics (e.g. ensuring data collection and analysis is robust, interpreting significance of results); and
  - Use of Velos eCompliance software.

During the reporting period, just over four-in-five HRECs (82%; n=131) reported that new members were provided with induction training. Eighteen HRECs (11%) reported that there were no new members appointed during the reporting period.

F. Review of research proposals

Number of research proposals

There were a total of 18,768 new[6] research proposals considered in the 2015 reporting period. Of these, 1,092[7] proposals were not approved but may be re-considered in a subsequent reporting period, and 153[8] proposals were denied ethical approval and would not be re-considered by the HREC.

Table 2 shows the number of research proposals considered by HRECs from 2011 to 2015. The total number of research proposals for 2011 to 2013 may include the assessment of amendments and not just new applications.

Table 2: **Research proposals reviewed by HRECs**

Details of research proposals	2011	2012	2013	2014	2015
Total number of new research proposals **considered**	25,022	26,257	24,882	20,892	18,768
Total number of new research proposals **approved**	23,283	24,540	22,551	19,134	17,056
Percentage of new research proposals **approved**	93%	93%	91%	92%	91%
Highest number of proposals **approved** by a single HREC	1,341	1,344	885	1,223	1,270
Number of HRECs that accepted the ethical approval of an external HREC	139	140	137	126	111

[6] The reporting of 'New research proposals' was not intended to include proposals that had already been considered by the HREC during a previous reporting period. It was also not intended to include amendments or annual reports related to approved projects.

[7] As it was not mandatory for HRECs to provide this data in their reports, there were nine HRECs that did not advise on the number of proposals that were not approved but that may be re-considered in a subsequent reporting period.

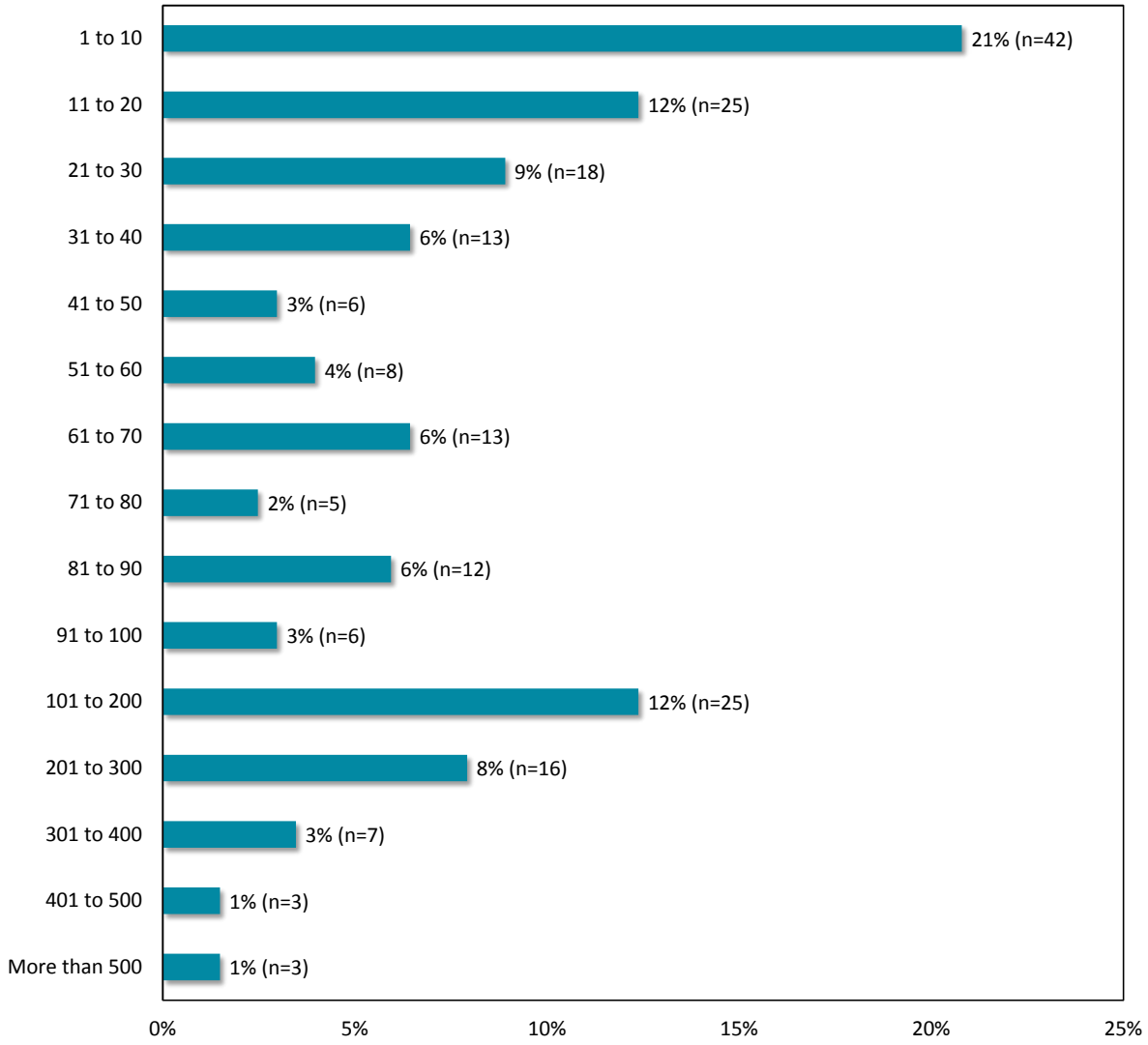
[8] As it was not mandatory for HRECs to provide this data in their reports, there were four HRECs that did not advise on the number of proposals that were denied ethical approval and will not be re-considered by the HREC.

The distribution of the number of new research proposals considered by HRECs during the reporting period is shown in **Figure 3**.

The highest number of new research proposals considered by any single HREC during the reporting period was 1,270 (n=1), and the lowest number was 1 (n=2). The HREC that reported considering 1,270 proposals met 23 times and comprised a pool of 66 members.

Figure 3: Number of research proposals considered by HRECs in 2015

Base: HRECs that considered new research proposals during the reporting period (n=202)

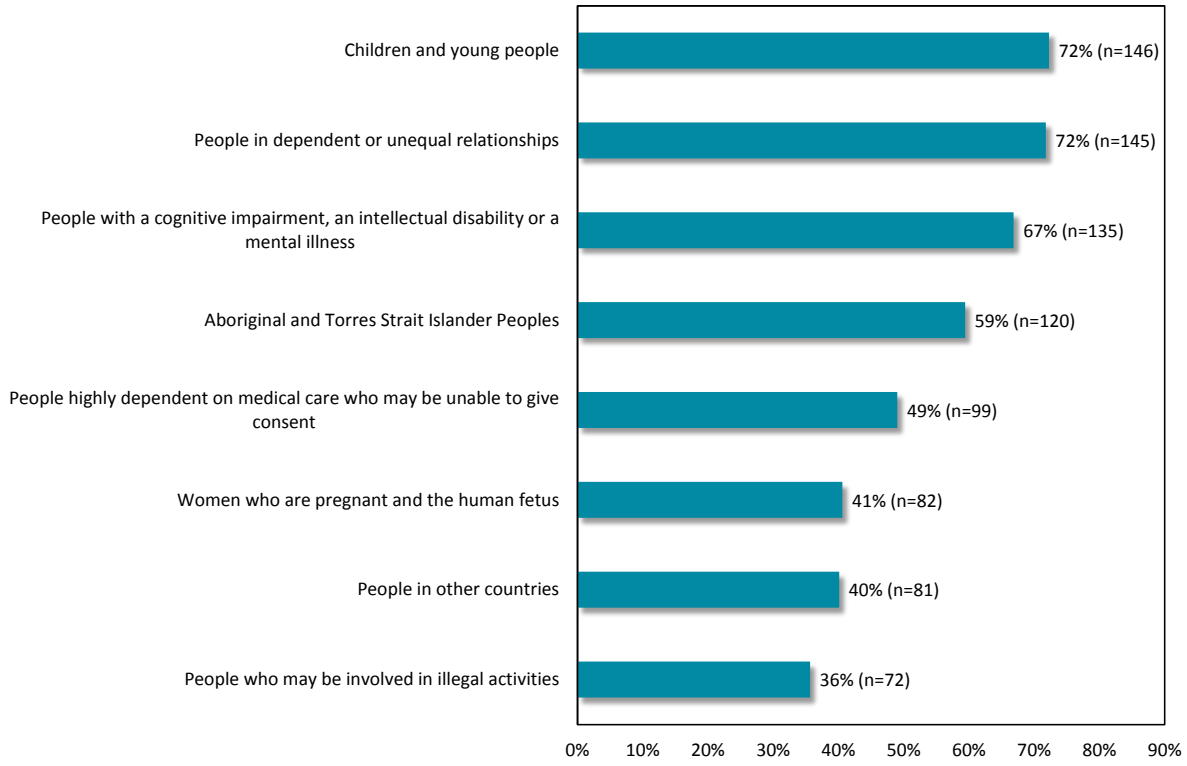


Types of research proposals considered by HRECs

The proportion of HRECs considering various types of research proposals is shown in **Figure 4**.

Figure 4: Proportion of HRECs that considered specific types of research/participants in 2015

Base: HRECs that considered new research proposals during the reporting period (n=202)



In the 2015 reporting period, 127[9] HRECs (63%) considered a total of 2,505 clinical trial research proposals. In the previous reporting period (2014), 2,050 research proposals involving clinical trials were considered.

Eight HRECs (4%) considered proposals involving human gametes (eggs or sperm) or excess Assisted Reproductive Technology (ART) embryos during the reporting period.

[9] One HREC was unable to provide data on whether clinical trial research proposals had been considered by the HREC during the reporting period.

G. Health research involving Aboriginal and Torres Strait Islander Peoples

Of the 120 HRECs that considered new research proposals that involved Aboriginal and Torres Strait Islander Peoples during the reporting period, just under three-quarters (74%; n=89) considered proposals related to health research. Of these HRECs, around nine-in-ten (91%; n=81) reported that they used the *NHMRC Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Research (2003)* when considering these proposals. Other guidelines reported to have been used in considering health related research proposals involving Aboriginal and Torres Strait Islander Peoples included:

- The National Statement; and
- AIATSIS Guidelines for Ethical Research in Australian Indigenous Studies (GERAIS).

The total number of new health related research proposals involving Aboriginal and Torres Strait Islander Peoples considered during the reporting period was 758 (or 4% of all new research proposals considered in 2015). While the number of proposals considered had been steadily declining from 2011 to 2014, it increased in 2015.

Of the new proposals involving Aboriginal and Torres Strait Islander Peoples considered in 2015, 85% were approved. This is below the historical average rate of approval for these types of research proposals (see **Table 3**)[10].

Table 3: Research involving Aboriginal and Torres Strait Islander Peoples

Total number of health research proposals involving Aboriginal and Torres Strait Islander Peoples	2011	2012	2013	2014	2015
Considered	917	877	859	634	758
Approved	890	844	832	571	641
Percentage of research proposals **approved**	97%	96%	97%	90%	85%
Denied ethical approval	27	33	27	27	4
Review outcome unknown	-	-	-	36	113[11]

[10] The total number of research proposals for 2011 to 2013 may include the assessment of amendments etc. and not just new applications.

[11] In 2015, there were a total of 113 proposals across 17 different HRECs for which the outcome of the proposal considered was unaccounted for.

The highest number of health related research proposals involving Aboriginal and Torres Strait Islander Peoples considered by any one HREC was 158.

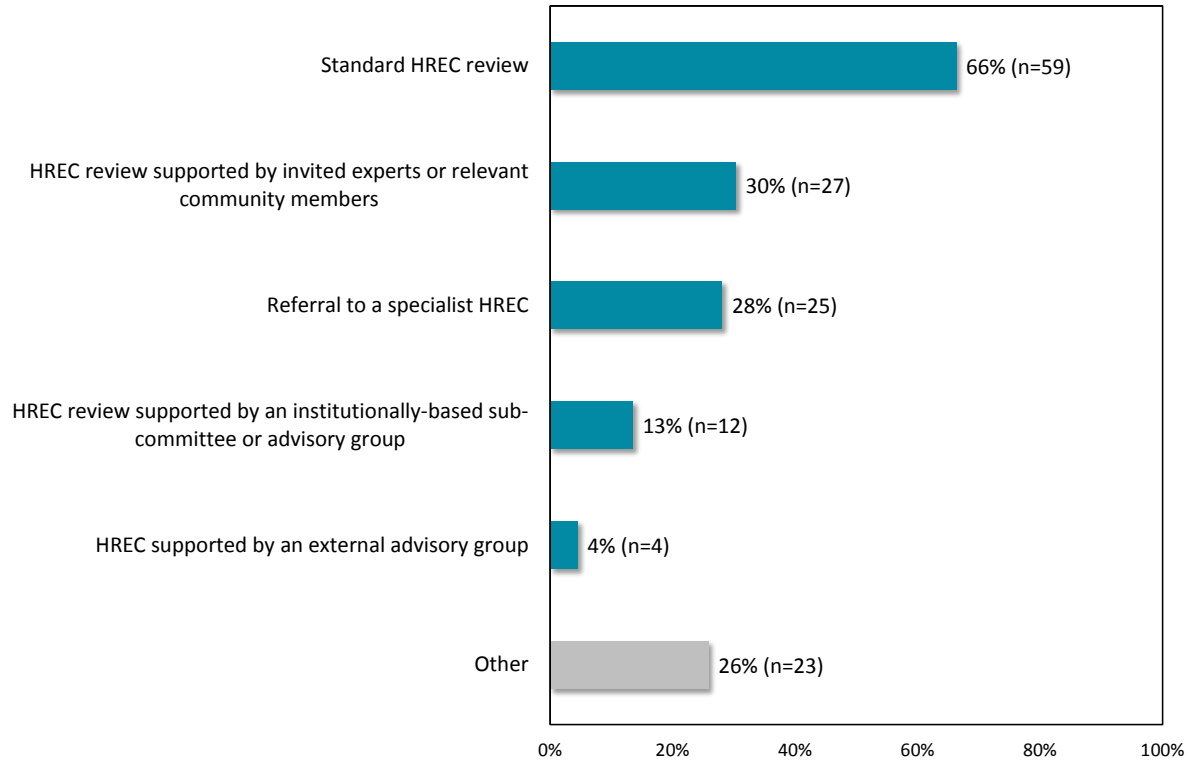
The reasons provided for denying ethical approval for health related research proposals involving Aboriginal and Torres Strait Islander Peoples included:

- Absence of letters of support from relevant Aboriginal and Torres Strait Islander stakeholders;
- Citation utilised was not relevant to the study methods;
- Concerns regarding the methodological rigour, appropriateness of community consultation, and beneficence;
- Failure to demonstrate an understanding of the *Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003*);
- Lack of understanding of the cultural landscape; and
- Research did not satisfy the principles and requirements of the National Statement.

Mechanisms used by HRECs for the review of health related research proposals involving Aboriginal and Torres Strait Islander Peoples are shown in **Figure 5**.

Figure 5: Mechanisms used by HRECs for the review of health related research proposals involving Aboriginal and Torres Strait Islander Peoples in 2015

Base: HRECs that considered new health research proposals involving Aboriginal and Torres Strait Islander Peoples during the reporting period, multiple responses accepted (n=89)



Around one-quarter of these HRECs (26%; n=23) reported using other mechanisms for the review of health related research proposals involving Aboriginal and Torres Strait Islander Peoples, including:

- Advice from Aboriginal and Torres Strait Islander representatives on the committee;
- Advice from HREC members with extensive research experience and networks with Aboriginal and Torres Strait Islander Peoples;
- Advice from institutional or departmental Aboriginal and Torres Strait Islander liaison staff;
- Advice from the Indigenous Research Ethics Advisory Panel (IREAP) established by the HREC;
- Applications are reviewed by Aboriginal and Torres Strait Islander human ethics advisors before submission;
- Evidence of community support is required;
- HREC is specialised in Aboriginal and/or Torres Strait Islander health research;
- Review and approval sought from a specialist HREC that reviews Aboriginal and/or Torres Strait Islander health research; and
- Studies are initially reviewed by a local community jury, which makes a determination about the study from a cultural and community perspective.

H. Research involving low or negligible risk

Just under two-thirds of HRECs that considered new research proposals (65%; n=131) reported that their institution had an established mechanism for ethical review other than the HREC for research proposals that involve low or negligible risk[12].

Of those who reported that the HREC reviews low or negligible risk proposals, all but nine HRECs (87%) reported that the HREC had actually considered these research proposals during the reporting period.

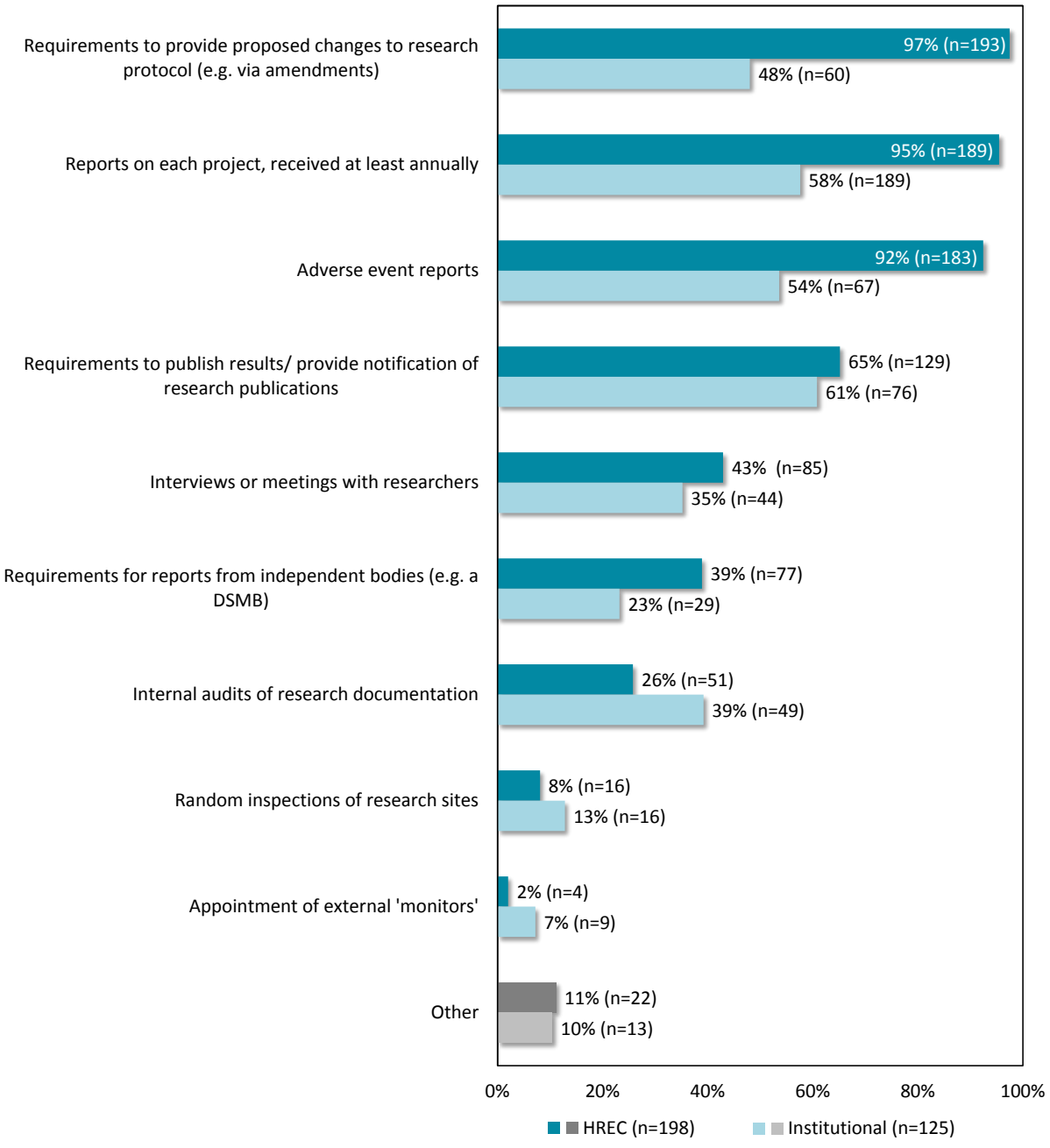
[12] An alternative mechanism could include review by the HREC Chairperson or delegate, review by a sub-committee of the HREC, review by another institutional group or delegated individual etc. (see paragraph 5.1.18-5.1.21 of the National Statement).

I. Monitoring of research

During the reporting period, all 212 HRECs that submitted an annual report indicated that the institution and/or the HREC had procedures in place for monitoring approved research. Of these, all but nine (96%; n=203) reported that the institution and/or the HREC undertook monitoring for approved research. **Figure 6** provides information on the reported monitoring processes in 2015.

