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 2016 to 31 December 2016

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RESEARCH

Background

ORIMA Research was commissioned to design and conduct the 2016 annual reporting survey on behalf of NHMRC. The information collected provides an annual overview about the activity of Human Research Ethics Committees (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 2016 – 31 December 2016

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 during the reporting period from 1 January 2016 to 31 December 2016.

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

A. Number of HRECs

During 2016, 214 HRECs were registered with NHMRC, and 210 HRECs submitted an annual report on their activities to NHMRC (see **Table 1**). The four HRECs that did not submit annual reports have since advised NHMRC that they closed during 2015. There were 215 HRECs in the previous (2015) reporting period, of which 212 submitted an annual report.

Table 1: Reportable HRECs by Jurisdiction

Jurisdiction	Number of HRECs
Victoria	60
New South Wales	53
Queensland	40
Western Australia	20
South Australia	20
Australian Capital Territory	12
Northern Territory	3
Tasmania	2
Total	**210**

B. HREC membership

The minimum membership of an HREC is eight members, as 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’.

Sixteen HRECs (8%) reported that they did not meet the minimum membership requirements during the reporting period. Issues identified were:

- No layman (n=3);
- No laywoman (n=1);
- Only one member with knowledge of, and current experience in, the areas of research regularly considered by the HREC (n=4);
- No members with knowledge of, and current experience in, the professional care, counselling or treatment of people (n=3);
- No members who perform a pastoral care role in a community (n=2); and
- No lawyer (n=3).

Additional membership

In addition to representation from the minimum membership categories, other members appointed to HRECs during the 2016 reporting period were identified by HRECs as representing the following categories:

- Aboriginal and Torres Strait Islander representatives;
- Academic representatives;
- Back-up or proxy members;
- Consumer representative and consultant;
- Departmental and institutional representatives;
- Deputy Chair;
- Donor (bone marrow);
- Executive representatives (e.g. Board members, CEO, Director);
- Ex-officio members;
- Graduates (medical and health);
- Health service representatives;
- Medical professionals (e.g. clinicians, medical and general practitioners);
- Member appointed to a pool of inducted members with current research experience (National Statement 5.1.31);
- Member experienced in reflecting on and analysing ethical decision-making (National Statement 5.1.32);
- Member with the expertise necessary to enable the HREC to address the ethical issues arising from the categories of research likely to be considered (National Statement 5.1.33);
- Person with a disability;
- Student representatives or trainees;
- Sub-committee Chair;
- Support staff (e.g. secretary, coordinator, executive officer, administrative staff); and
- Members with expertise in:
  - Aboriginal and Torres Strait Islander research;
  - Bio-statistics;
  - Clinical psychology;
  - Clinical trials;
  - Coaching;
  - Diagnostic services;
  - Ethics (medical, research and bio-);
  - Information technology and security;
  - International development;
  - Mechanical engineering;
  - Medical administration;
  - Mental health;

- Moral psychology and moral deliberation;
- Nursing;
- Patient safety;
- Pharmacology;
- Pharmacy;
- Psychiatry;
- Quality and risk management;
- Reproductive health;
- Statistics; and
- Tissue typing.

During the reporting period, just over one-quarter of HRECs (26%; n=54) 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 paragraph 5.1.29(b) states that, as far as possible, at least one-third of HREC members should be from outside the institution for which the HREC is reviewing research[1]. Thirteen HRECs (6%) 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. The rationale for this guidance is that decision making may be affected in situations where there is a significant imbalance in either direction. It is recognised that this may be difficult to attain. Therefore, NHMRC considered instances in which there was at least an 80:20 gender imbalance as significant and requiring attention. Five HRECs (2%) reported a male: female or female: male ratio of greater than or equal to 80:20.

C. Administration and general operation of the HREC

Terms of reference and procedures

During the reporting period, all but eight HRECs (96%; n=202) indicated that their Terms of Reference met the requirements of National Statement 5.1.27. The remaining HRECs reported that their Terms of Reference were either awaiting approval, or will be revised in 2017 to comply with the requirements.

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[1] This includes members who have no affiliation, connection or relationship with the institution for which the HREC is reviewing research.

Almost all HRECs (98%; n=205) also reported that their Standard Operating Procedures supporting the operations of the HREC met the requirements of National Statement 5.1.37. The remaining HRECs (2%; n=5) reported that:

- While the HREC requires researchers to ensure that research projects are conducted in accordance with the National Statement and relevant guidelines, researchers have not been required to report annually to this HREC (National Statement 5.1.37(n)) without specific request, and the HREC is currently arranging for the procedure for reporting and handling adverse events to be documented (National Statement 5.1.37(o)); or
- Their Standard Operating Procedures have since been revised to comply with the requirements, and are awaiting review or approval.

Record keeping and reporting

Out of the 210 HRECs, 195 (93%) reported that the HREC had considered new[2] research proposals during the 2016 reporting period. All 195 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 5.2.23-5.2.27.

During the reporting period, all but two HRECs (99%; n=193) 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[3] level of the organisation(s) (79%; n=153), followed by the provision of minutes of HREC meetings to the management[4] level of the organisation(s) (60%; n=115).

Under one-in-five HRECs (16%; n=31) cited other reporting mechanisms, including:

- Regular meetings with management to provide updates and discuss any areas of concern;
- HREC refers issues to an advisory council as required;
- HREC Chair provides updates and reports to management in meetings and as required;
- Management representative attends and observes HREC meetings;
- Management representative is an ex-officio committee member;
- Executives are provided with project records for review prior to providing institutional approval;
- Executive committee established to discuss ethics and governance issues;
- Regular reports are provided to a central oversight ethics committee;
- Regular reports are provided to various levels of the executive body; and

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

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

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

- Agendas, minutes, submissions, and approvals are stored in a secure clearinghouse for information and through a smartsheet database directly accessibly by management.