Figure 6: Monitoring processes

Base: HRECs that reported that the institution and/or the HREC undertook monitoring of all approved research, multiple responses accepted (n=125-198)



Other processes used to monitor research included:

- Introduction of start-up meetings to ensure that researchers have processes in place to appropriately follow the approved protocol;
- Peer review processes;
- Quarterly reporting of clinical trials conducted under the Clinical Trials Notification (CTN) Scheme with the institutions sponsoring the trial;
- Researchers are requested to provide the HREC with a copy of any statement of findings that are provided to participants at the conclusion of the project;
- Self-audits; and
- Sub-committee reviews for complaints, breaches, and adverse events.

Reasons reported as to why the institution and/or HREC did not undertake monitoring for approved research included:

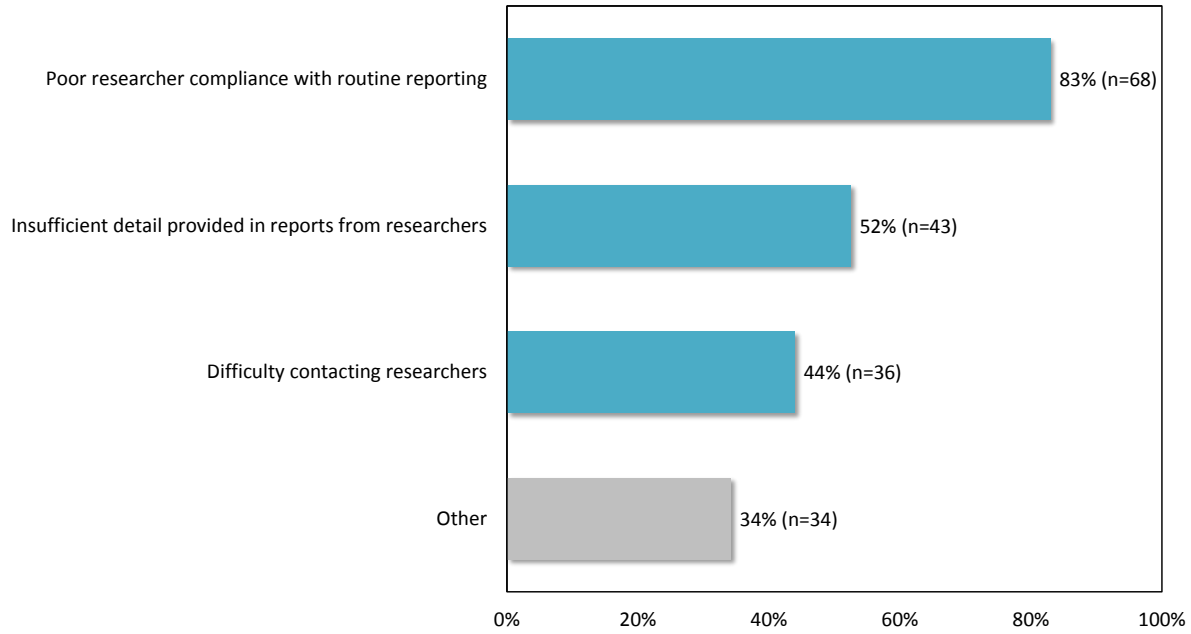
- Lack of resources;
- Approved research projects are low-risk (survey or registry);
- Approved research projects are small-scale (theses) and are supervised by an academic staff member; and
- Work could not be completed as the host institution closed shortly after the inaugural HREC meeting.

Problems encountered in monitoring approved research

Four-in-ten HRECs (40%; n=82) reported that the HREC or institution encountered problems in monitoring research during the reporting period. The types of problems encountered are shown in **Figure 7**.

Figure 7: Problems encountered in monitoring research

Base: HRECs that reported that they encountered problems in monitoring research during the reporting period, multiple responses accepted (n=82)



Other problems reported to have been encountered in monitoring research included:

- Lack of cooperation from researchers;
- Duplication of reporting;
- Late report submissions; and
- Need for management of annual reports to be electronic and not manual.

Of the 82 HRECs that reported that they encountered problems in monitoring research, all but one (99%; n=81) indicated that these problems had been communicated to an appropriate level of management within the institution.

The responsibilities for institutions, HRECs and researchers in monitoring approved research are set out in Chapter 5.1 and 5.5 of the National Statement.

J. Complaints handling

During the reporting period, all but one HREC (n=211) indicated that the institution responsible for the HREC had a procedure(s) for receiving and handling complaints or concerns **about researchers or the conduct of approved research projects**. The remaining HREC reported that their institution had identified the need for a complaints handling procedure.

Just over four-in-five HRECs (85%; n=180) reported that the procedure(s) for receiving and handling complaints or concerns about researchers or the conduct of approved research projects were available on the institution's website[13].

During the reporting period, all but four HRECs (98%; n=208) reported that the institution responsible for the HREC had a procedure(s) for receiving and handling complaints or concerns **from researchers about the conduct of the HREC in consideration of their research proposal(s)**. The reasons provided as to why the remaining four HRECs did not have the relevant procedures in place were:

- Procedures were under review;
- HREC procedures were being drafted, while institutional procedures are contained within the HREC Terms of Reference;
- An informal procedure is in place whereby a researcher may raise any complaints or concerns with the Deputy Director (Research); and
- All projects are low risk surveys (with opt out options) or data reviews.

Again, just over four-in-five HRECs (82%; n=171) reported that the procedure(s) for receiving and handling complaints or concerns from researchers about the conduct of the HREC in consideration of their research proposal(s) were available on the institution's website (see footnote 13).

The requirements for complaints handling are set out in Chapter 5.6 of the National Statement.

[13] As per paragraph 5.6.7 of the National Statement, institutions should publicise their complaints-handling procedures.

Types of complaints received

During the reporting period, around one-third of HRECs (33%; n=70) received a combined total of 229 complaints **about researchers or the conduct of an approved research project**, while just over one-in-ten HRECs (12%; n=25) received a combined total of 34 complaints from researchers about the **consideration of their proposal(s) by the HREC** (see **Table 4)**.

Table 4: Number of complaints or concerns received by HRECs

Nature of concerns or complaints	Total number of complaints	Highest number received by any one HREC
Complaints received about researchers or the conduct of an approved research project	229	19
Complaints received from a researcher about the consideration of their research proposal by the HREC	34	2
Complaints received about researchers or the conduct of an approved research project that involved Aboriginal and Torres Strait Islander Peoples	6	2
Complaints received from Aboriginal and Torres Strait Islander researchers about the consideration of their research proposal by the HREC	2	1

Complaints received **about researchers or the conduct of approved research projects** were related to the following issues:

- Access to information about a study;
- Administration errors;
- Concerns about questionnaire (content, language, wording);
- Concerns about reimbursement;
- Conduct of unapproved research;
- Conflict of interest;
- Consent processes (including opt-out);
- Data security;
- Disruption/distress/medical effects caused by research;
- Failure to report adverse outcomes;
- Fraud;
- Gathering of data outside of approved timeframes;
- Inability to contact researcher;
- Lack of appropriate research supervision;
- Lack of community consultation;

- Lack of follow-up;
- Lack of support;
- Medical care;
- Missed appointments;
- Misunderstandings about research conduct;
- Modification to research methodology without prior approval from review body;
- Personal results from research intervention not provided;
- Privacy and confidentiality concerns/breaches;
- Protocol violations/breaches of ethics approval;
- Recruitment methods (including coercion, correspondence sent to deceased persons, inclusion/exclusion criteria, unsolicited/unapproved approach, contacting ineligible participants, concerns about advertising, lack of information);
- Rights, safety, and wellbeing of participants;
- Risk vs benefit;
- Time delays;
- Unauthorised access to staff, clients, and records;
- Unauthorised sending of data, samples or specimens overseas;
- Unexpected phone calls; and
- Validity of research.

Complaints received from researchers about the **consideration of their research proposal(s) by the HREC** were related to the following issues:

- Concerns about not receiving umbrella ethics approval;
- Concerns that the HREC acted beyond remit;
- Concerns that the HREC did not understand the research proposal;
- Concerns that proposals had not been reviewed in accordance with NHMRC guidelines;
- Conditions or restrictions imposed by the HREC were not appropriate;
- Dissatisfaction or disagreement with the ethical review process;
- Dissatisfaction or disagreement with the HREC's decision (relating to reasons for denial of ethical approval, denial of modification request, review comments or queries, and methodology);
- Length of time between proposal submission and receipt of HREC response;
- Onerous application forms;
- Proposal did not receive approval after being submitted multiple times;
- Researcher was unhappy with level of community engagement;
- Supervisor did not receive a copy of correspondence sent to student researcher; and
- Timing of HREC meetings.

II. Report on the Activity of Certified Institutions' Human Research Ethics Committees for the Period 1 January 2015 – 31 December 2015

The aim of certification under the *National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research* (National Certification Scheme) is to provide an independent validation of the rigour of the institutional ethical review processes for multi-centre research. Institutions should have confidence that a certified institution's HREC is reviewing research proposals using policies, processes and procedures that meet an agreed national set of criteria. Certification is one means to build confidence in single ethical review by all institutions participating in multi-centre research.

Under the National Certification Scheme, certified institutions are obliged to submit an annual report to NHMRC, outlining the number of multi-centre reviews conducted, research categories considered and a summary of administrative support for their ethical review process. This forms part of the ongoing monitoring and reporting requirements.

The annual reporting process provides NHMRC with a snapshot of certified institution HREC activities during a calendar year.

The following overview of the certified institutions' HRECs is drawn from information provided during the reporting period from 1 January 2015 – 31 December 2015.

Any queries regarding this report can be directed to hrep@nhmrc.gov.au.

A. Number of Certified Institutions and institutional HRECs

During 2015, 46 institutions were certified under the NHMRC National Certification Scheme and these included 51 HRECs (see **Table 5**). There were 46 certified institutions in the 2014 reporting period.

Table 5: Reportable HRECs by jurisdiction

Jurisdiction	Number of Certified Institutions	Number of HRECs
New South Wales	15	16
Victoria	10	11
Queensland	10	10
South Australia	6	9
Western Australia	4	4
Australian Capital Territory	1	1
Total	**46**	**51**

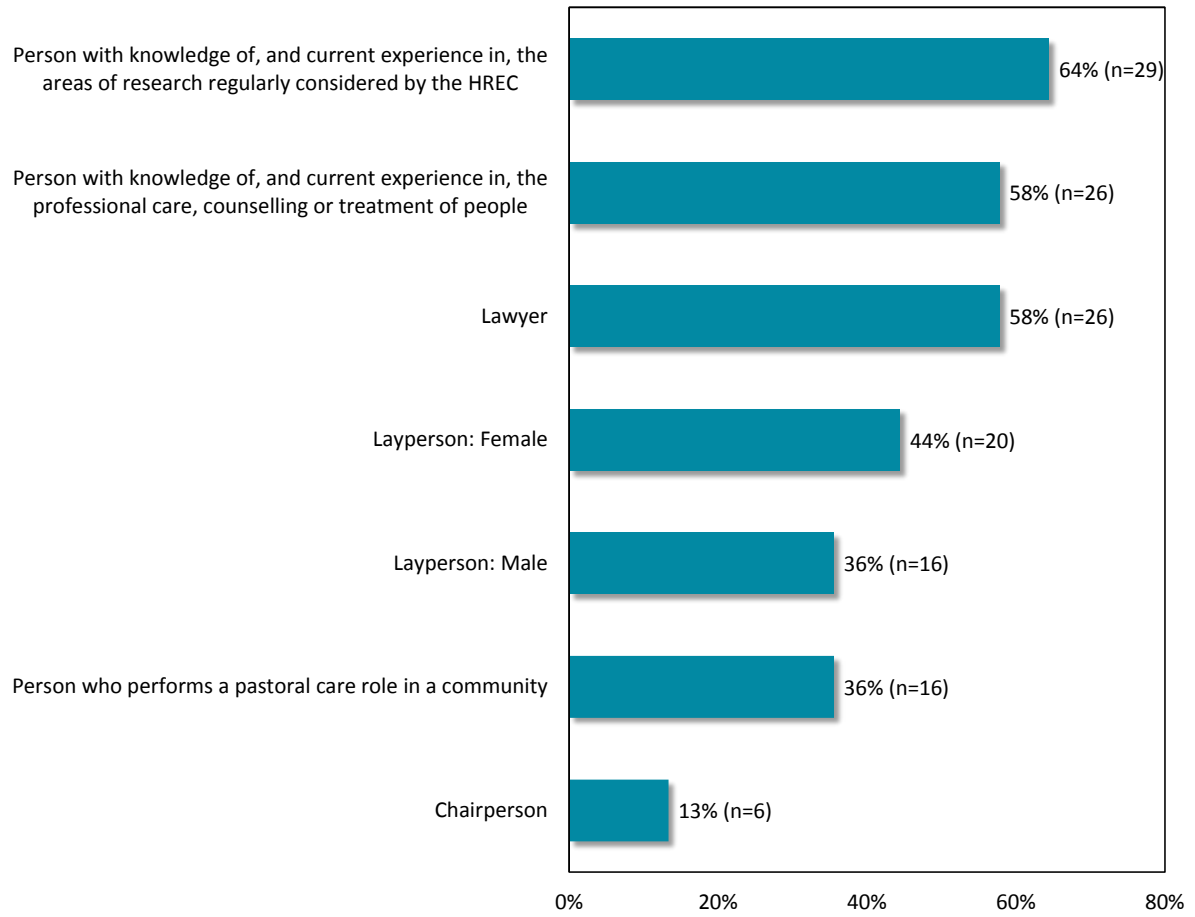
B. HREC composition

Membership

Just under nine-in-ten HRECs (88%; n=45) reported a change to committee membership during 2015. The categories of membership in which changes occurred are shown in **Figure 8**. One HREC reported that they did not meet the minimum membership requirements during the reporting period[14].

Figure 8: Categories of membership in which the change occurred

Base: Certified institutions that reported a change to committee membership, multiple responses accepted (n=45)



Sub-committee expertise

Over half of HRECs (57%; n=29) reported that they used the expertise of a sub-committee(s) as part of their consideration of research proposals.

[14] This HREC reported that, during the reporting period, it did not have a member in the category of female layperson (see paragraph 5.1.30(b) of the National Statement). NHMRC is working with this certified institution and HREC to resolve this issue.

C. Review of multi-centre research proposals

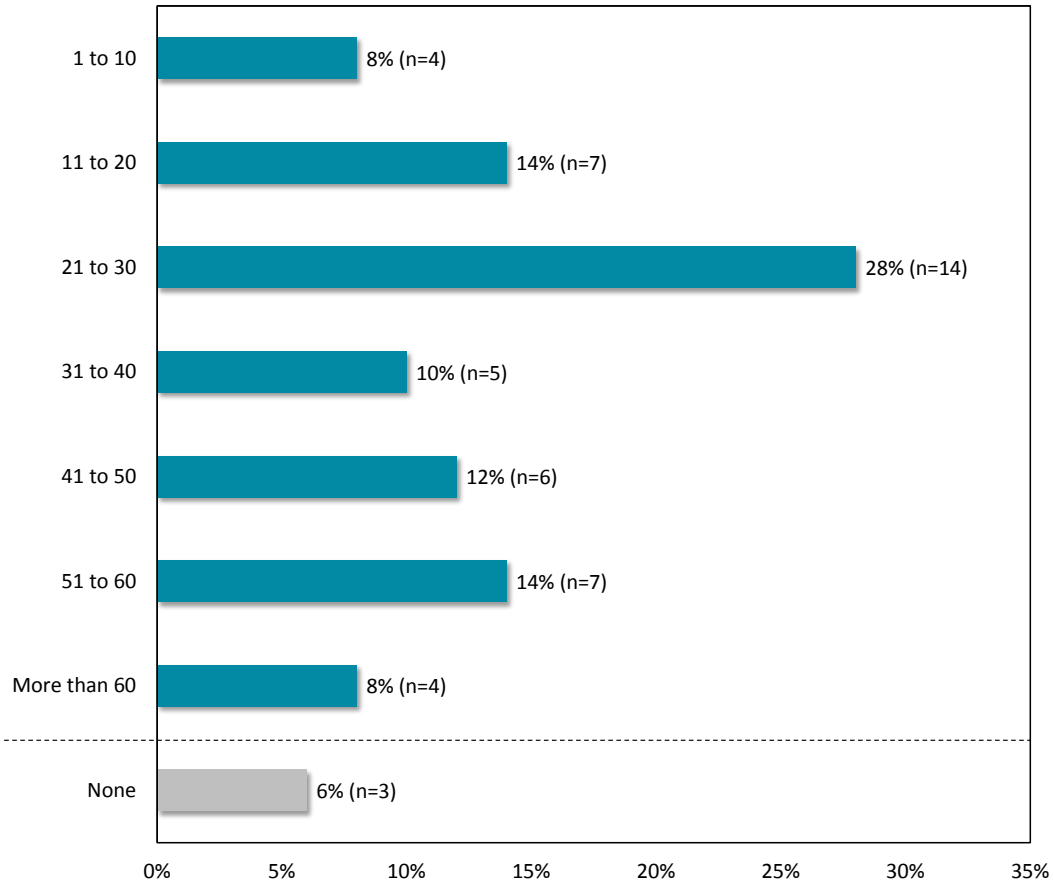
Of the 51 HRECs from certified institutions, there were 50 that considered new research proposals during the reporting period. Of these 50, all but three (94%; n=47) reported that they had considered new **multi-centre**[15] research proposals during 2015.

Number of multi-centre research proposals

The distribution of the number of new multi-centre research proposals considered by HRECs during the reporting period is shown in **Figure 9**.

Figure 9: Number of multi-centre research proposals reviewed by HRECs

Base: Certified institution's HRECs that considered new research proposals (n=50)



The total number of new multi-centre research proposals considered during the reporting period was 1,811 (1,537 in the previous reporting period). The highest number of multi-centre research proposals considered by any one HREC during the reporting period was 193 (n=1) and the lowest was 0 (6%; n=3).

[15] Multi-centre research includes research conducted through the collaboration of at least two unique institutions that may be situated in more than one state or territory or within a single jurisdiction. It does not refer to research being conducted at several sites or locations within a single institution. Responses included any new multi-centre research proposal that the HREC has considered, not just multi-centre research proposals that have been reviewed under the NHMRC National Approach to Single Ethical Review of Multi-Centre Research or another single ethical review scheme.

Around nine-in-ten HRECs (89%; n=42) considered new multi-centre research proposals as the lead HREC[16]. Just under half of the HRECs (45%; n=21) considered new multi-centre research proposals where they were not the lead HREC[17].

During the reporting period, three-in-five HRECs (60%; n=28) reviewed a combined 325 new multi-centre research proposals where their institution was not participating in the research. All but three HRECs (94%; n=44) reported that they were aware of instances where the HREC's approval had been accepted by another institution, and four-in-five HRECs (80%; n=40) indicated that they accepted one or more ethical approvals of multi-centre research from another certified institution.

Research activity – quality, timeliness and reduced duplication

Of the new multi-centre research proposals reviewed during the reporting period, just under nine-in-ten (88%; n=1,595) were completed within 60 calendar days.

The reasons provided as to why proposals were not completed within the 60 calendar day timeframe included:

- Administrative errors and delays (e.g. clock was not stopped as appropriate);
- Delays due to back and forth correspondence;
- Delays due to the large number of documents in the submission;
- Delays due to the need to wait for data custodian approval, which is difficult to track via the 'stop-clock' method;
- Multiple rounds of review;
- Office was understaffed;
- Outstanding issues with the proposal (e.g. scientific merit, study design, ethical issues, privacy issues, safety concerns, unsatisfactory researcher response to HREC comments and conflict of interest);
- Pending response from researcher;
- Proposals required amendments/re-submission;
- Review was out of sync with the next scheduled HREC meeting; and
- 'Stop-clock' method was not yet established.

Just over half (56%; n=1,017) of the new multi-centre research proposals considered were intended for conduct within one state or territory, and just over two-in five (44%; n=794) were intended for conduct in two or more states or territories.

[16] The 'Lead HREC' is the one that has been designated to conduct the review on behalf of all other institutions participating in the multi-centre research. As it was not mandatory for HRECs to provide this data, some certified institutions' HRECs did not indicate if they did or did not consider new multi-centre research proposal(s) as the lead HREC.

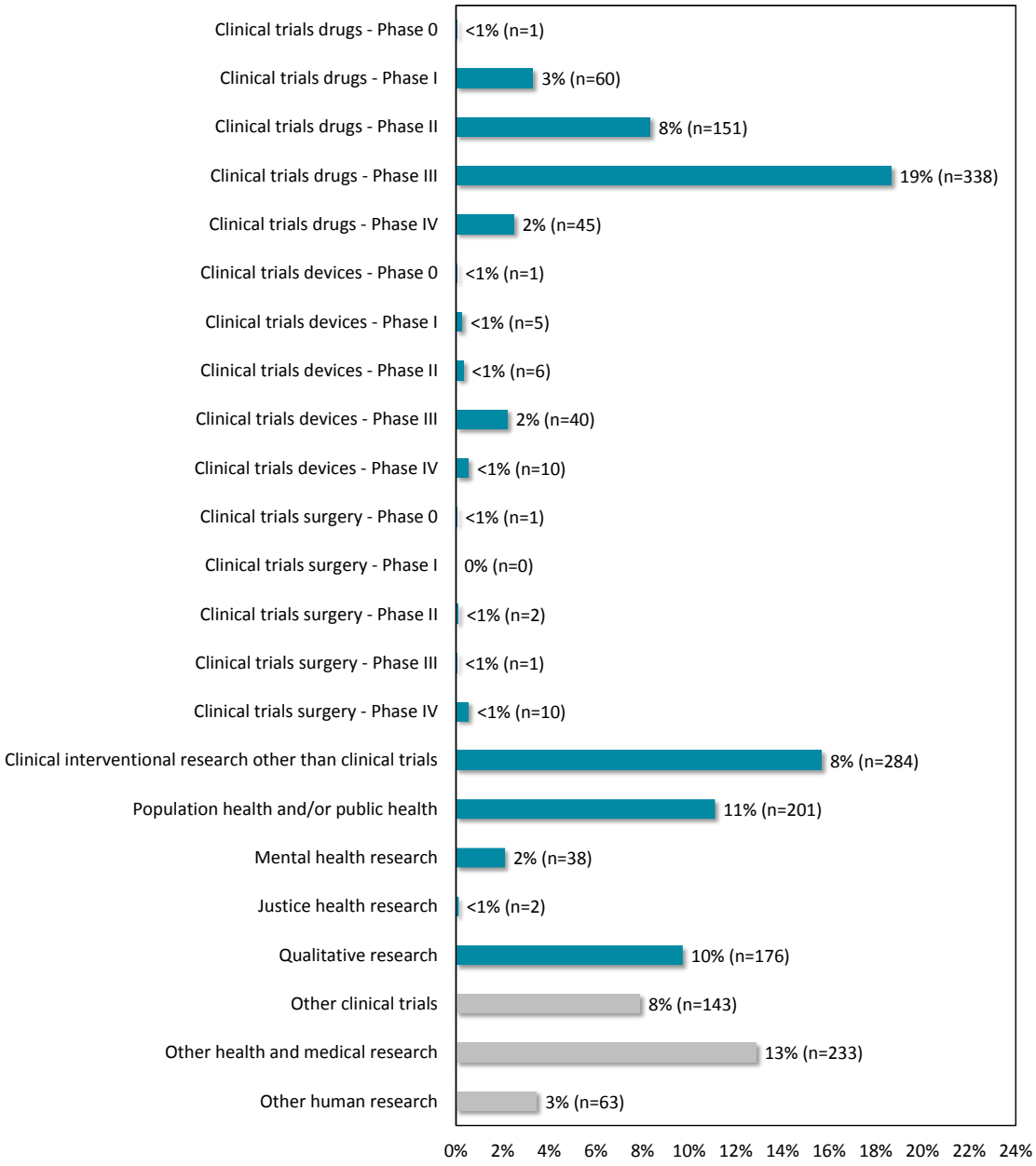
[17] This may be the result of HRECs reviewing multi-centre research outside of formal single ethical review schemes where a lead HREC was not identified or where the project was not eligible for review. This data also reflects that it was not mandatory for HRECs to provide this data.

D. Research categories considered

The distribution of the research categories considered by HRECs during the reporting period is shown in **Figure 10**.

Figure 10: Categories of multi-centre research proposals considered[18]

Base: Total number of multi-centre research proposals considered by certified institution's HRECs (n=1,811)



[18] Definitions for the categories of multi-centre research proposals that are included in Figure 10 can be found in the *National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research Certification Handbook, November 2012.*

Other **clinical trials** considered during the reporting period included[19]:

- Observational trials;
- Paediatric trials;
- Registry trials;
- Trials related to:
  - Biobank;
  - Dentistry;
  - Deprescribing;
  - Diagnostic testing;
  - Dietary advice;
  - Drug and device;
  - Exercise;
  - Evaluation of vaccine effectiveness;
  - Factors affection compression garments;
  - Imaging;
  - Interventions (including educational and nursing interventions);
  - Ketone diabetes;
  - Smartphone programs;
  - Model of Care;
  - Nasal biopsy;
  - Neonatal care;
  - Nutrition;
  - Physiotherapy;
  - Radiology; and
  - Telehealth or telemedicine.

Other **health and medical research** considered during the reporting period related to:

- Audits and evaluations;
- Biobanking;
- Biomedical engineering;
- Biostatistics;
- Case cohort studies;
- Clinical research;
- Collection/use of human samples;
- Community interest in health research;
- Cross-sectional research;
- Data linkage;
- Dentistry;

[19] Some HRECs incorrectly reported 'other clinical trials' to be microsampling, reproductive medicine and stem cell trials.

- Dietetics;
- Genetics;
- Geriatrics;
- Health economics;
- Health outcomes;
- Health services;
- Incident reporting research;
- Laboratory/diagnostic research;
- Longitudinal studies;
- Medical records review;
- Mixed methods research;
- Nursing training;
- Nutrition;
- Observational studies;
- Oncology and carcinogenesis;
- Paediatrics;
- Quality of life;
- Quantitative research (including surveys);
- Registries;
- Review of dosing regime;
- Safety follow-up;
- Social work;
- Telehealth;
- Tissue/data banks;
- Women's health; and
- Work practices.

Other **human research** considered during the reporting period related to:

- Applied ethics;
- Data analysis;
- Data linkage;
- Social science; and
- Validation of tool.

During the reporting period, just over half of HRECs (55%; n=26) reviewed multi-centre research proposals that involved Children and Young People/Paediatrics.

III. Report on Human Research Ethics Committee Application of the Guidelines Under Section 95 of The Privacy Act 1988 and The Guidelines Approved Under Section 95A of the Privacy Act 1988 for the Period 1 January 2015 – 31 December 2015

The Privacy Act 1988

The *Privacy Act 1988* (Privacy Act), regulates the handling of **personal information**[20] about individuals by Commonwealth agencies and some private sector organisations. The term 'handling' includes the collection, use, storage and disclosure of personal information, and access to and correction of that information.

Guidelines approved under the Privacy Act

In some circumstances, such as the conduct of research that is deemed to be in the interest of public health and safety, or the management, funding or monitoring of health services, the protection of privacy must be weighed against the benefit to the public as a whole, if such information were to be disclosed. Sections 95 and 95A of the Privacy Act permit the collection, use and disclosure of personal information that would otherwise breach one, or more of the Australian Privacy Principles (APPs) for research purposes, if the research is conducted in accordance with the *Guidelines under Section 95 of the Privacy Act 1988* (s95 guidelines) or the *Guidelines approved under Section 95A of the Privacy Act 1988* (s95A guidelines).

The s95 and s95A guidelines are issued by the CEO of NHMRC, with the agreement of the Australian Information Commissioner.

The s95 guidelines apply where the proposed research is **medical research** involving the use of personal information (including **sensitive information**), held by a Commonwealth Agency; and it is impractical to seek consent.

The s95A guidelines apply where the proposed activity involves the collection, use or disclosure of **health information** by/or held by an organisation in the private sector, for the purposes of research, the compilation or analysis of statistics relevant to public health or public safety, or the collection of health information for the management, funding or

[20] Bolded terms are defined in Section 6 of the *Privacy Act 1988.*

monitoring of a health service; it is impracticable to seek consent; and de-identified information will not achieve the purpose of the research or compilation or analysis of statistics activity.

Procedure for the review of HREC Application of the s95 and s95A guidelines

In addition to collecting information about the application and requirements of the National Statement, NHMRC's HREC annual report process also collects information on behalf of the Australian Information Commissioner on the application of the s95 and s95A guidelines.

In this report:

- Part A reports on the HREC application of the s95 guidelines during the period 1 January 2015 – 31 December 2015; and
- Part B reports on the HREC application of the s95A guidelines during the period 1 January 2015 – 31 December 2015.

A. Application of the s95 guidelines during the period 1 January 2015 – 31 December 2015

During the reporting period, 202 HRECs considered new research proposals. Of these HRECs, around one-in-ten (11%; n=23) reported that they had considered medical research proposals which:

- Required the use or disclosure of information from a Commonwealth agency;
- Required the use or disclosure of personal information; and
- Were conducted without obtaining consent from all individuals to whom the information related.

These 23 HRECs considered a combined **2,438** new research proposals during the reporting period. Of these, **88** proposals were reported to have required the use or disclosure of personal information from a Commonwealth agency where consent was not obtained from all individuals, as described in the s95 guidelines. All 88 proposals were reported to have had the s95 guidelines applied.

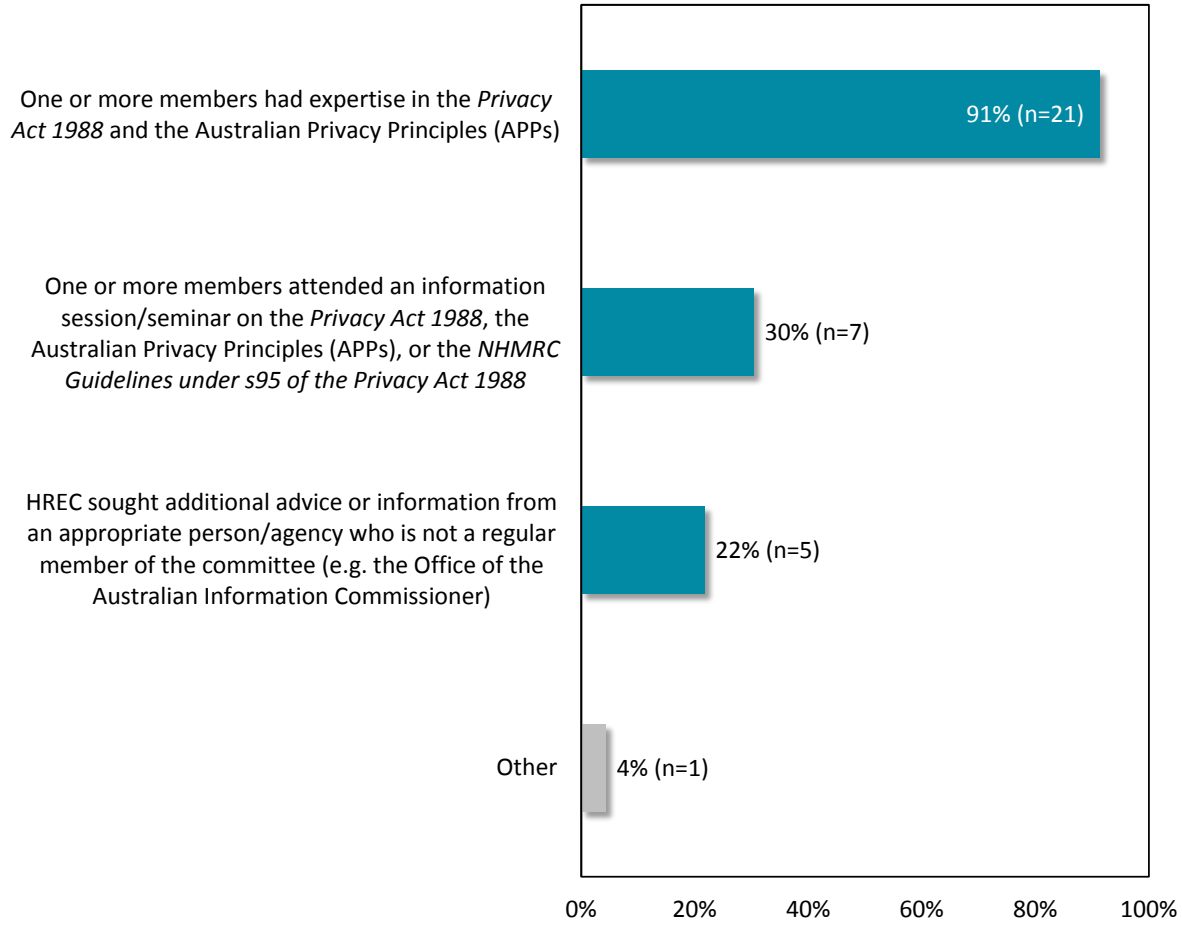
HREC assessment of expertise and understanding of privacy issues (Paragraphs 3.1, 3.2(b) and 3.4)

All 23 HRECs that considered proposals requiring the application of the s95 guidelines reported that they had sufficient expertise and understanding of privacy issues, in order to make a decision that takes proper account of privacy.

HREC assessment of expertise and understanding of privacy issues is shown in **Figure 11**.

Figure 11: HREC assessment of their expertise and understanding of privacy issues (s95)

Base: HRECs that reported that they considered proposals requiring the application of the s95 guidelines and had sufficient expertise and understanding of privacy issues in order to make a decision that takes proper account of privacy, multiple responses accepted (n=23)



Other expertise included training related to applying Commonwealth and Victorian privacy and health records guidelines.

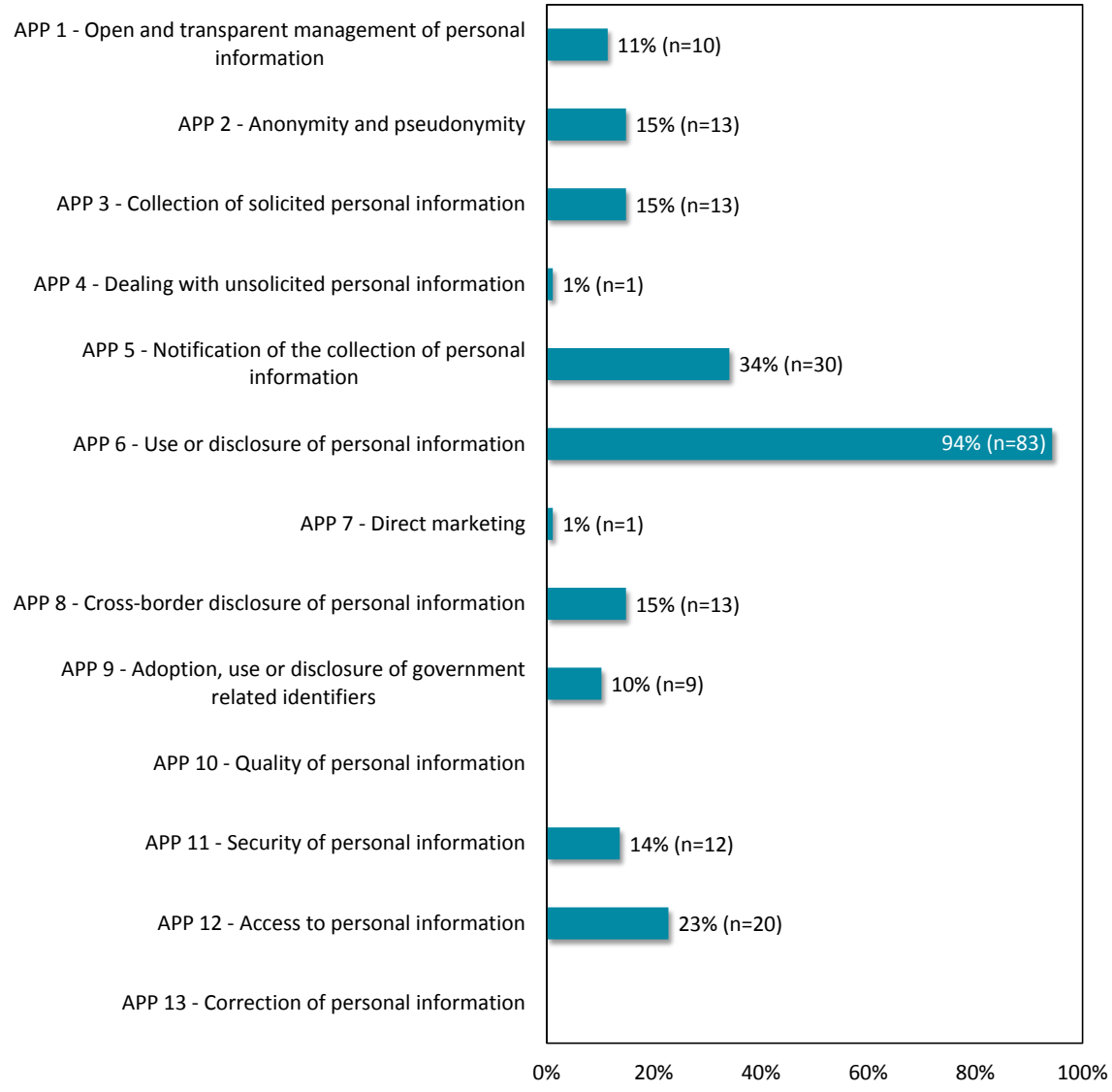
HREC assessment of relevant Australian Privacy Principles (APP) (Paragraphs 3.2(a) and 3.4)

All but one HREC reported that they recorded the APPs that would have been infringed had the HREC not applied the s95 guidelines in reaching the decision to approve proposals. The remaining HREC reported that their documentation currently refers to the National Privacy Principles (NPPs), and needs to be updated to include provision for the APPs.

Figure 12 identifies the APPs which would have been infringed if not for the approval of research proposals under the s95 guidelines.

Figure 12: APPs that would have been infringed had s95 not been applied

Base: Research proposals for which the s95 guidelines were applied, multiple responses accepted (n=88)[21]



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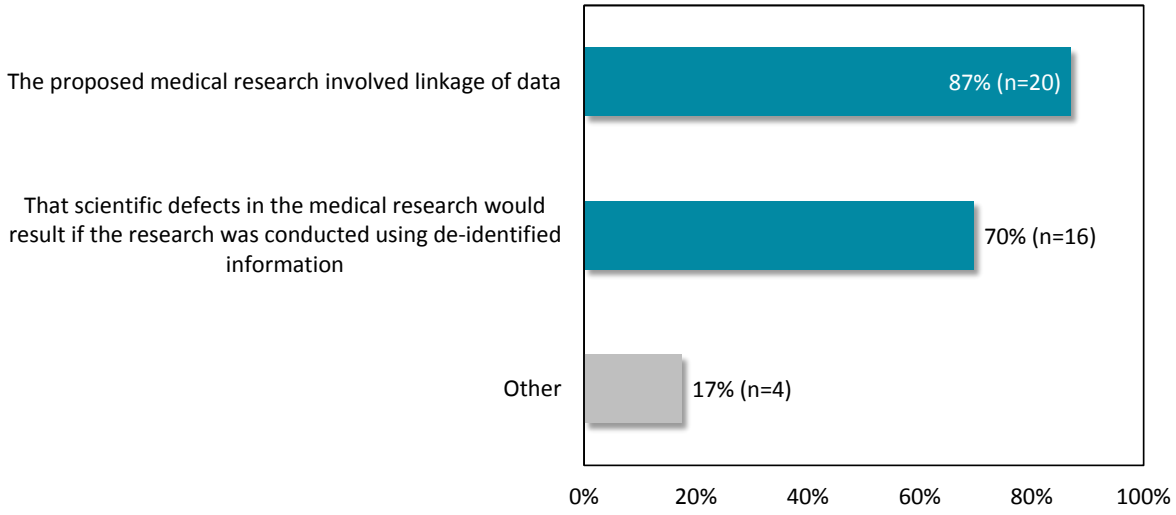
[21] Data was not collected for one HREC (n=7 proposals).

Personal information and consent (Paragraph 3.2(a))

Figure 13 illustrates the issues considered by HRECs in assessing whether it was necessary for identifiable or potentially identifiable information to be used in the proposed medical research.

Figure 13: HREC considerations with regard to identifiability of data (s95)

Base: HRECs that reported that they considered proposals requiring the application of the s95 guidelines, multiple responses accepted (n=23)



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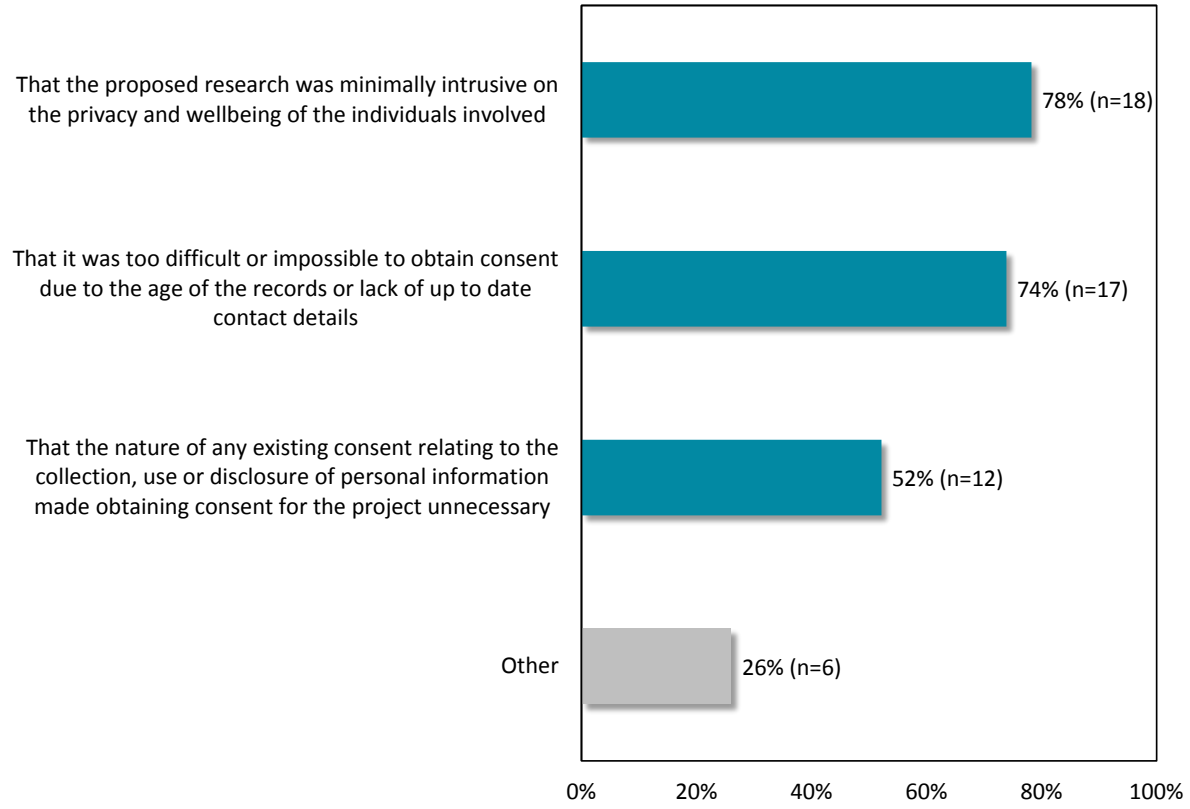
Other considerations with regard to identifiability of data included:

- Adequate data security;
- De-identification to the maximum extent possible;
- Only institutional clinical staff had access to the data;
- Substantial public interest;
- Test of impracticability regarding obtaining consent;
- The proposed research used administrative data to evaluate outcomes of Commonwealth health programs; and
- The proposed research was not against the interests of those whose data was being handled.

Figure 14 illustrates the issues considered by HRECs in assessing whether it was reasonable for the medical research to proceed without consent.

Figure 14: HREC considerations with regard to consent (s95)

Base: HRECs that reported that they considered proposals requiring the application of the s95 guidelines, multiple responses accepted (n=23)



Other considerations with regard to consent included:

- De-identification to the maximum extent possible;
- Identified data used only for data linkage;
- Only institutional clinical staff had access to the data;
- Participants are deceased;
- Size of the population involved (i.e. number of records);
- Substantial public interest;
- Test of impracticability regarding obtaining consent; and
- The proposed research was not against the interests of those whose data was being handled.

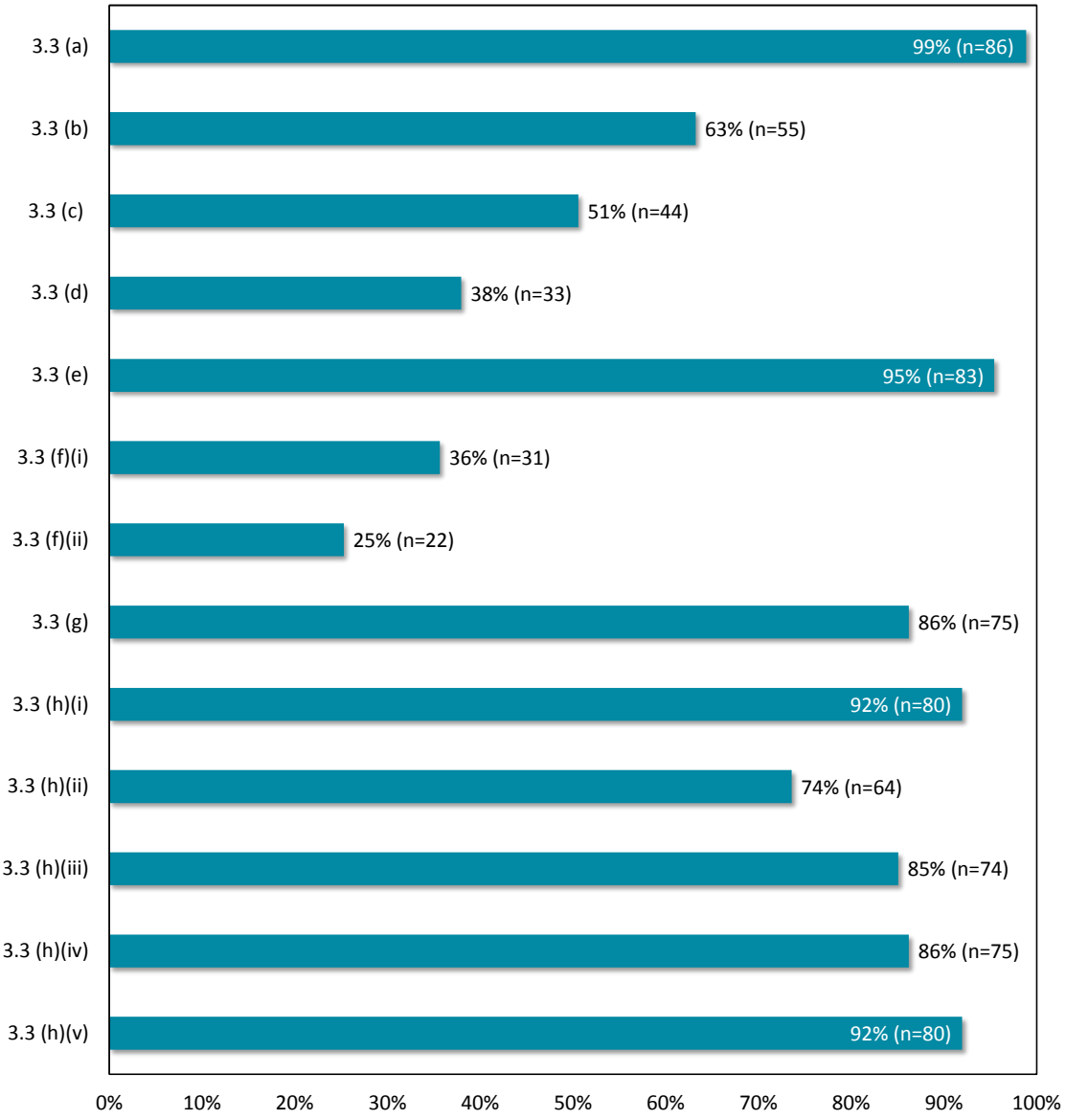
Weighing the public interest (Paragraph 3.3)

Of the 88 proposals reported to have required the use or disclosure of personal information held by a Commonwealth agency where consent was not obtained from all individuals, the public interest in the proposed medical research was determined to outweigh, to a substantial degree, the public interest in the protection of privacy in 87 cases (i.e. 87 proposals were approved). There was one proposal for which it was determined that the public interest in the proposed medical research did not outweigh the public interest in the protection of privacy (i.e. one proposal was denied approval).

Figure 15 shows the matters reported to have been considered relevant in approving a research proposal under the s95 guidelines.

Figure 15: Matters reported to have been considered relevant in approving a research proposal

Base: Proposals for which it was determined that the public interest in the proposed medical research outweighed, to a substantial degree, the public interest in the protection of privacy, multiple responses accepted (n=87)



For the one proposal that was not approved, the matters that were reported to have been considered relevant in not approving the research proposal under the s95 guidelines were 3.3 (c) and 3.3 (g).

Recording and monitoring of decisions (Paragraphs 3.4 and 3.5)

Recording

All 23 HRECs reported that they recorded the following information when considering research proposals that require access to personal information held by a Commonwealth agency:

- The name of the Commonwealth agencies from which the information was sought;

- The data items sought from the Commonwealth agency, and approved by the HREC; and
- The number of records involved.

Appendix A lists the information provided by HRECs regarding where the information was sought (Item 1), details of those data items sought (Item 2), and the number of records involved (Item 3).

Monitoring

During the reporting period, all 23 HRECs had procedures in place for monitoring approved research, and all HRECs also undertook monitoring for approved research.

Around two-thirds of the HRECs (65%; n=15) encountered problems in monitoring approved research, the most common of which was poor researcher compliance with routine reporting.

All of these HRECs reported that the problems encountered in monitoring approved research had been communicated to an appropriate level of management within the institution.

Complaints

No HREC reported receiving any complaints under the s95 guidelines.

B. Application of the s95A guidelines during the period 1 January 2015 – 31 December 2015

Of the 202 HRECs that considered research proposals during the reporting period, just under one quarter (23%; n=28) reported that they had considered proposals which involved the collection, use or disclosure of health information held by a private sector organisation for which it was impractical to obtain consent. **Table 6** shows the types of research proposals considered within the context of the s95A guidelines.

Table 6: Types of research proposals considered within the context of the s95A Guidelines

Research proposals involving:	Number of proposals considered
Research relevant to public health or safety	66
The compilation or analysis of statistics relevant to public health or safety	29
The management, funding or monitoring of a health service	28
Total	**123**

The s95A guidelines were reportedly applied to all 123 proposals.

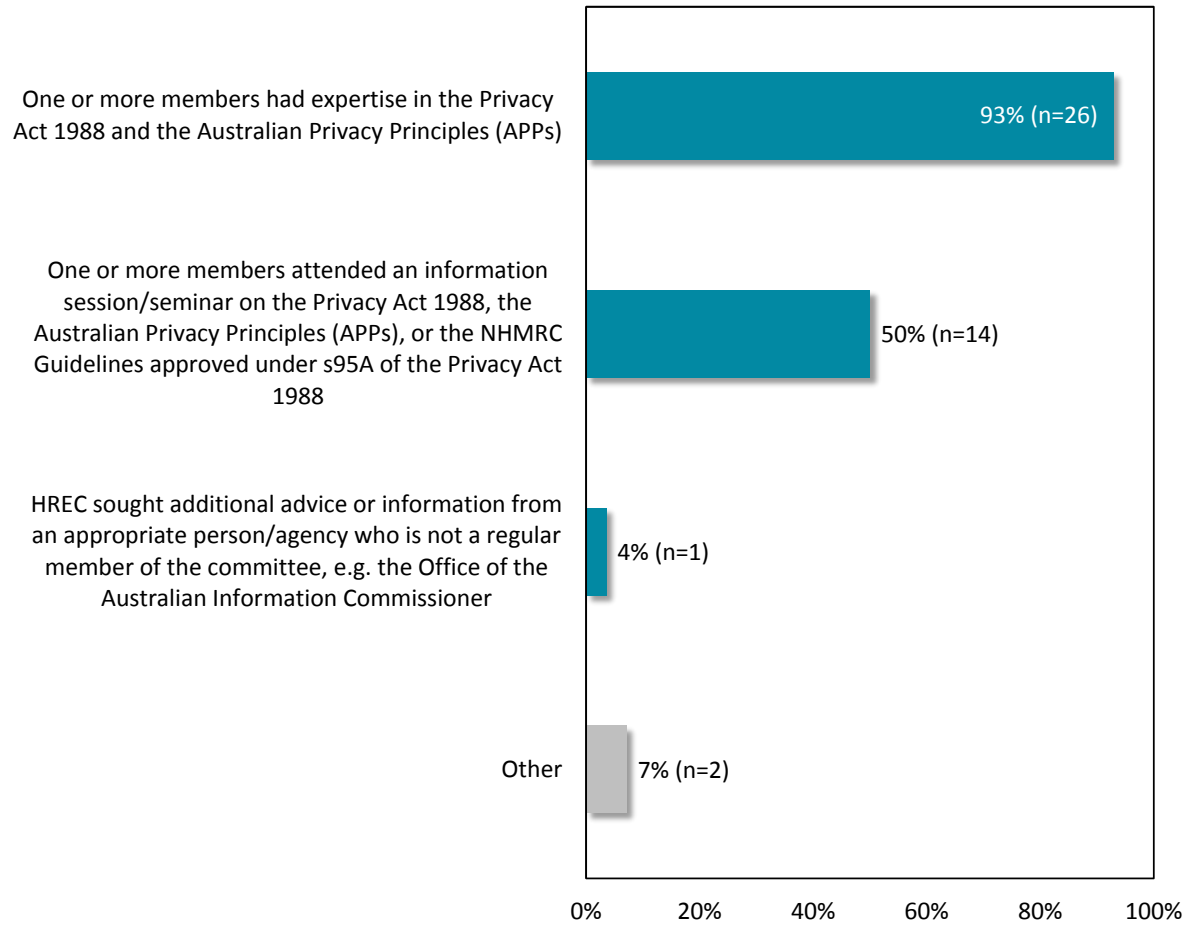
HREC assessment of expertise and understanding of privacy issues (Paragraphs D.1, D.3 and D.6(e))

During the reporting period, all 28 HRECs that considered proposals requiring the application of the s95A guidelines reported that they had sufficient expertise and understanding of privacy issues in order to make a decision that takes proper account of privacy.

HREC assessment of expertise and understanding of privacy issues is shown in **Figure 16**.

Figure 16: HREC assessment of their expertise and understanding of privacy issues (s95A)

Base: HRECs that reported that they considered proposals requiring the application of the s95A guidelines and had sufficient expertise and understanding of privacy issues in order to make a decision that takes proper account of privacy, multiple responses accepted (n=28)



Other expertise included:

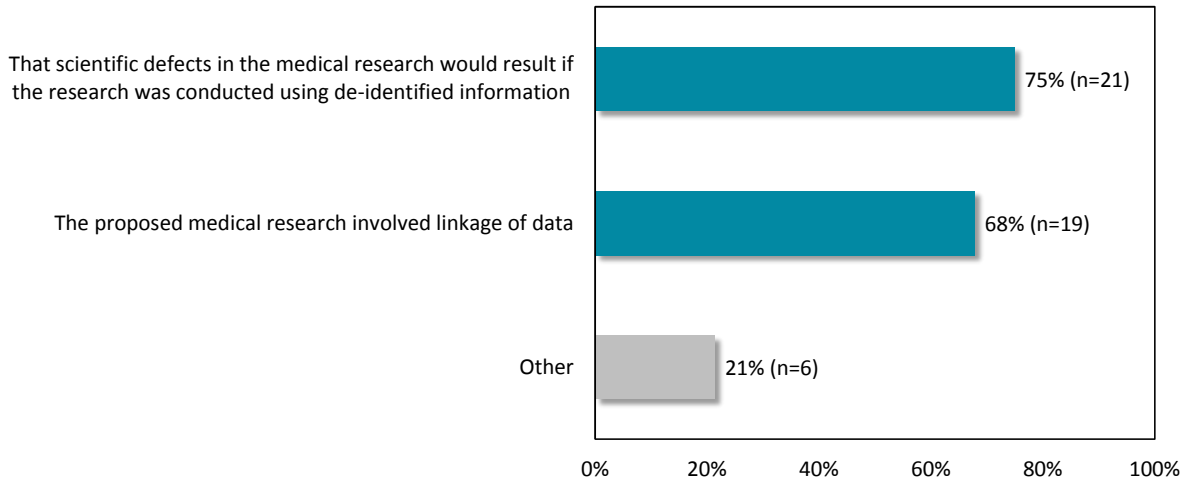
- Lawyer members had knowledge of privacy issues; and
- Members accessed written guidance about privacy issues.

Use of de-identified data (Paragraphs D.2 and D.6(f)) and consent (Paragraphs A1.3, B1.3, C1.3 and D.2)

The issues considered by HRECs in deciding that the purpose of the proposed activity could not be achieved using de-identified information are illustrated in **Figure 17**.

Figure 17: HREC considerations in the use of de-identified data (s95A)

Base: HRECs that reported that they had applied the s95A Guidelines, multiple responses accepted (n=28)



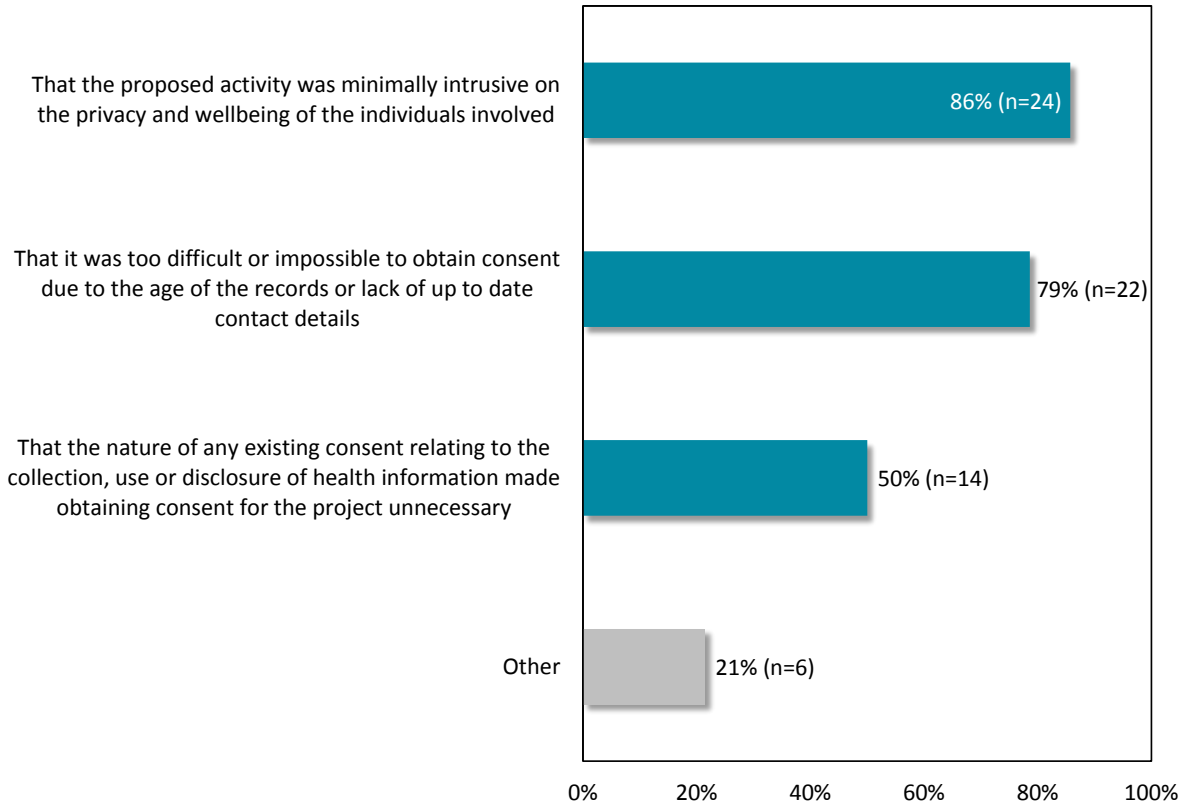
Other considerations with regard to the use of de-identified data included:

- It was necessary to collect health information for the purpose of the compilation and analysis of statistics, relevant to public health;
- It was necessary to collect health information for the purpose of health service management;
- It was necessary to ensure that a patient's records are not audited more than once as this would skew the results;
- New diagnostic testing on historical samples which may have implications for patient management;
- Patient information collected from registries was initially identifiable, but was de-identified before analysis;
- Researchers at the health service had matched identifiable pre- and post-treatment data, and then de-identified the data before providing it to the external researcher; and
- Researchers were to access data with scrambled identification – it was not the intention to obtain personal information however it may be possible to re-identify some of the patients from a unique combination of characteristics.

Figure 18 illustrates the issues considered by HRECs in deciding that it was impracticable to seek consent.

Figure 18: HREC considerations with regard to consent (s95A)*

Base: HRECs that reported that they had applied the s95A Guidelines, multiple responses accepted (n=28)



* HRECs may identify more than one matter as relevant in their consideration of consent.

Other considerations with regard to consent included:

- Availability of resources and the hardship that would be placed on the agency;
- It was reasonable not to seek consent in the interests of public health and safety;
- Risk of creating additional threats to privacy by having to link information in order to locate individuals;
- Risk of inflicting harm (social, psychological or other) by contacting participants;
- Size of the population involved (i.e. number of records);
- Strong public interest or benefit; and
- Study registry adopted an opt-out consent process.

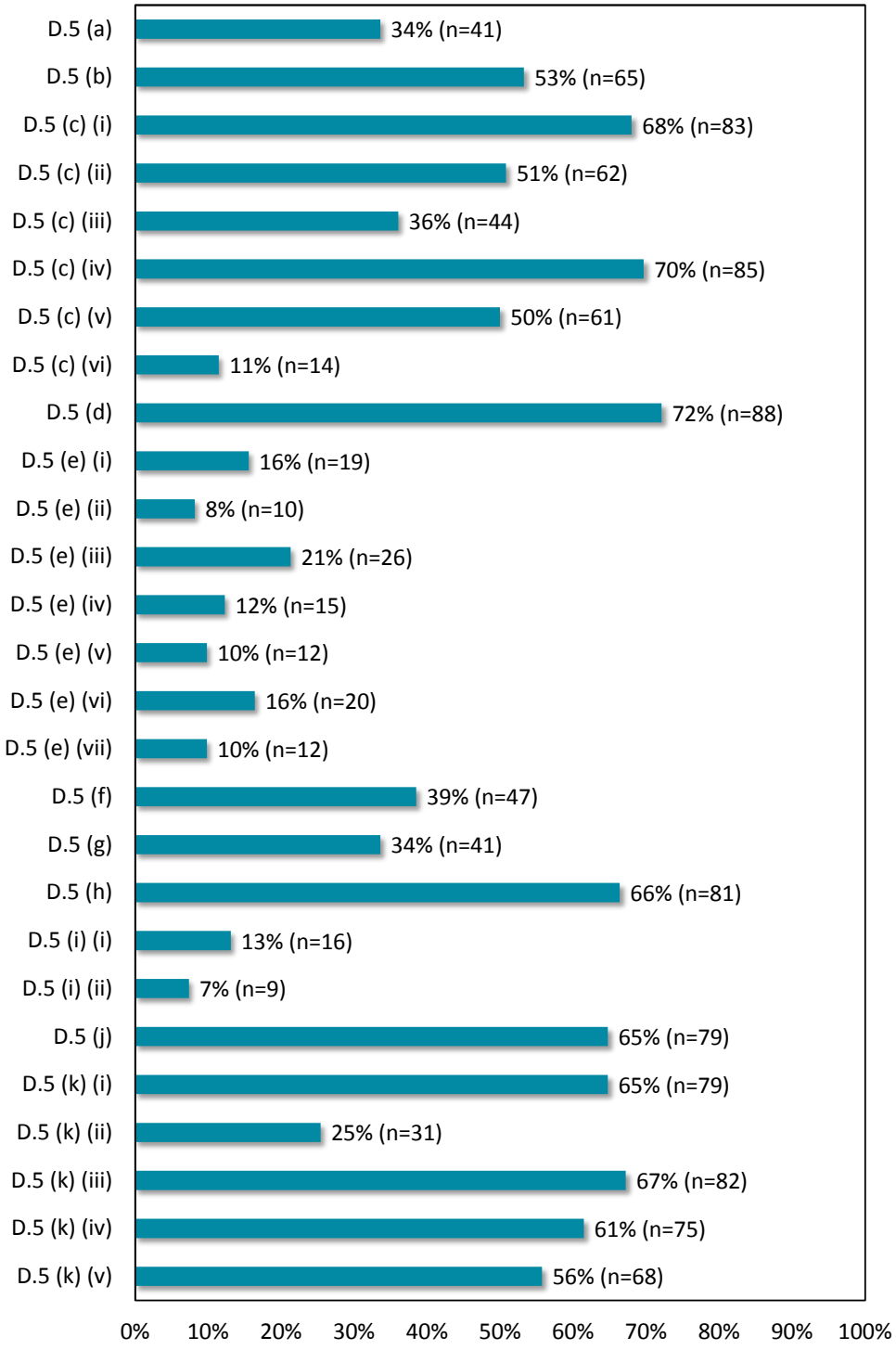
Weighing the public interest (Paragraphs D.4 and D.5)

Of the 123 proposals reported to have required the application of the s95A guidelines, the public interest in the proposed activity outweighed the public interest in the protection of privacy in 122 cases (i.e. 122 proposals were approved). There was one proposal for which it was determined that the public interest in the proposed activity did not outweigh the public interest in the protection of privacy (i.e. one proposal was denied approval).

Figure 19 shows the matters reported to have been considered relevant in approving a research proposal under the s95A guidelines.

Figure 19: Matters reported to have been considered relevant in approving a research proposal

Base: Proposals for which it was determined that the public interest in the proposed activity substantially outweighed the public interest in the protection of privacy, multiple responses accepted (n=122)



For the one proposal that was not approved, the matters that were reported to have been considered relevant in not approving the research proposal under the s95A guidelines were D.5 (i) (i), D.5 (j), D.5 (k) (iii), and D.5 (k) (iv).

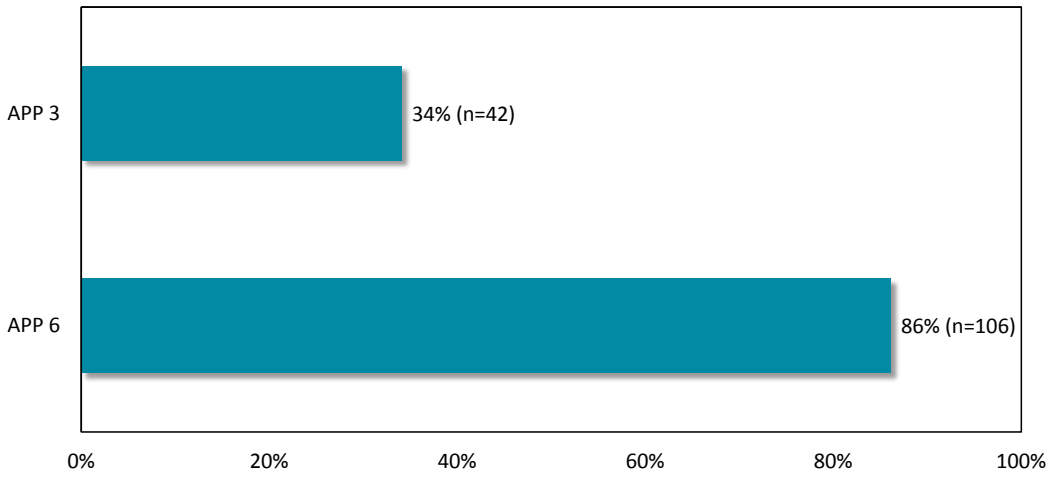
HREC assessment of relevant Australian Privacy Principles (APP) (Paragraph D.6(d))

All but one HREC reported that they had recorded the APPs which apply to proposals as required under s95A guideline D.6(d). The remaining HREC reported that the applicants indicated that none of the APPs were being infringed as a result of carrying out the project; hence no further information was sought or recorded as the HREC was satisfied that the requirements under the s95A guidelines were met.

HREC assessment of expertise, information and understanding of privacy issues is shown in **Figure 20**.

Figure 20: APPs that would have been infringed had s95A not been applied

Base: Research proposals for which the s95A guidelines were applied, multiple responses accepted (n=123)



Recording and monitoring of decisions (Paragraphs D.6 and D.7)

Recording

All but one HREC reported that they recorded the following information:

- The names of private sector organisations from which health information was sought;
- The data items sought from the private sector organisations, and approved by the HREC; and
- The number of records involved.

The remaining HREC reported that the information was recorded for some, but not all proposals, as the range of records has not always been able to be provided given the audit nature of these proposals, as the sample sizes are not known until the study is undertaken.

Appendix B lists the information provided by HRECs regarding where information was sought (Item 1), details of those data items sought (Item 2), and the number of records involved (Item 3).

Monitoring

During the reporting period, all 28 HRECs had procedures in place for monitoring approved research, and all HRECs also undertook monitoring for approved research.

Twenty of these HRECs encountered problems in monitoring approved research, the most common of which was poor researcher compliance with routine reporting. All of these HRECs reported that the problems encountered in monitoring approved research had been communicated to an appropriate level of management within the institution.

Complaints (Paragraph G.1(b))

One HREC received one complaint under the s95A guidelines during the reporting period. This HREC reported that a patient was ‘upset that the bariatric surgery registry was opt-out’. This patient was assisted in the process of opting out, and the rationale behind the registry and its consent process was outlined to them.

C. Discussion

During the reporting period, the number of research proposals for activities which involve the application of the s95 and/or s95A guidelines comprises 1.12% of the total number of proposals assessed by HRECs. As shown in **Table 7**, 18,768 new research proposals were reviewed by HRECs during the reporting period. Of these, only 211 proposals required application of the s95 and/or s95A guidelines. A comparison with previous reporting periods is also shown.

Table 7: Comparison with previous reporting periods – Number of proposals

Reporting period	Total proposals	Proposals reviewed which required the application of the Privacy Guidelines	
		Number	%
2015	**18,768**	**211**	**1.12**
2014	20,892	235	1.12
2013	24,882	184	0.74
2012	26,257	255	0.97
2011	25,022	171	0.68
2010	23,696	158	0.67
2009	22,306	128	0.57
2008	21,087	97	0.46
1 July – 31 Dec 2007	10,664	24	0.23
2006/2007	21,928	54	0.25
2005/2006	21,589	96	0.44

Table 8 shows that approximately one-in-five HRECs (19%; n=41) reviewed proposals or activities which may have required the application of the s95 or s95A guidelines.
A comparison with previous reporting periods is also shown.

Table 8: Comparison with previous reporting periods – Number of HRECs required to apply the Privacy Guidelines

Reporting period	Total HRECs	HRECs which reviewed proposals which may require application of the s95/s95A Guidelines	
		Number	%
2015	**212**	**41**	**19.3**
2014	217	41	18.9
2013	218	33	15.1
2012	225	38	16.9
2011	227	33	14.5
2010	222	27	12.2
2009	221	31	14.0
2008	232	31	13.4
1 July – 31 Dec 2007	225	20	8.9
2006/2007	238	30	12.6
2005/2006	230	32	13.9

Appendix A: Recording and monitoring of decisions – s95 Guidelines

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00100	Australian Institute of Health and Welfare; Medicare	Given name; surname; date of birth; date of death; sex; state of residence; cause of death; year of registration; state of registration; Residential Medication Management Review; Follow-up service provided by a practice nurse or Aboriginal and Torres Strait Islander health practitioner; Provision of monitoring and support for a person with a chronic disease by a practice nurse or Aboriginal and Torres Strait Islander health practitioner; Allied Health Services for Chronic Disease Management; Group Allied Health Services for patients with Type 2 Diabetes; Allied Health Services for Indigenous patients who have had a health check; Multi-channel ECG monitoring and recording during exercise; Selective coronary angiography; Endovascular Interventional Procedures (PCI); Echocardiography (includes exercise and pharmacological stress echocardiography); General Practitioner Attendance Items; Other non-referred attendances to which no other item applies – Group A2; Specialist Attendances to which no other item applies – Group A3; Consultant Physician Attendances to which no other item applies – Group A4; General Practitioner After-Hours Attendances to which no other item applies – Group A22 of Professional Attendances; Cardiac catheterisation; Coronary Artery Bypass; financial year; state and LHD; Medicare Local/Primary healthcare network; Australian Government Department of Health funded status; Age group (10 year) - From 20 years of age; gender; Indigenous status - Voluntary Indigenous Identifier (VII); Bill type - Cheque to Claimant; Cheque to Provider via Claimant; Cash; PCe (Easyclaim Patient Claim); Simplified Bill; EFT; and Bulk Bill; Provider type (public/private); Provider type (hospital/other)	4.5 million per year
	Medicare	Reimbursement for PBS and MBS; health care costs incurred by individuals	258,490
	Australian Institute of Health and Welfare	Project person number; weight of matched pair; warning flags for the match pair; death status; date of death; cause of death	14,805,827
	Medicare	Hospital visits; primary care visits and medications; out of hospital investigations	160 maximum
	Health Round Table	Following hospital adverse events; pressure areas; pneumonia; delirium; UTIs	20,000

[1] This table lists agency names as reported by HRECs and these may be different to the formal agency names.

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00100	Australian Institute of Health and Welfare	Mother's date of birth; other parents' date of birth; baby's date of birth; Aboriginality; Torres Strait Islander; date of registration; year of registration; sex of baby; stillbirth flag; birth order; age of other parent; age of mother; postcode; plurality; Age at onset (years); Sex; Indigenous Status**;Country of Birth; Language spoken at home; Condition Notified; Site of infection; Person Deceased?; Condition caused person's death?; Symptom onset date; Symptomatic; Date first notified; Date of notification; Date of onset; Date notification received; Specimen date; Type of specimen; Notifier; Method of identification; Laboratory confirmed?; Laboratory testing method; State of disease acquisition; Place of disease acquisition; Postcode of disease acquisition; Admitted to hospital?; Hospital of admission; Hospital admission date; Hospital separation date; Occupation; High risk occupation; Postcode of residence; Statistical Local Area of residence; Local Health District of residence; Number of vaccine doses received; Case immunised?; Vaccination status; Vaccine; Vaccine validation; Vaccine dose date; vaccine validation (partial); Vaccine dose date (partial); Reason not vaccinated; Reason not vaccinated (other specify); Vaccine (other); date of birth; date of death	50,000
	Australian Institute of Health and Welfare; Department of Health	Date of death; all causes of death; medications relating to the cardiovascular system; medications relating to the nervous system; drugs used in diabetes; antithrombotic agents	3,328
	Australian Institute of Health and Welfare	30 day readmission; 30 day mortality; length of stay	16,182
	Australian Institute of Health and Welfare	Death status; cause of death; date of death; location of death; cancer diagnosis; cancer type; date of diagnosis	2,900
	Australian Institute of Health and Welfare; Department of Human Services	Address; name; sex; date of birth; postcode; date of death; cause of death	750,000
	Australian Institute of Health and Welfare; Department of Health	Cancer status; full name; date of birth; sex; postcode; date of diagnosis; age at diagnosis; basis of diagnosis; topography; histology; breast tumour size; date of death; all causes of death; date of invitation; date of participation; screen result; reason for non-participation; date of vaccination; age at vaccination; vaccination type; clinical completion status; vaccination status; vaccination completion date; vaccination program; Medicare number	20,000,000

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00103	Australian Institute of Health and Welfare	1. Pooled Cohort Data – Age, Year of birth, Sex, Income, Education, Occupational status, Ethnicity, Country of origin, Date of baseline assessment, Main language spoken at home, Dietary intake, Smoking status, Physical activity, Menopause status, Oral Contraceptive use, Date participant entered the study (age), Parity, Weight, Height, Body Mass Index (BMI), Waist circumference, Hip Circumference, Australia (ARIA), IRSD- Index, Diabetes related variables: (Diabetes status, Duration of diabetes, Insulin levels, Family history of diabetes, Treatment, Self-reported diabetes, Fasting Plasma Glucose, 2 hour plasma levels, HBA1C levels), Hypertension related variables: (Systolic BP, Diastolic BP, BP Treatment, History of HT, LDL levels, HDLs, Triglycerides, Total cholesterol), Other: (Prior cancer history, Family history of cancer, Cholesterol treatment, History of cardiovascular disease, Use of health professionals/health services utilization, Renal parameters: microalbuminuria, estimated glomerular filtration rate (EGFR)) 2. Australian Cancer Database – Date of cancer diagnosis, Age of cancer diagnoses (in 5 year age group), ICD-10 disease code, ICD-O-3 topography code, ICD-O-3 morphology code, Most valid basis of diagnoses, Socio-Economic Index for Areas (in deciles) at diagnosis mapped from postcode at diagnosis, IRSD- Index of relative socioeconomic advantage (in deciles) at diagnosis mapped from postcode at diagnosis, Accessibility/Remoteness Index of Australia (ARIA) at diagnosis mapped from postcode at diagnosis 3. National Death Index – Vital status flag, Underlying and additional causes of death, Date of death, Age of death (in 5 year age group), Socio-Economic Index for Areas (in deciles) at death–mapped from postcode of death, IRSD- Index of relative socioeconomic advantage (in deciles) at death mapped from postcode of death, Accessibility/Remoteness Index of Australia (ARIA) at death– mapped from postcode of death	80,000
	Australian Institute of Health and Welfare	1. National Diabetes Service Scheme (NDSS) (from 2004 onwards) – Postcode, Date of Birth (Month/Year), Indigenous status, Country of birth, Diagnosis date, Diabetes type, Date of first insulin injection 2. National Death Index (NDI) – Date of Death, Underlying cause of death, Other causes of death	20,000

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00103	Australian Institute of Health and Welfare	NDSS variables – Indigenous status, Sex, Country of birth, BMI, Date of birth, Language spoken at home, State at time diagnosed, Country at time of diagnosis, Date of death, Date of diagnosis, Diabetes treated by (diet, exercise, tablets), Diabetes type, Initial diagnosis approx dates, Last HBA1c, NDI match applied, NDI match probability, Registrant Height, weight, Registration date, Status of NDSS, Status reason code, Type of health professional, Concession card type. Postcode will be coded into ARIA and SEIFA. All variables related to GDM – GDM consent, GDM expiry date, GDM start date, GDM history (date of birth), GDM history (date of death), (GDM history) GDM treated by diet, (GDM history) GDM treated by insulin, Relative with diabetes All variables related to diabetes drug use – Date first insulin use, Date first non-insulin inject, Date pump therapy commenced, First insulin approx date, Insulin type pump, Non-insulin injectable allowed, Pump brand, Pump model, Type of injectable required, Diabetes type at time of sale. NDI Variables – Date of birth (estimated year of birth), date of death, sex, age at death, State/Territory of registration, code of underlying cause of death as well as other causes of death (in order). Part 1 and part 2 contributory causes of deaths. PBS/RPBS Variables – Unit record data on each matched NDSS registrant over a period of 13 years (2002 to 2014), divided into 6 month time periods. Data collected on diabetes; CVD including Hypertension, cancer, chronic kidney disease, Steroid and AD related PBS/RPBS items. ANZDATA variables – Date of birth, sex, Racial origin, State, Primary renal disease, Biopsy (y/n), Creatinine at entry, Country of birth, Co-morbid conditions at entry, last or Current (Chronic Lung, Coronary artery disease, Peripheral arterial disease, Diabetes, cerebrovascular disease), Cancer Ever, Cause of death, Date of death, Indigenous flag For all patients dialysed: type of dialysis, Epo agent, Ferritin, Current graft: date of this transplant, Number of rejection episodes this survey, donor source, age and sex, total ischemia, immediate function, disease in graft, date first, cause of graft failure proven Treatment type at entry and 12 months Treatment table at entry and 12 months Co-morbidity table; as described above information on Chronic Lung, Coronary artery disease, Peripheral arterial disease, Diabetes, cerebrovascular disease and other co-morbid conditions. Postcode will be coded into ARIA and SEIFA	1,200,000

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00103	Australian Institute of Health and Welfare	Pharmaceutical Benefit Scheme – Drugs Used in Diabetes Item No. Chemical Name 1531N Insulin Neutral Human, 1762R Insulin Neutral Human, 1713E Insulin Neutral Bovine, 1921D Insulin Glulisine, 9224L Insulin Glulisine, 8084L Insulin Lispro, 8212F Insulin Lispro, 8435Y Insulin Aspart, 8571D Insulin Aspart, 1533Q Insulin Isophane Human, 1761Q Insulin Isophane Human, 1711C Insulin Isophane Bovine, 1426C Insulin Isophane Human + Insulin Neutral Human, 1763T Insulin Isophane Human + Insulin Neutral Human, 2062M Insulin Isophane Human + Insulin Neutral Human, 8390N Insulin Lispro + Insulin Lispro Protamine, 8874C Insulin Lispro + Insulin Lispro Protamine, 8609D Insulin Aspart + Insulin Aspart Protamine, 9039R Insulin Glargine, 9040T Insulin Detemir, 1801T Metformin, 2430X Metformin, 3439B Metformin, 8607B Metformin, 9435N Metformin, 2440K Glipizide, 2449X Gliclazide, 8535F Gliclazide, 9302N Gliclazide, 2939Q Glibenclamide, 8450R Glimepiride, 8451T Glimepiride, 8452W Glimepiride, 8533D Glimepiride, 9059T Rosiglitazone + Metformin, 9060W Rosiglitazone + Metformin, 9061X Rosiglitazone + Metformin, 9062Y Rosiglitazone + Metformin, 8810Q Metformin + Glibenclamide, 8811R Metformin + Glibenclamide, 8838E Metformin + Glibenclamide, 5474D Vildagliptin + Metformin, 5475E Vildagliptin + Metformin, 5476F Vildagliptin + Metformin, 10038H Linagliptin + Metformin, 10044P Linagliptin + Metformin, 10045Q Linagliptin + Metformin, 10032B Alogliptin + Metformin, 10033C Alogliptin + Metformin, 10035E Alogliptin + Metformin, 10048W Saxagliptin + Metformin, 10051B Saxagliptin + Metformin, 10055F Saxagliptin + Metformin, 10089B Sitagliptin + Metformin, 10090C Sitagliptin + Metformin, 9449H Sitagliptin + Metformin, 9450J Sitagliptin + Metformin, 9451K Sitagliptin + Metformin, 2391W Simvastatin + Sitagliptin , 2377D Simvastatin + Sitagliptin , 2383K Simvastatin + Sitagliptin , 8188Y Acarbose, 8189B Acarbose, 8689H Rosiglitazone, 8690J Rosiglitazone, 8694N Pioglitazone, 8695P Pioglitazone, 8696Q Pioglitazone, 3415R Vildagliptin, 3387G Linagliptin, 2933J Alogliptin, 2944Y Alogliptin, 2986E Alogliptin, 8983T Saxagliptin, 9180E Sitagliptin, 9181F Sitagliptin, 9182G Sitagliptin, 10011X Dapagliflozin, 2873F Canagliflozin, 2987F Canagliflozin, 3423E Exenatide 3424F Exenatide. Medicare Benefits Schedule – Optometrical Services Schedule Item No. Medicare Service, 10914 Progressive disorder requiring comprehensive re-evaluation, 10915 Examination of the eyes of a patient with diabetes mellitus Extended Medicare Safety Net and EMSN capping specialist and consultant physician consultations Item No. Specialist Consultations , 104 Initial specialist consultation, 105 Subsequent specialist consultation, 106 Initial specialist ophthalmologist consultation, Medicare Benefits Schedule - Cycle of Care for Patients with Established Diabetes Mellitus, Item No. Medicare Service , 2517 Assess diabetes control by measuring HbA1c, 2518 Ensure that a comprehensive eye examination is carried out, 2521 Measured weight and height and calculate BMI, 2522 Measure blood pressure, 2525 Examine feet, 2526 Measure total cholesterol triglycerides and HDL cholesterol , 2620 Test for micro albuminuria, 2622 Provide self-care education, 2624 Review diet, 2631 Review levels of physical activity, 2633 Check smoking status , 2635 Review of Medication	2,000,000

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00103	Australian Institute of Health and Welfare	National Death Index – Date of death, coded underlying cause of death, coded other causes, state of death registration.	3,000
	Australian Institute of Health and Welfare	National Death Index (NDI) – Variables for linkage are surname, up to three given names, sex and date of birth. Variables for research purposes are fact of death, date of death, year of death registration, state/territory registration of death, underlying cause of death, and other or contributing causes of death.	150,000
	Australian Institute of Health and Welfare	1. Residential Aged care (RAC) data on the Aged and Community Care Management Information System (ACCMIS), Person project number/ linkage, Date of birth (mm/yyyy), Sex, Postcode of usual residence, Date of discharge from residential care, Date of admission to residential care, Leave start date, Leave return date, Postcode of residence, Postcode of residential aged care, Type of admission, Type of housing, Reason for leave, Reason for discharge, Postcode of residential care facility, State of usual residence, State of aged care facility, Dependency levels – high/low, Resident Classification Scale (RCS) items used to calculate RCS score, Data variables relating to situation prior to hospital admission 2. Aged Care Assessment Program National Minimum Dataset Where assessment status is shown as completed:, Person project number/ linkage key, Sex, date of birth (mm/yyyy), country of birth, postcode of residence, assessment dates, accommodation setting usual, living arrangements, current assistance with activities, activity limitations, first face to face contact setting, health condition , activity limitations, recommended long term care setting, recommended formal assistance with activities , information relating to carers, including: carer availability, carer living arrangement, carer relationship – main carer, carer relationship – other carers, information relating to approvals, including: emergency care, all variables relating to home care level 1 and 2 and approval dates, all variables relating to home care level 3 and 4 and approval dates, no care, all variables relating to residential care and approval dates, and transition care, previous use of services	198,000
	Australian Institute of Health and Welfare	National Death Index – Date of death, Cause of death, Age at death, Sex, State/Territory of registration	2,000

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00103	Australian Institute of Health and Welfare	ACD database elements – Person level attributes, Date of death, Age at death, Cause of death Tumour level attributes, State / territory of usual residence at diagnosis, Tumour identification number, Date of diagnosis, Age at diagnosis, ICD-O-3(a) topography code, ICD-0-3(a) morphology code, ICD-10(b) disease code, Most valid basis of diagnosis, Statistical local area at diagnosis, Postcode at diagnosis, Melanoma thickness, Tumour size Medicare (MBS) – MBS Item number (Items Numbers from the Medicare Benefits Schedule); Medicare benefit (Amount paid by the Government) ; Date of service (Date that the service was rendered by the provider); Date of processing (Date the service was processed by Medicare Australia); Date of referral (Date that the referral was written by the servicing provider); Hospital Indicator (Indication of whether or not the service was provided in hospital); Number of services, rendered or referred (count of valid services rendered or referred); Number of patients; and (count of distinct patients); and State of patient (address (at the time of claiming) of the patient to whom the service was rendered)	1,300
	Australian Institute of Health and Welfare	Medicare Benefits Schedule – Demographics: Month and year of birth, Sex, Patient area of residence, Indigenous status. Claim details: Date of service, Date of processing, Medicare item number, Item description. Cost details: Provider charge, Schedule fee, Benefit paid, Service type code. Service provider and referrer details: Scrambled rendering provider number, Rendering provider SLA, Hospital indicator, Provider specialty (MC_ASM_PRV_SPEC), Item category, Item group, Item subgroup. Created variables (created by AIHW DISC): Mobility indicator National Death Index – Month and year of birth, Date of death, Year of death registration, State/territory of registration of death Centrelink Income Assistance Data for Family Tax Benefit A (FTBA) for Maximum Rate customers – AIHW Unique child identifier, AIHW Unique customer identifier, Customer payment type (FTBA - max rate payments, Income Support Payments, Single Parent Payments, Disability Payments), Customer Payment date, Child month and year of birth, Child Gender	182,000
	Australian Institute of Health and Welfare	NDI – Date of death, Age at time of death, Whether a post mortem was/was not/is yet to be carried out, Post mortem code, Cause of death based on ICD codes	1,500
	Australian Institute of Health and Welfare	National Death Index – Fact of Death (FOD), Date of Death (DOD), Cause of Death (COD) - we understand the limitation where recent, within the last 18months, COD may not be available. Both underlying and all cause of death information.	541

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00103	Australian Institute of Health and Welfare	Records of interest are those for all patients aged 20 years and over who were provided a Medicare-rebatable service of interest (as listed in appendix 6 of the protocol) by a provider in NSW or ACT and All NSW or ACT residents aged 20 years and over who were provided a Medicare-rebatable service of interest by a provider outside NSW or ACT. This is to enable analysis by reverse catchment. Checklist for Medicare Benefits schedule (MBS) data Variables required for data linkage purposes only include – Full name, Full address, Sex, Date of birth, Date associated with record Variables to be provided to the project analysts/investigators – Financial year , State and LHD, Medicare Local/Primary healthcare network, Australian Government Department of Health funded status*, Age group (10 year) - From 20 years of age, Gender , Indigenous status, Bill type - Cheque to Claimant; Cheque to Provider via Claimant; Cash; PCe (Easyclaim Patient Claim); Simplified Bill; EFT; and Bulk Bill, Provider type (public/private) , Provider type (hospital/other) The variables listed above will be requested for the following MBS data items (see attached email from Medicare acknowledging this request) – 715-Health Assessment for Aboriginal and Torres Strait Islander People; 704, 706, 710 (pre May 2010); 701, 703, 705 and 707; 700, 702; 721, 723, 729, 731 and 732; 725, 727; 735, 739, 743, 747, 750, 758; 820 – 838; 900; 903; 10987; 10997; 10950-10970; 81100-81125; 81300-81360; 11712; 38300 to 38318; 55113, 55114, 55116 to 55119, 55120, 55122, 55123, and 55125; 3 to 51; 52 to 65; 99, 104-105, 107, 108, 113; 110, 112, 114, 116, 119, 122, 128, 131 to 133; 5000 to 5067; 38200, 38203 and 38206; 38497 to 38504 NDI records of interest are for people over 20 years of age who died in NSW or the ACT, or were residents of NSW or the ACT with any recorded diagnosis of cardiac disease as defined by the ICD-10-AM codes outlined above as an underlying cause of death or contributor to death. In addition, people of any age with an ICD-10-AM code of I00 to I02 – acute rheumatic fever, will be included. Variable checklist for National Death Index (NDI) dataset: Variables required for data linkage purposes only include – Full name, Full address, Sex, Date of birth, Date of death	100,000
	Australian Institute of Health and Welfare	**(Continued)** Variables to be provided to the project analysts/investigators – Date of birth- Year and month (To calculate 30-day and 12-month mortality rates), Date of death- Year and month (To calculate 30-day and 12-month mortality rates) , Sex- (Required for analysis by sex) , State of residence- (Extracted from address details. Required to capture deaths of NSW, ACT and Queensland residents who died interstate and to enable reverse catchment – data will be shared between NSW, the ACT and Queensland for residents of these respective jurisdictions), Underlying cause of death (ICD)- (To enable calculation of cardiac-related mortality rates), Other causes of death (ICD-10)- (To enable calculation of cardiac-related mortality rates),State of registration- (To allow analysis by state (location) of death)	100,000

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00103	Australian Institute of Health and Welfare	National Death Index (NDI) – Matching name, surname, sex, date of birth and state/territory to identify date of death and all causes of death.	2,500
	Australian Institute of Health and Welfare	NDI – Fact of death and date of death for patients in our cohort discharged alive from Canberra Hospital	856
	Australian Institute of Health and Welfare	NDI – Date of death, State/Territory of registration of death, All Causes of Death: Cause of death, Underlying cause of death (as ICD codes until 1996; as ICD10 since 1997), Codes for other (associated) causes of death (as ICD10 codes since 1997).	88,000
	Australian Institute of Health and Welfare	National Death Index file containing the ANZDATA identity number, Unique AIHW linkage id, Primary cause of death, and Associated causes of death	88,000
	Australian Institute of Health and Welfare	National Death Index (NDI) – Date of Death, Year of Death, State/territory the death was registered in, underlying cause of death code Medicare Benefits Schedule (MBS) – Date of referral, Date of Service, Item Category, Item Description, MBS Item Number Pharmaceutical Benefits Scheme (PBS) – Date of Prescribing, Date of Supply, Form Category, Item Description, PBS Item Code We will also be requesting the AIHW link the following external datasets: National HIV database, National AIDS registry	50,000
	Australian Institute of Health and Welfare	MBS – MBS Item number, MBS item description, date of service, hospital indicator PBS – Date of supply, Date of prescribing, PBS Item number, PBS item description, patient category, ATC code and ATC name NDI – fact of death, date of death, causes of death	6,000
	Australian Institute of Health and Welfare	ACD STANDARD VARS – Sex , State of cancer registration, Date of diagnosis, Date of diagnosis accuracy indicator, Age at diagnosis, Topography (ICD-O-3), Morphology (ICD-O-3), Site/type of Cancer (ICD-10), Most valid basis of diagnosis, Melanoma thickness (cutaneous melanomas), Size of tumour, Date of death*, Age at death , Age group at death, Underlying cause of death# (ICD-10) NDI vars – Sex, Date of birth, Date of death, State/territory the death was registered in, Year of death, Cause of death (ICD-10 since 1997), Other causes of death (ICD-10 since 1997) PBS vars – ATC, DDD, Date start, date stop for AEDs and all other prescribed medications during the study period	10,800

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00103	Australian Institute of Health and Welfare	The data requested from the NDI will be – PDC or PMRC Pseudo ID (assigned by State Health Departments, PMRCs or state data linkage units on their behalf); AIHW ID Number (IDNUM, a unique record identifier for your use); Link ID (if you have duplicate records relating to the same person); Sex; Date of birth (or month and year) / or year of birth; Date of death (or month and year) / or age in days at death an year of death; Postcode/SLA of usual residence; State/Territory of death registration; Death Status (specify D for deceased, if the person is known to have died from PDC or PMRC); Year the death was registered in; Underlying cause of death (ICD); Other causes of death (ICD); Race (Indigenous status - mother); Place of death; Mother's age at giving birth; Year of delivery; Professional type of the person who certified the death; The weight of the matched pair; Warning flags for the matched pair	750,000
	Australian Institute of Health and Welfare	National Death Index – Name, DOB, Address, Gender Data required: Vital status, Date and all cause of death	4,000
	Australian Institute of Health and Welfare	From the NDI, the following variables are requested – Sex, Date of birth, ATSI status, Marital status, Country of birth, Death status, Date of death, Year the death was registered in (NDI only), Underlying cause of death, Other causes of death From MBS – Date of enrolment, Date of service, Medicare item number, Provider charge, Schedule fee, Benefit paid, Patient out of pocket, Bill type, Scrambled rendering provider number, Rendering provider postcode, Hospital indicator, Item category, number of services rendered, de-identified Person ID, case number, Scrambled practice number, patient age at time of service, Postcode of residence of patient, gender, Indigenous status, year of birth, Data of registration in WA with Medicare	1,000,000
	Australian Institute of Health and Welfare	National Death Index (NDI) on participants from several Indigenous cohorts as outlined in the research objectives section: (i) personal identifiers (names, date of birth, state of death registration) to allow for clerical review of the matches, and (ii) NDI-ID, NDI-date of death, NDI-causes of death ICD codes (underlying & multiple contributory deaths), order of the causes of death from the death certificates.	4,110
	Australian Institute of Health and Welfare	National Death Index – The following variables are required: Death Status, Date of Death, State	3,000

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00103	Australian Institute of Health and Welfare	PBS – We are requesting data from the start of 2002 to most recently available, AIHW advice is that PBS data is not available prior to 2002. For each individual patient, we are requesting data from 5 years before the epilepsy diagnosis to current processing. Patients diagnosed from 2002 to 2006 will have less than 5 years pre-diagnosis data available - but in these cases we request as much pre-diagnosis data as is available. We are requesting pre-diagnosis drug information because sometimes epilepsy drugs are used for other disorders, and this may impact on seizure recurrence and other outcomes. We are requesting data for epilepsy medications (Anatomical Therapeutic Chemical Classification System [ATC] N03), psycholeptics (ATC N05) and psychoanaleptics (ATC N06). These three ATC groups are requested as seizure conditions may occasionally be treated with drugs outside the ATC NO3 group. Data requested for each of the ATC groups above: Prescribed drug ATC classification code or name for each drug, date of prescribing, specialty of prescribing doctor, number repeats, script type (new, repeat etc.), Supplied drug: ATC classification code or name for each drug, date of supply, strength & pack size.	2,100
	Australian Institute of Health and Welfare	1. Medicare and Pharmaceutical Benefits Scheme (PBS) – Full reporting range requested: 1/3/2012 - 31/12/2030. Data extraction requested for end of 2018 (for data 1/3/2012 - 31/12/2018) and 4 yearly thereafter (2022, 2026, 2030). Data items requested: a. Medicare: i. Date of service ii. Medicare item number: 3, 23, 36, 2546-2559, 2664-2677, 11503, 2700-2717, 2721 iii. Item description b. PBS: i. Date of supply ii. Date of prescribing iii. PBS item code: D04, D07, R03A, R03AC, R03AK, R03AL, R03BA, R03BB, R03BC, R03CA, R03CC, R03DA, R03DC, R03DX, R05, RO6, J01, J05, H02 iv. Item description 2. Australian Early Development Census (AEDC) – Data range requested: 2018 and 2021 AEDC results. Data extraction requested for end of 2021/as soon 2021 data available. Data items requested: a. AEDC physical health and wellbeing score b. AEDC social competence score c. AEDC Emotional maturity score d. AEDC Language and cognitive skills score e. AEDC Communication skills and general knowledge score 3. National Death Index (NDI) – Full reporting range requested: 1/3/2012 – 31/12/2035. Data extraction requested: 2025 (for data 1/3/2012 - 31/12/2025) and 2035 (for data 1/1/2026–31/12/2035).Data items requested: a. Year of death b. Primary cause of death	283,547
	Australian Institute of Health and Welfare	Australian Cancer Database – Only standard items will be required by the researchers for the analysis of the data, including: sex, age at diagnosis, date of diagnosis, ICD-O-3 topography code, ICD-O-3 morphology code, ICD-10 disease code, state/territory of usual residence at diagnosis, postcode at diagnosis, date of death and cause of death. Variables required for linkage include full name, sex, date of birth and address. National Death Index – Data required by the researchers for the analysis are date of death and underlying and other causes of death. Variables required for linkage include full name, sex, date of birth and State/Territory of registration.	500,000

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00103	Australian Institute of Health and Welfare	PBS variables – Month/Year of birth, Patient postcode, Pharmacy postcode, PBS Item Number, Item description, ATC code & name, ATC name Strength, Quantity supplied, Date of supply, Date of prescribing, Number of scripts, PBS Benefit, Patient category, Gross price, Original or Repeat prescription, Prescriber type by peer group, Scrambled provider number MBS variables – Medicare Item Number, Item description, Item category, Date of Service, Provider charge, Schedule fee, Benefit paid, Patient out of pocket, Scrambled rendering provider number, Date of referral, Hospital indicator, Provider specialty	650,000
	Australian Institute of Health and Welfare	National Death Index – The following variables are sought for the period 1982 to present (this list is consistent with the standard fields identified in the NDI Data Provision Package): The weight of the matched pair; Warning flags for the matched pair; Surname; First given name; Second given name; Third given name; Sex; Date of birth; Birth dummy flag; Date of last contact; Death status; Date of death; Death dummy flag; State i.e. State of residence at last contact; State the death was registered in; Year the death was registered in; ID number i.e. IDNUM; NDI ID; Underlying cause of death – ICD codes if cause is cancer-related. If death is from other causes, a general category of 'Other causes' would be sufficient.	40,000
	Australian Institute of Health and Welfare	National Death Index – The following variables are sought for the period 1982 to present (this list is consistent with the standard fields identified in the NDI Data Provision Package): The weight of the matched pair; Warning flags for the matched pair; Surname; First given name; Second given name; Third given name; Sex; Date of birth; Birth dummy flag; Date of last contact; Death status; Date of death; Death dummy flag; State i.e. State of residence at last contact; State the death was registered in; Year the death was registered in; ID number i.e. IDNUM; NDI ID; Underlying cause of death – ICD codes if cause is cancer-related. If death is from other causes, a general category of 'Other causes' would be sufficient.	40,000
	Australian Institute of Health and Welfare	NDI – Year and month of birth, Date of death, Sex, Country of birth, SLA of residence, Cause of death (ICD), Contributing Cause of death (ICD), Duration of residence in Australia, Month and Year of death registration, State of death registration MBS item numbers – Attendances 3, 20, 23, 24, 35, 36, 37, 43, 44, 47 & 51, 52-65. Specialist 104 & 105. Consultant Physician 110, 116 & 119, 132, 133. Professional attendances 721 to 732. Therapeutic procedures 13506, 30411, 30412, 30414, 30415, 30418, 30419, 30421, 30473, 30476, 30606. Operations 50950, 50952 Path Services 69445, 69475, 69478, 69481, 69482, 69483, 69484, 69488, 69491, 69499, 66512, 65120 PBS – 2437G, 2433C, 5606C, 5711N, 5712P, 5770Q, 5771R, 5772T, 5773P, 5774X, 9515T, 9516W, 9524G, 9525H, 9526J, 9527K, 9529M, 9530N, 9531P, 9534T, 9536X, 9538B, 9539C, 9540D, 9563H, 10200W	172,000

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00103	Australian Institute of Health and Welfare	The MBS and PBS data elements to be included in the linkage include: • PBS Item Number (Items Numbers from the Pharmaceutical Benefits Scheme); • PBS Benefit (Amount paid by the Government); • Original or repeat prescription (Original or repeat) [N.B., this is important for data checking]; • Date of supply (Date the prescription was supplied by the pharmacy); • Authority reason codes (but not for streamlined authorities); • Number of scripts; and (count of scripts); • MBS Item number (Items Numbers from the Medicare Benefits Schedule); • Medicare benefit (Amount paid by the Government); • Date of service (Date that the service was rendered by the provider); • Hospital Indicator (Indication of whether or not the service was provided in hospital); • Number of services, rendered or referred (count of valid services rendered or referred);	50,000
EC00106	Australian Institute of Health and Welfare; Department of Health	Department of Health: Medicare Benefits Schedule (MBS); Pharmaceutical Benefits Scheme (PBS). Australian Institute of Health and Welfare: National Death Index.	Department of Health: MBS 1996 to current; PBS 2002 to current. Australian Institute of Health and Welfare: National Death Index - not specified.

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00106	Australian Institute of Health and Welfare; Department of Health; Department of Veterans' Affairs	Department of Health: Medicare Benefits Schedule (MBS); Pharmaceutical Benefits Scheme (PBS); Residential Aged Care (RAC)/Aged Care Funding Instrument (ACFI); System for Payment of Aged Residential Care (SPARC) - Community Aged Care Programme (CACP); Extended Care at Home Programme (EACH); Extended Care at Home Dementia Programme (EACH-D); Home and Community Care (HACC) Minimum Data Set (MDS); Aged Care Assessment Program (ACAP). Department of Veterans' Affairs: Veterans Community Support Service; Veterans Home Care. Australian Institute of Health and Welfare: National Death Index.	Department of Health: MBS 1996 to current; PBS 2002 to current; RAC from 1998/ACFI until 2016; SPARC - CACP 1998 to 2016, EACH July 2003 to 2016, EACH-D March 2006 to 2016; HACC MDS 2003 to 2016; ACAP 2003 to 2016. Department of Veterans' Affairs: Veterans Community Support Service 1996 to 2016; Veterans Home Care 1996 to 2016. Australian Institute of Health and Welfare: National Death Index - not specified.
	Australian Bureau of Statistics; Department of Social Services	Australian Bureau of Statistics: Australian Health Survey; National Survey of Mental Health and Wellbeing; various labour force statistics. Department of Social Services: The Household, Income and Labour Dynamics in Australia (HILDA) Survey.	Australian Bureau of Statistics: Australian Health Survey - not specified; National Survey of Mental Health and Wellbeing - not specified; various labour force statistics - not specified. Department of Social Services: The Household, Income and Labour Dynamics in Australia (HILDA) Survey - not specified.
	Australian Bureau of Statistics	Australian Bureau of Statistics: Culturally and Linguistically Diverse Population data including country of birth, ancestry, religious affiliation, year of arrival and main languages spoken at home.	Australian Bureau of Statistics: Culturally and Linguistically Diverse Population data - not specified.
EC00109	Australian Hearing[2]	Name, date of birth, hearing thresholds, hearing devices, presence of disabilities, and contact details. These extracted data will be used to confirm eligibility for the study and to invite families of individual children to participate in the study.	Estimated at 250 records.
EC00145	Australian Electoral Commission	Titles, names, mailing addresses, email addresses and/or telephone numbers, age and gender of randomly selected citizens from the electoral roll/AEC in order to recruit participants to the Citizen's Juries with the necessary location, age and gender balance. We will not use the information in any other way.	Approx 450 records
EC00153	Australian Institute of Health and Welfare; Department of Health	Mortality Data, Hospitalisation data, Disease registration	14,600,000

[2] As this is a non-Commonwealth agency, the data is not required to be reported to NHMRC under the reporting obligations of the s95 guidelines.

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00153	Department of Health	HRN, Demographics, Pre Hospital Care, In hospital care, in hospital events, medications pre hospital, in hospital and on discharge	3,700-3,750
	Australian Bureau of Statistics; Department of Health; Australian Coordinating Registry[3]	ABS Death registration data for NT 1989-2006 and ABS death registration data for Australia 1985-2006; ACR death data for NT 2007–2012 and for Australia 2007–2012; ABS death registration data for NT 1967-1988; ABS death registration data for Australia 1967-1984; Australian population data for the period of 1967-2012; and NT population data 1967-2012 collated by Health Gains Planning. The population datasets will be sourced from the ABS.	34,400 NT 5,600,000 Australia
	Department of Health	Age, sex ,cancer diagnosis and staging	120-180
	Australian Bureau of Statistics; Department of Health	Name, HRN, DOB, date when sample collected, location of collection	350-400
	Department of Health	Demographics of patient, age, locations, Indigenous status, tumour size, unifocal multifocal, grade of cancer, type of cancer, presence of lymphovascular invasion, Receptor status- ER, PR and Her-2, nodal metastasis and distant metastasis	400
	Department of Health	Demographics; comorbidities and underlying risk factors; disease; treatments; treatment intent; time to disease progression; time to death or lost to follow-up; uptake, attendance and compliance to radiotherapy	3,600
EC00197	Department of Human Services	Name and Medicare number	1,000
EC00213	Australian Health Professionals Registration Authority	Mandatory notification database and case notes including: All collected data will be re-identified and data to be extracted are: Division in which the nurse is registered; Place of work; Demographic characteristics of the nurse; Type of incident reported such as medication error or patient injury; Day and time the incident occurred; Precipitating factors that occurred before the reported incident; Fishbone analysis of reported incident-precipitants, environment, model of care, work processes; Detailed description of reported incident; Findings of the hearing panel; and Conditions imposed by the panel particularly regarding nursing restrictions on registration.	1,400

[3] As this is a non-Commonwealth agency, the data is not required to be reported to NHMRC under the reporting obligations of the s95 guidelines.

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00227	Australian Institute of Health and Welfare	Data collected will relate to hospital admissions and stay; relevant diagnosis and care provided, (cardiac procedures/interventions); discharge information; & personal identifying information to accurately link records with existing records in the project. This includes name, sex, date of birth, date of death and other causes of death (as per ICD 10 codes)	400-600 in total across all sites
EC00238	The Royal Women's Hospital Melbourne IVF database[4]; Births, Deaths and Marriages Victoria (see footnote 4)	Results of tests, information related to surgical procedures, treatment and fertility preservation discussions and procedures, attempted IVF procedures, results regarding hormone function, reproductive function post treatment	109
	Births, Deaths and Marriages Victoria (see footnote 4)	Age at death, Cause of death (including whether death was classified as SCD) from the death certificate	400
	Victorian Neural Tube Defects Register (VNTDR) (see footnote 4)	Each patient's basic data information at the "Ascertainment tier"– name, VNTDR identifier, hospital number, date of birth, diagnosis and (if applicable) date of death (but no contact details or further medical information)	100
	Djerriwarrh Health Services (DjHS) (see footnote 4)	DOB, details of pregnancy, details of birth, paediatric growth details, developmental milestones, early developmental concerns, general development, medical investigations completed, medications, general health details, language and skill information, summary of the results from clinical assessment (e.g., autism diagnostic classification, cognition, language, and communication skills) as well as information about early development and clinical diagnoses.	120
	Murdoch Children's Research Institute (see footnote 4)	Archival diagnostic tissue, patient details including name, date of birth, age at time of tissue sampling and basic clinical details (lesion features, associated lesions or syndromes, family history of similar lesions, any treatment undertaken).	50
	Victorian Clinical Genetics Service (VCGS) (see footnote 4)	Prenatal cytogenetic data from amniocentesis and CVS, first and second trimester serum screening results, NIPT results from VCGS (percept™ prenatal test), Postnatal cytogenic sample results including Products of Conception (POC) and newborn karyotype results	50,000

[4] As this is a non-Commonwealth agency, the data is not required to be reported to NHMRC under the reporting obligations of the s95 guidelines.

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00240	Australian Institute of Health and Welfare; Australian Electoral Commission; Department of Health	Medical Benefits Scheme (MBS): items no, item description, data of service, hospital indicator. Pharmaceutical Benefits Scheme (PBS): data of supply, date of prescribing, item no, item description, patient category, ATC code and name. National Death Indicator (NDI): fact of death, date of death, causes of death. Australian Electoral Commission: names, sex and DOB	5,500-6,000 (2,759 + 3,124)
EC00247	Australian Institute of Health and Welfare	The AIHW conducted the earlier linkage of the cohort to cancer and death records from 1985-2007*. The data has a unique patref number, assigned originally by DOHA, that bears no systematic relation to the Medicare number. This number allows linkage of the de-identified Medicare records to a file of cancer and death data that has been indexed by AIHW using the same patref number. The researchers will receive information in DE-IDENTIFIED form only.	Approximately 11 million
EC00262	Department of Health	Archived patient records.	20 records
EC00263	National Coronial Information System[5]	The project will seek information pertaining to socio-demographics of the deceased persons, circumstances surrounding death, and toxicology reports.	The project will access all opioid related closed cases between the years 2008–2012.
EC00268	Department of Human Services	Australian Childhood immunisation Registry - Date of Birth, most recent Medicare listed postcode and jurisdiction of residence, sex, indigenous status, commercial names and dates of all administered vaccines	300,000 records accessed to determine 10,000 controls for 1000 cases

[5] As this is a non-Commonwealth agency, the data is not required to be reported to NHMRC under the reporting obligations of the s95 guidelines.

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00278	Australian Electoral Commission; The Hospital Morbidity Data System; The WA Cancer Registry[6]; Midwives Notifications; RBDM	Study ref P2145: The WA Electoral Roll – The Electoral Roll is used to define the cohort. All women on the Roll (excluding silent electors) in 1988 will be included and those who join the roll each year after that until 1st January 2012 will also be included. Flags for those who have left the state and moved off the roll will be used to determine periods at risk. For women who have no other information, the midpoint of their 5-year year-of-birth category will be used to estimate age and postcode will be used (where possible) as an indicator of socioeconomic status. The Hospital Morbidity Data System – hysterectomy including whether they had a concurrent salpingo-oophorectomy; insurance status; diagnosis codes; salpingo-oophorectomy; oophorectomy or salpingectomy including among women who had a prior or subsequent hysterectomy and those who did not; hip fracture; admissions prior to 1982 for a diagnosis of one of the specified cancers (as the cancer registry only has data from 1982); tubal ligation/sterilisation. The WA Cancer Registry – data on all diagnoses of ovarian, fallopian tube, primary peritoneal, breast, colorectal, renal cell and thyroid cancers between 1982 and latest available for the women in the Electoral Roll cohort. Midwives Notifications – the numbers of births that included women have had, including any births women may have had before age 18 years (before joining the Electoral Roll). Birth Registrations – information from this data set about births that individual women had before the MNS began in 1980. PI has requested this information going back to 1950 and understands that the linkages for this time may be incomplete. They will conduct sensitivity analyses to estimate the effects of missing birth information on their study estimates. Death Registrations – these data will be used to identify women included in the Electoral Roll cohort who have died and their causes of death.	The WA Electoral Roll – The Electoral Roll is used to define the cohort. All women on the Roll (excluding silent electors) in 1988 will be included and those who join the roll each year after that until 1st January 2012 will also be included. The Hospital Morbidity Data System – hysterectomy & hip fracture (1970 to most recent) - separate codes for hysterectomy and oophorectomy are only available between 1979 and 2008; insurance status; diagnosis codes; salpingo-oophorectomy; oophorectomy or salpingectomy including among women who had a prior or subsequent hysterectomy and those who did not; admissions prior to 1982 for a diagnosis of one of the specified cancers (as the cancer registry only has data from 1982). The WA Cancer Registry – data on all diagnoses of ovarian, fallopian tube, primary peritoneal, breast, colorectal, renal cell and thyroid cancers between 1982 and latest available for the women in the Electoral Roll cohort. Midwives Notifications – matched numbers depending on total obtained from Electoral Roll as stated above. Birth Registrations – information from this data set about births that individual women had before the MNS began in 1980. PI has requested this information going back to 1950 and understands that the linkages for this time may be incomplete. They will conduct sensitivity analyses to estimate the effects of missing birth information on their study estimates. Death Registrations – these data will be used to identify women included in the Electoral Roll cohort who have died and their causes of death from 1988 until the most recently available date.

[6] As this is a non-Commonwealth agency, the data is not required to be reported to NHMRC under the reporting obligations of the s95 guidelines.

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00302	Australian Institute of Health and Welfare	Survival information i.e. death date and cause	1-50
	Australian Institute of Health and Welfare	Date of death	1-50
EC00304	Australian Institute of Health and Welfare	State, Age, sex, hospital remoteness classification, care type, admission month, admission year, admission mode, separation month, separation mode, length of stay, same day flag, urgency of admission, principal diagnosis, additional diagnosis, procedure codes, block, external cause codes, external cause activity	2001–02 to 2012–13
	Department of Human Services	Medicare Benefits Scheme: date of service, Medicare item number, item description, provider charge, schedule fee, benefit paid, patient out of pocket, hospital indicator, item category	2007–2013
	Australian Institute of Health and Welfare; Department of Human Services	Medicare: Full historical address information, full name, sex and date of birth. AIHW: full name, sex, date of birth and address, date of death and cause of death.	1984-2014
EC00337	Australian Institute of Health and Welfare	Cancer database: Date of diagnosis, Age at diagnosis, Cancer type, Topography, Morphology, Best basis of diagnosis.	Not provided - national study
	Australian Institute of Health and Welfare; Department of Health	Australian Cancer Database: all diagnoses of cancer from 01/07/2002 until 30/06/2013, excluding women with a prior diagnosis of invasive cancer from 1982 to 30/06/2002. Requested data fields cover demographics, diagnosis details, and tumour characteristics. PBS and Medicare Registrations: data on supply of any scripts for metformin and other diabetes medications (for comparison)3, statins and other cholesterol-lowering drugs (for comparison) and hormones and chemotherapy drugs, for comparison and adjustment for confounding, from 01/07/2002 to the date of linkage (estimated mid-2015); Requested fields cover Medicare registration details and dispensing details for each script. National Death Index: all deaths of women in the study cohort from 01/07/2002 until the date of linkage (estimated mid-2015).Requested fields cover date/cause of death and age at death.	Not specified

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00337	Australian Institute of Health and Welfare; Department of Health	MBS (by category): Category 1 Attendances; Category 2 Diagnostic Procedures; Category 3 Therapeutic Procedures; Category 6 Pathology Services; Category 8 Miscellaneous Services (Group M3-Allied Health Services, Group M12- Services provided by a Practice Nurse or Aboriginal and Torres Strait Islander Health Practitioner on behalf of Medical Practitioner, Group Ml- Management of Bulk billed services, Group M6-Psychological therapy services, Group M7-Foccussed Psychological strategies, Group M9-Allied Health Group Services, Group Mll- Allied health services for Indigenous Australians who have had a health check, Group M14- Nurse practitioners) PBS (by Body System): A Alimentary Tract and Metabolism- Drugs used in diabetes (AlO); B Blood and blood forming organs: Antithrombotic agents (BOl); C Cardiovascular System; N Nervous System	3,391
	Australian Institute of Health and Welfare; Department of Health; Department of Human Services	Surname, given names, date of birth, sex, postcode	5 million
EC00366	Department of Veteran's Affairs	DVA administrative health claim data. Analysis of DVA records of veterans for specific period, including age, gender, past medical history, medication history and other relevant variables as described above to achieve study objectives	Depends on eligible cases in DVA dataset, number of records involved to be confirmed on data extraction
EC00410	Australian Institute of Health and Welfare	Project Person Number; Weight of the matched pair; Warning flags for the match pair; Death status (D); Date of death (date, month, year); Underlying cause of death (ICD-9/ICD-10); Other causes of death (ICD-9/ICD-10); Medicare data(MBS, PBS)	NDI: Approx. 140,000 deaths per annum; xvii. MBS: Approx. 13,000,000 records; xviii. PBS: Approx. 920,214 records
EC00422	Australian Institute of Health and Welfare	Mortality ID unique record identifier; First name; Middle Name; Surname; Sex; Date of birth; Date of death; Year of registration; State of registration; SLA of usual residence; Age at death; Underlying cause of death; Additional causes of death	229,000
	Australian Institute of Health and Welfare	Full Name; Sex; Date of birth; Postcode; Address; Date of death; Cause of death	Approx. 600,000

HREC	Item 1: Commonwealth agencies from which information was sought[1]	Item 2: Data items sought from the Commonwealth agencies and approved by the HREC	Item 3: Number of records involved
EC00422	Australian Institute of Health and Welfare	Date of supply; Date of prescribing; PBS item code; Item description; Patient Category; Patient Contribution; Net benefit; ATC Code; ATC Name	380,000
EC00448	National Coronial Information System[7]	Injury & mortality data	Over 40,000 records

[7] As this is a non-Commonwealth agency, the data is not required to be reported to NHMRC under the reporting obligations of the s95 guidelines.

Appendix B: Recording and monitoring of decisions – s95A Guidelines

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00100	Menzies Research Institute; Victorian private clinicians	Age at diagnosis; gender; cancer site; TNM-T, -N and -M stage; staging basis; derived stage; Gleason score	10,300
	Mater Mother's Private Hospital QLD	Pregnancy and birth outcomes: onset of labour; mode of birth; major maternal pregnancy and birth complications including antepartum haemorrhage, preeclampsia, gestational hypertension, diabetes; maternal admission to intensive care; antenatal diagnosis of fetal growth restriction; stillbirth; neonatal death; causes of neonatal death and stillbirth; gestation at birth; birth weight; fetal growth restriction; major congenital abnormality; Apgar Score at 5 minutes; umbilical artery pH; intubation and ventilation at birth; hypoxic ischemic encephalopathy; neonatal seizures; Meconium Aspiration Syndrome; use of mechanical ventilation; neonatal death; reason for admission to nursery; onset of labour; mode of birth; ARDRG data on the birth episode	258,490
	National Stroke Foundation; ANZ Hip Fracture Registry	Hospital name; hospital state; medical record number; date of birth; gender; care pathway; hospital admission; date and time of symptom onset; stroke assessment; patient history; thrombolysis; hospital separation; discharge and medication; pain management; surgery; mobilisation and medication	16,182
	Ted Noffs Foundation	Demographic information	4,500
EC00113	Chris O'Brien Lifehouse	Patient characteristics, Tumour characteristics, Treatment details, Responses, Toxicity	40
	Chris O'Brien Lifehouse	Date of Birth, Sex, immunosuppression, Tumour characteristics, Histopathology results, Disease status, surgical and adjuvant therapies, patient outcomes	450
	Chris O'Brien Lifehouse; Melanoma Institute Australia	Clinical data, Radiation treatment planning data, Treatment set up data, Type of treatment, Type of relapse, date of death	80 records
	Chris O'Brien Lifehouse	Patient characteristics, Image guided radiotherapy markers, radiotherapy dose, tumour data, toxicity, outcomes	300-400
	Chris O'Brien Lifehouse	Patient characteristics, radiotherapy dose, toxicity data, outcomes - performance status, date of death, cause of death, relapse	40

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00113	Chris O'Brien Lifehouse	Patient characteristics, chemotherapy regime, adverse events, biochemical data, outcome data, date of death, last follow-up	10
	Chris O'Brien Lifehouse	Patient characteristics, disease characteristics, treatment characteristics	40
	Chris O'Brien Lifehouse	Intensity modulated radiation therapy dosimetric information - dose prescription and dose reporting, patient characteristics	150 records
	Chris O'Brien Lifehouse	Patient characteristics, clinical information- medications, co-morbidities, MRI scan data15	15
	Chris O'Brien Lifehouse	Lactation abscess formation, recurrence, patient demographics	109
EC00118	Local General Practices (GPs)	Demographics; comorbidities; fracture history; cause of renal disease; usual medications; management of kidney disease; biochemistry; survival; receipt of renal replacement therapy	1-50
	Local General Practices (GP)	Physical health diagnosis; interventions, treatment; medication; last episode of contact	1-50
	Community pharmacies: Health Advice Pharmacy, North Ryde NSW Cincotta Chemist, Five Dock, NSW; Blooms Chemist, Balmain, NSW; Cincotta Chemist, Burwood, NSW	Was a hospital medication list received at discharge (Y/N); were there medication changes made and if so what were they.	1-50

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00145	ACA Health Benefits Fund; CDH Benefits Fund; CUA Health Limited; Defence Health Limited; Doctors' Health Fund; Transport Health Pty Ltd; Frank Health Insurance; GMF Health; GMHBA Limited; Health Care Insurance Limited; health.com.au; Health Insurance Fund of Australia Limited; Latrobe Health Services; Mildura Health Fund; Navy Health Ltd; National Health Benefits Australia Pty Ltd (onemedifund); Peoplecare Health Insurance; Phoenix Health Fund Limited; Police Health; Queensland Country Health Fund Ltd; RACT Health Insurance (under GMHBA after 31 May, 2015); Reserve Bank Health Society Ltd; St. Lukes Health; Teachers Health Fund; TUH	The data will include a random identity key for each participant, so multiple hospital admissions can be matched. The data will be presented as admission records, which will include: Health insurance fund member/Patient ID (anonymised); Date of the admission; Length of stay; Patient age in years; Patient gender; Anonymised ID of the admitting hospital or other institution type; Anonymised ID key of the health care professional, such as the surgeon that performed a procedure; Anonymised ID key of the health insurance fund that the patient was a member of; Diagnoses codes related to the patient's admission, coded in the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (or earlier), Australian Modification (ICD-10-AM); Procedures that were performed on the patient, coded in the Australian Classification of Health Interventions (ACHI), the Diagnosis Related Grouping (DRG) and the Medical Benefits Schedule number; Medical, prostheses and hospital benefits billed to the insurance fund.	The data set has over one million hospital admission records and approximately 700,000 individuals.
EC00153	Amoonguna Health Clinic; Ampilatwatja Health Centre Aboriginal Corporation; Katherine West Health Board; Laynhapuy Homelands Association; Ltyentye Apurte (Mpwelerre); Malabam Health Board; Marthakal Homeland; Miwatj Health; Mutitjulu Health Service; Ngalkanbuy Health Service; Pintupi Homelands Health Service; Sunrise Health Service; Urapuntja Health Service; Utju Health Service; Western Aranda Health Aboriginal Corp	Hospital admissions by clinic; Primary care utilisation; Medical retrievals by clinic; Expenditure by clinic and per capita; Primary care staff turnover, stability and median length of stay; Outreach visits - nature and cost; Proportion of diabetics with a chronic disease management plan; Proportion of eligible adults with an annual Adult Health Check; Proportion of diabetics with proteinuria on appropriate renal protective medication; Proportion of patients with cardiac disease on aspirin; Timely antenatal care; Pap smear coverage; immunisation coverage; proportion of children screened for anaemia; Preventable admissions to hospital by clinic; Proportion of known diabetics with blood sugar controlled (HbA1C<7%); Proportion of known hypertensives with controlled blood pressure; Mortality estimates by location	280-300

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00153	Central Australian Aboriginal Congress (CAAC); Sunrise Health Service; AMSANT	Electronic Health Records	900-1,000
	Western Diagnostic Pathology; AMSANT	Serology results from 1998 to April 2015: HBcAb, HBsAg, HBsAb; Name; DOB; HRN; Sex; Address	60,000
	CareFlight NT	Age; Ethnicity; Demographics; Date and time of bite; Clinical signs and symptoms and treatment	104
	Wurli Wurlinjang; Katherine West Health Board Aboriginal Corporation; Central Australian Aboriginal Congress	Demographic Variables: name, sex, date of birth, residential community/suburb, HRN, Indigenous status. Pregnancy related variables: Gestational status (estimated starting date), birth order. STI Testing variables: Test name, test date, clinic name, laboratory, test results, past history of syphilis infection (date of infection and treatment date and details)	1,300
EC00155	Central Australian Aboriginal Congress	Patient Management Data	100
EC00161	Greenslopes Private Hospital; John Flynn Private Hospital; Pindara Private Hospital; Cairns Private Hospital; St Andrews Private Ipswich	Personal details such as name, DOB, postcode, family history, Healthcare Provider, Diagnosis date, PSA level details, Tumour details, clinical management, relapse/recurrence, follow-up	Ongoing as this is a registry
EC00171	Genomics Research Centre	Clinical symptoms, diagnostic sequencing results, age, gender	1-900
EC00172	Sullivan Nicolaides Pathology	Pathology tissue samples	24 samples
	Mater Hospital Brisbane; Barwon Health University Hospital, Geelong	Clinical records and pathology results - diagnosis of influenza	50
	Private pathology organisations e.g. Sullivan Nicolaides Pathology	Diagnosis of Hereditary Haemochromatosis - on basis of serum ferritin and HFE C282Y homozygote	300 in total over three states, i.e. 100 in the State for which this HREC approved the study
EC00197	Repromed	Polycystic ovarian syndrome status, antral follicle count	1,000
EC00203	Private hospitals and clinicians	TNM tumour stage at diagnosis including prognostic indicators that contribute to derivation of this stage; namely T-stage, N-stage. M-stage, basis of stage (clinical/pathological or both) and Gleason score and PSA score.	Approx. 1,000

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00203	I-Med MIA Monash Radiology	Participant name, date of birth, breast density, breast volume, individual radiation dose, breast compression	3,000
	Victorian private hospitals and clinicians	Tumour stage at diagnosis (TNM or other stating scheme as appropriate to the tumour type) including prognostic indicators that contribute to derivation of this stage	Approx. 1,000
	Private radiology services	Date of MRI done, type of MRI imaging phases used, number of suspicious lesions seen, on MRI prostate, PI-RADs score assigned for each suspicious lesion, location of suspicious lesion/cancer within the prostate, evidence of cancer spread to seminal vesicles and evidence of enlarge lymph nodes in pelvis seen on the MRI prostate, involvement of cancer seen in distal urethral sphincter, evidence of extra capsular extension seen on MRI prostate	1,400 - 2,000
EC00208	Barwon Health[1]	Patient clinical records	Data for patients who attended the Cachexia & Nutrition Support Service at Barwon Health from 2008 to present will be collected
	Barwon Health (see footnote 1)	Emergency presentation data: Patient UR number, name, date of birth, date of admission, emergency presentation diagnosis and departure status	1,307 records
	Barwon Health (see footnote 1)	Demographics, breast cancer and colorectal diagnosis, treatment management, recurrence, outcomes, death	2,000 records
	Barwon Health (see footnote 1)	Sex, age, BMI, blood pressure, fasting (glucose, insulin, triglycerides and cholesterol), haemoglobin A1c, history of either anti-diabetic or anti-hypertensive medication, history of heart disease, echocardiography data	Approx. 2,000 records
	Barwon Health (see footnote 1)	Demographic information, clinical information, reason for admission, length of stay, whether there was a MET call during the admission and how soon the MET call was before discharge, diabetes-related care delivered during the admissions, whether specific information is documented about post discharge diabetes management	Approx. 65 records

[1] As this is a non-private sector organisation, the data is not required to be reported to NHMRC under the reporting obligations of the s95A guidelines.

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00208	Barwon Health (see footnote 1)	Demographics, diagnosis, injured hand, dominant hand, date of injury/surgery/discharge, number of appointments, pain, grip strength, pinch strength, infection, time in splint, line of work, valued occupations, smoker, diabetes	200 records
	Barwon Health (see footnote 1)	Demographics, presence and completion of a completed Barwon Health Alert Summary Resuscitation and Management Goals Form, completion of a patient centred care patient satisfaction survey	200 - 300 records
	Barwon Health (see footnote 1)	Demographics, presence and completion of a completed Barwon Health Alert Summary Resuscitation and Management Goals Form, completion of a patient centred care patient satisfaction survey	- [2]
	Barwon Health (see footnote 1)	Demographics, medical information, length of stay, discharge status, investigations undertaken, IV fluids delivered, medications given and prescribed on discharge, interpreter costs, re-presentation to ED or re-admission to hospital, overall costs of admission, referrals made on discharge	A maximum of 120,000 records
	Barwon Health (see footnote 1)	Birth date, age, prognostic scores, previous chemotherapy and response, status of remission, survival, histology of lymphoma and markers	Approx. 150 records
	Barwon Health (see footnote 1)	Name, date of birth, UR number, date of diagnosis, interim PET scan and MRD assessment, MIPI score	Approx. 15 records
	Barwon Health (see footnote 1)	Demographics, diagnosis, symptoms, current psychiatric treatment, identified risks, number of previous admissions, recent stressors/documented antecedents, substance use history, social status, contact with police, recent contact with health services, triage urgency category, mode of referral, time of day, recent discharge	400 records
	Barwon Health (see footnote 1)	Demographics, insertion date, indication, side, intended removal date, stent size, date of removal presence of stent-related complications, stent encrustation	Approx. 200 - 300
	Barwon Health (see footnote 1)	Demographics, date of presentation and diagnosis, mode of presentation, symptoms, duration of symptoms, family history and complications of coeliac disease, associated autoimmune conditions present, coeliac antibody blood test results, histopathology results, whether compliant with gluten free diet	120 records

[2] Data not reported.

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00208	Barwon Health (see footnote 1)	Demographics, ventilator data, surveillance algorithm data, antibiotic data	50 - 100 records
	Barwon Health (see footnote 1)	Patient age, duration of admission, type of heart failure, treatment, heart rate on discharge	Patients coded with an ICD code for Exacerbation of CCF between January and June 2015
	Barwon Health (see footnote 1)	Patient medical records	Approx. 10 - 15 records
	Barwon Health (see footnote 1)	N/A - samples are cadaveric (see footnote 2)	(see footnote 2)
EC00242	The Avenue, Peninsula Private, Waverley Private, Wangaratta Private and Warringal Private hospitals	Bariatric surgery clinical quality registry information	11,615
	The Avenue Private hospital	Medium term follow-up of patients with symmetrical luminal dilatation after laparoscopic adjustable gastric banding	80
EC00262	Oceanic Medical Imaging	Patient database	600 records
EC00263	Joondalup Health Campus	Information will be collected relating to the documentation of care of peripheral intravenous catheters from medical records, including medical and nursing notes.	Approximately 100 records will be accessed to obtain a sample size of 50 patients with peripheral intravenous catheters.
EC00266	Hollywood Private Hospital; SKG Radiology; Uropath	Patient age; PSA; MRI scan report, including PI-RADS score; Prostate biopsy and/or whole mount specimen pathology report	400
EC00267	Western Diagnostic Pathology	Blood culture isolate data, patient demographics	~700
	Joondalup Health Campus	Patient demographics, procedures during admission, length of stay	~50
	Joondalup Health Campus	Patient demographics, co-morbidities, outcomes following treatment, subsequent hospitalisation and treatment, survival.	5-10
	Joondalup Health Campus	Patient demographics, medication usage pre-, during and post-hospitalisation, medical history.	~200
	Joondalup Health Campus	Patient demographics, procedure, post-procedure feeding, length of hospital stay, complications, nutrition	~150

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00267	Joondalup Health Campus	Patient demographics, medication, investigations, mortality, recurrence.	~60
	Joondalup Health Campus	Patient demographics, hospital admission date, diagnosis	6
	Joondalup Health Campus	Hospital admission details, eating and medication details, blood glucose record, type of diabetes.	50-70
	Joondalup Health Campus	Patient demographics, pregnancy status, time of referral, ED examination and working diagnosis, admitting team tests and referrals, discharge date and diagnosis.	~120
	Joondalup Health Campus	Patient demographics, diagnosis, treatment, discharge planning and community support.	~1,000
	Joondalup Health Campus	Integrated progress notes, Nursing Care Plan, skin assessment, Emergency Department assessment, intravenous therapy chart, blood transfusion/products chart, National In-patient Medication Chart	~100
	Joondalup Health Campus	Patient demographics, diagnosis, time in department, consultations received, disposition and representation +/- pathology information.	100-200
	Joondalup Health Campus	Patient demographics, cognitive assessment, osteoporosis risk factors, biochemistry, medication	~150
	Joondalup Health Campus	Patient demographics, post-operative analgesia, pain and mobility, length of stay.	~50
	Joondalup Health Campus	Patient demographics, cognitive assessment, medications, fall incidents	~150
	Joondalup Health Campus	Patient demographics, surgical outcomes (complications, morbidity, mortality), treating hospital and surgeon, length of stay and readmission.	0-50
	Joondalup Health Campus	Patient demographics, fracture details, osteoporosis diagnosis and treatment/referrals.	100-150
	Joondalup Health Campus	Patient and obstetric demographics, medical conditions, risk factors, food allergies and vaccinations.	~500
EC00270	Private cardiology laboratories	Echocardiogram results	500-600
EC00286	SJG Hospitals in Bunbury, Subiaco, Mt Lawley & Murdoch	Patient demographic data, hospital, chemotherapy & surgery treatment details, histology at time of surgery, co-morbidities	Approx. 55

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00286	SJG Subiaco Hospital	Patient demographic data, disease free survival and specific survival details, date of recurrence & treatment of recurrence.	6-10
	SJG Hospitals in Ballarat, Bendigo, Berwick, Bunbury, Geelong, Geraldton, Mt Lawley, Murdoch, Subiaco, Warrnambool	Patient demographic data	Approx. 1,500 per annum
	SJG Subiaco Hospital	Patient age at time of diagnosis, stage of disease, details of any surgery & any adjuvant treatment, co- morbidities & recurrence of disease, and how this correlates with immunohistochemical profile of the tumours.	4
	SJG Subiaco Hospital, SJG Murdoch Hospital & SJG Pathology	Patient age at time of diagnosis, comorbidities, ECOG performance status, smoking status, hormone replacement therapy pre &/or post treatment, surgical reports, histopathology reports, chemotherapy regime, oncological outcomes.	200
	SJG Subiaco Hospital	Patient demographic data, diagnosis, treatment, radiological response to chemotherapy, blood test results, any cancer recurrence and date and cause of death where applicable.	30-40
	SJG Hospitals in Subiaco & Murdoch	SJG Patient Colorectal Cancer Database data transfer to national database.	2,000
	SJG Subiaco Hospital	Patient demographic and treatment details as discussed at MDT meetings.	Approx. 130
	SJG Subiaco Hospital	Patient demographic data, medical history, serum tumour maker levels, imaging, operational reports, pathology & doctor correspondence.	12
	SJG Subiaco Hospital	Patient demographic data, medical & surgical history, operation records, pathology results & doctor correspondence.	15
	SJG Subiaco Hospital	Patient demographic data, medical & surgical history, operation records, pathology results & doctor correspondence.	20
EC00302	Calvary Health Care Adelaide Hospitals	Demographics and medical information	1-50
	Calvary Health Care Adelaide Hospitals	Demographics and medical information	1-50
EC00315	Telethon Kids Institute	Western Australian Aboriginal Child Health Survey Data and Infant, child and youth mortality database	637,000

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00332	Mater Health Services Brisbane	Medical Charts; Medical Databases[3]	500
	Mater Health Services Brisbane	Medical Database (see footnote 3)	~100,000
	Mater Health Services Rockhampton	Medical Charts; Medical Databases (see footnote 3)	2,000
	Mater Health Services	Medical Charts (see footnote 3)	294
	Mater Health Services Brisbane	Medical Charts; Medical Databases (see footnote 3)	~500
	Mater Health Services Brisbane	Medical Database (see footnote 3)	60
	Mater Health Services Brisbane	Medical Database (see footnote 3)	4,050
	Mater Health Services Brisbane	Medical Database (see footnote 3)	200
	Mater Health Services Brisbane	Medical Charts; Medical Databases (see footnote 3)	1,200
	Mater Health Services Brisbane	Medical Databases (see footnote 3)	200
	Mater Health Services Brisbane	Medical Charts (see footnote 3)	500
	Mater Health Services Brisbane	Medical Charts (see footnote 3)	1,000
	Mater Health Services Brisbane	Medical Charts (see footnote 3)	30
EC00336	Relationships Australia in Tasmania (RATas)	Standard Client/Community Outcome Reporting (SCORE) Relationships Australia Client Satisfaction Evaluation Form Age, sex, relevant client history and presentation	Approximately 8,000 per year, over a 10 year period
EC00337	Hobart Private Hospital; Calvary Hospital	Diagnosis of lung cancer	Not specified
	Calvary Hospital; Hobart Pathology	St John's Hospital - name, sex, date of birth, post code, date of diagnosis, diagnosis, treatment regimen (including autologous stem cell transplantation and bridging to allogeneic transplant rates; complications) and survival. The exact numbers of cases treated through St John's Hospital is unknown, but is likely to be less than 10. Hobart Pathology - histological subtype.	Records from 2003 -2013

[3] NHMRC will seek further information on data items in future reporting periods.

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00337	Launceston Eye Institute	Date of birth; visual outcomes; use of intravitreal avastin; visual acuity pre and post op; post op complications	Range of 2000 - 2014
	From GP practices in the northwest of Tasmania that have 4th year medical students on rotation in them (15 practices)	Discharge summaries	110
	Ballawinne Road, Lindisfarne; Bishop Davies Court, Kingston; Bupa South, South Hobart; Corumbene Nursing Home, New Norfolk; Glenview Community Service, Glenorchy; Hawthorn Village, Blackmans Bay; Presbyterian Care Tas, Warrane; Snug Village, Snug; Southern Cross Care Rosary Gardens, New Town; St Ann's, Hobart; St Ann's, Old Beach; United Age Well Lillian Martin, Mornington; Uniting Age Well Queenborough Rise, Sandy Bay; Uniting Age Well Rosetta Community, Berridale; Huon Eldercare, Huonville.	The management of persistent pain in residents of ACFs in southern Tasmania All residents within the RACF at time of visit. Patient Code; RACF Code; DOB; Date of data collection; Sex; Weight; Height; Current palliative care patient?; Does the patient currently have a syringe driver?; Able to communicate in English language?; Any communication problems (e.g. dysphasia, deafness)?; Any swallowing difficulties?; Cognition score (if on file, record type of assessment and score); How ambulant is the resident?; Medical history; Medication allergies; Medication list; Medication Strength Direction If as required number of doses per week; For as required analgesics, how many additional doses/day; Was a pain scale used for this resident in the last week?; How many times was the patient's pain score recorded in the medical notes?; Does the pain have a diagnosed cause?; No What location(s) was the pain?; What did the nursing staff do?; Were any other notes made in relation to the patient's pain or pain management?; Current amount of physical activity (minutes per week), if recorded; Type/intensity of activity; Lab and test results (if available).	800
	Hobart Private Hospital; North West Private Hospital	Family history, provider details (healthcare provider identifier), diagnosis date, assessment at diagnosis (PSA level, biopsy results, tumour size, histology results, tumour type), clinical management details (surgery, radiotherapy, ADT, chemotherapy, other systemic therapies, other treatments, watchful waiting, active surveillance)	Not specified
	Launceston Eye Institute	Age, sex, treatment type (epiretinal membrane peel surgery alone or combined with cataract surgery), date of operation, surgical complications (perioperative and post-surgery), visual acuity and macular thickness at several time points (prior to surgery, 3 months post, 1 year post and final visit).	Nine year period of all patients eligible

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00337	Calvary health; Tasman Spine Launceston	Data to be extracted from patient records and the KEOPS database used at Tasman Spine includes: Demographic information - patient age, sex, follow-up period; The primary diagnosis/indication for surgery; Surgical information - date of surgery, primary or revision surgery, staged or unstaged surgery, use of posterior fixation, use of anterior plate, graft details, cortical screw details regarding number used and size, levels fused, salvage techniques utilised in event of failure of intraoperative cortical screw use, immediate complications; Complications -end-plate breach, graft subsidence at 3 months, loss of position, revision fixation required; Radiographic information - fusion rates, pre-operative and follow-up sagittal balance; Patient reported outcomes - pre-operative Visual Analogue Scale, follow-up Visual Analogue Scale, pre-operative Oswestry Disability Index, follow-up Oswestry Disability Index, pre-operative SF-12, follow-up SF-12 Additional data to be extracted from patient records at St Luke's Hospital (Calvary Health Care) includes: Additional demographic information - height, weight, body mass index, comorbidities, smoking status; Additional surgical information - operation time, operative blood loss.	99
	National Stroke Foundation	Data collected from the NSF will be in line with the Stroke Medical Record Review form	1,800 (across six sites)
EC00410	Lifehouse Australia; Genesis Cancer Care; Riverina Cancer Care	Pathology data items	Approx. 270,000 cases between 1997-2013
	Sydpath[4]; RPA (see footnote 4); PathWest (see footnote 4)	Person identification number (PID), Identifiers, name code, date of birth, postcode, sex, country of birth, date of test, Phylogenetic data (multiple records), date of test, HIV sequence	800
	TED Noffs Foundation Client Dataset	Referral/Admission details, Demographic Info, Substance Use, Risk of Blood Borne Virus, Treatment history and motivation etc.	4,500

[4] As this is a non-private sector organisation, the data is not required to be reported to NHMRC under the reporting obligations of the s95A guidelines.

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00422	WA Melanoma Advisory Service (WAMAS); St John of God Hospital	Age; Gender; Melanoma histopathology; ethnicity; body site; lymph node involvement; metastasis; further surgery; mortality	25
	Western Australian Aboriginal Child Health Survey (WAACHS), Telethon Kids Institute WA; Infant, Child and Youth Mortality Dataset, Telethon Kids Institute	Natural/birth mother; Separations from current carer or birth mother; Smoking and drugs used in pregnancy; Duration breastfeeding; Household mobility; Health Conditions; Hearing; Speech; Breathing; Mobility; Functional Limitations; Use of hospital and other services; Day care and learning; CARER 1; Aboriginal culture; Education; Employment; Financial strain; Income; Parent/caregiver health; Parent Caregiver use of alcohol and tobacco; Forced separation of children; Functioning family; Problems with police and the law; Stressful life events; Housing and accommodation; Housing conditions; How far away is the local doctor or AMS; How far away is the local hospital; How long does it take to get to the hospital in an emergency; How happy are you with your access to services/facilities; Cause of Death code	5,289

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00422	Florey Institute of Neuroscience and Mental Health; Australian Stroke Clinical Registry	Project specific AuSCR registrant ID; Hospital State; Full Date of Birth; Gender; ATSI status; Country of Birth; Language spoken; Interpreter needed; ARIA code – Hospital; SEIFA code – Registrant; AuSCR (dummy) Hospital Id; AuSCR Episode ID; Full Date of Arrival; Date of Arrival – Accuracy; Full Time of Arrival; Time of Arrival – Accuracy; Full Date of Stroke; Onset Date of Stroke; Onset – Accuracy; Time of Stroke Onset; Time of Stroke Onset – Accuracy; Full Date of Admission; Date of Admission – Accuracy; Time of Admission; Time of Admission – Accuracy; Transfer from another Hospital; Stroke occurred while in Hospital; Able to Walk Independently on Admission; Documented Evidence of a Previous Stroke; Treated in Stroke Unit; Type of Stroke; Use of TPA; Cause of Stroke; ICD10 code – Diagnosis; ICD10 code - Medical Condition; ICD10 code – Complications; ICD10 code – Procedures; Date of Discharge Known; Full Date of Discharge; Date of Discharge – Accuracy; Discharge Destination; Discharged on an antihypertensive agent; Evidence of Care plan on Discharge if discharged to the community; Patient Deceased; Date of Death - source hospital; Date of Death Accuracy - source hospital; Activity Status; Completion Status NDI variables (obtained from the National Death Index): Date of Death – source NDI; Underlying cause of death – source NDI; Other causes of death – source NDI Follow-up variables: Year of admission; Follow Up Status; Number of attempts to contact registrant; Comments regarding contact attempts; Follow Up Created Date Time; Follow Up Modified Date Time; Follow Up Id Follow-up questions: Where are you staying?; Do you live on your own?; Have you had another stroke?; Have you been admitted to hospital?; What was the reason for your admission? EQ-5D questions: Which statement best describes your mobility?; Which statement best describes your self-care?; Which statement best describes your usual activities?; Which statement best describes your pain or discomfort?; Which statement best describes your anxiety or depression?; What number between 0-100 best describes your health today?; Other questions Would you like to speak to someone about support services?; Would you be willing to be contacted about future possible research?; Is this a telephone interview?; Who completed this interview? (i.e. was the interview completed by a proxy)	7,783

HREC	Item 1: Private sector organisations from which information was sought	Item 2: Data items sought from the private sector organisations and approved by the HREC	Item 3: Number of records involved
EC00422	St John of God Ambulance Data collections	Off stretcher times Ramping Diversions	Unstated
EC00445	Sydney Retinal and Day Surgery	Patients information including gender, age, date of birth, diagnosis, vital signs, physical examination, vision record, macular scans, micriperimetry results, medical and treatment histories, visit numbers	50 patients
	The Financial Services Council (FSC)	Details about insurance applications will include: Applicant ID, Application date, Year of birth, Gender, Smoking status, Cover description (death cover, disability income, total or partial disablement, trauma and crisis cover), Disorder name (e.g. polycystic kidney disease), Gene name, Test name, Date of test, Result description (e.g. carrier unaffected, negative, positive affected), Underwriting description (e.g. standard underwriter decision, deferred X years, permanent premium loading of Y%, standard, alternate product type, exclusion, declined).	At least 2,000 records