The two HRECs which did not have an established reporting mechanism between the HREC and the institution(s) to which it is accountable reported that:

- Quarterly reporting was in the process of being established; and
- New reporting mechanisms were established following an organisational merger.

Use of the National Ethics Application Form

The National Ethics Application Form (NEAF) was developed as a web-based tool to enable researchers of all disciplines to complete research ethics proposals for submission to HRECs, and to assist HRECs to consistently and efficiently assess these proposals. The NEAF was decommissioned on 30 June 2017 and has been replaced with the Human Research Ethics Application (HREA). Information on HREA can be found on the NHMRC website.

During the 2016 reporting period, four-in-five HRECs (80%; n=156) reported that they accepted the use of the NEAF for some or all submissions. Of these HRECs:

- 46 HRECs (29.5%) required the use of the NEAF for all submissions;
- 46 HRECs (29.5%) required the use of the NEAF for some submissions; and
- 64 HRECs (41%) did not require the use of NEAF for submissions.

D. HREC meetings

Among the 195 HRECs that considered new research proposals during the reporting period, 37% (n=73) 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 five HRECs (96%; n=117) 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 these views were recorded and considered. Reported reasons as to why the absent members did not have an opportunity to contribute their views prior to a decision being reached included:

- There was a vacancy in a minimum membership category;
- Where there was a vacancy in the category ‘person with knowledge of, and current experience in, the professional care, counselling or treatment of people’, the committee felt able to proceed as several other members had current experience in this area;
- The absent member was extremely ill and was unable to communicate with the committee;
- Low level applications were considered out of session; and

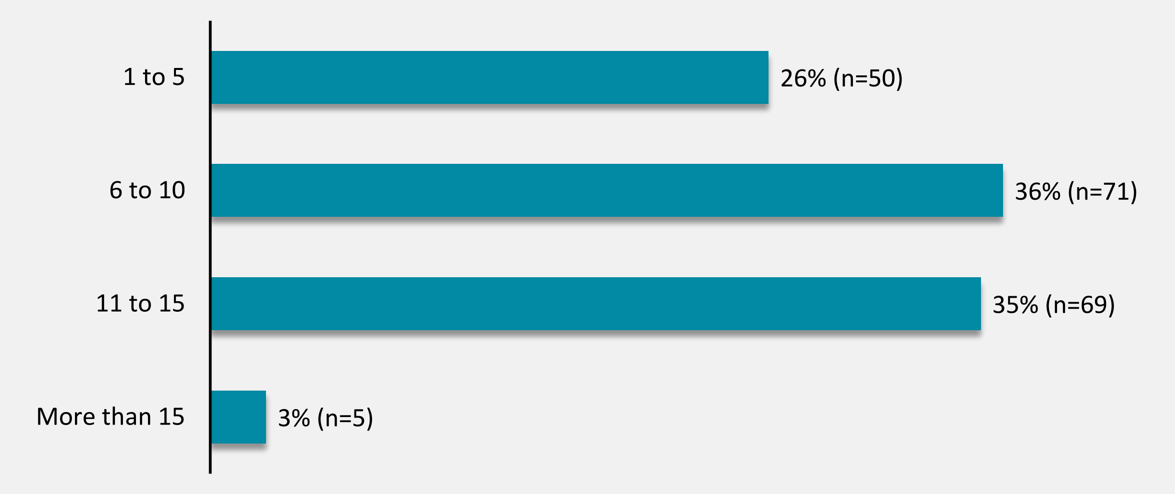
- Incoming members attended meetings as observers, prior to officially joining the committee.

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 2016

Base: HRECs that considered new research proposals during the reporting period (n=195)



The majority of HRECs (97%; n=190) reported that they had between 1 and 15 meetings during the 2016 reporting period. The maximum number of meetings held by any one HREC during the reporting period was 83 (n=1). This HREC also reported a total of 22 HREC members, with 596 new research proposals considered during the reporting period.

E. Training

During the reporting period, just over three-quarters of HRECs (77%; n=161) indicated that one or more members participated in training relevant to their work on the HREC (not including induction training). The requirements for HREC member training are included in paragraphs 5.1.28(b)(ii) and 5.2.3(c) of the National Statement.

Around two-in-three HRECs (67%; n=140) reported that all new members were provided with induction training (as per paragraph 5.1.28(b)(i) of the National Statement). Just under one-quarter of HRECs (23%; n=49) 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 18,039 new[5] research proposals considered[6] during the 2016 reporting period. Of these, 193 proposals were denied ethics approval.

Table 2 shows the number of research proposals considered by HRECs from 2011 to 2016. 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	2016
Total number of new research proposals **considered**	25,022	26,257	24,882	20,892	18,768	18,039
Total number of new research proposals **approved**[7]	23,283	24,540	22,551	19,134	17,056	16,191
Percentage of new research proposals **approved**	93%	93%	91%	92%	91%	90%
Highest number of proposals **approved** by a single HREC	1,341	1,344	885	1,223	1,270	880
Number of HRECs that accepted[8] the ethics approval of an external HREC	139	140	137	126	111	113

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[5] 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.

[6] ‘Considered’ refers to the consideration of research proposals by the full HREC (see 5.1.6 of the National Statement).

[7] ‘Approved’ refers to proposals that were either approved upon initial review or after re-consideration in this reporting period.

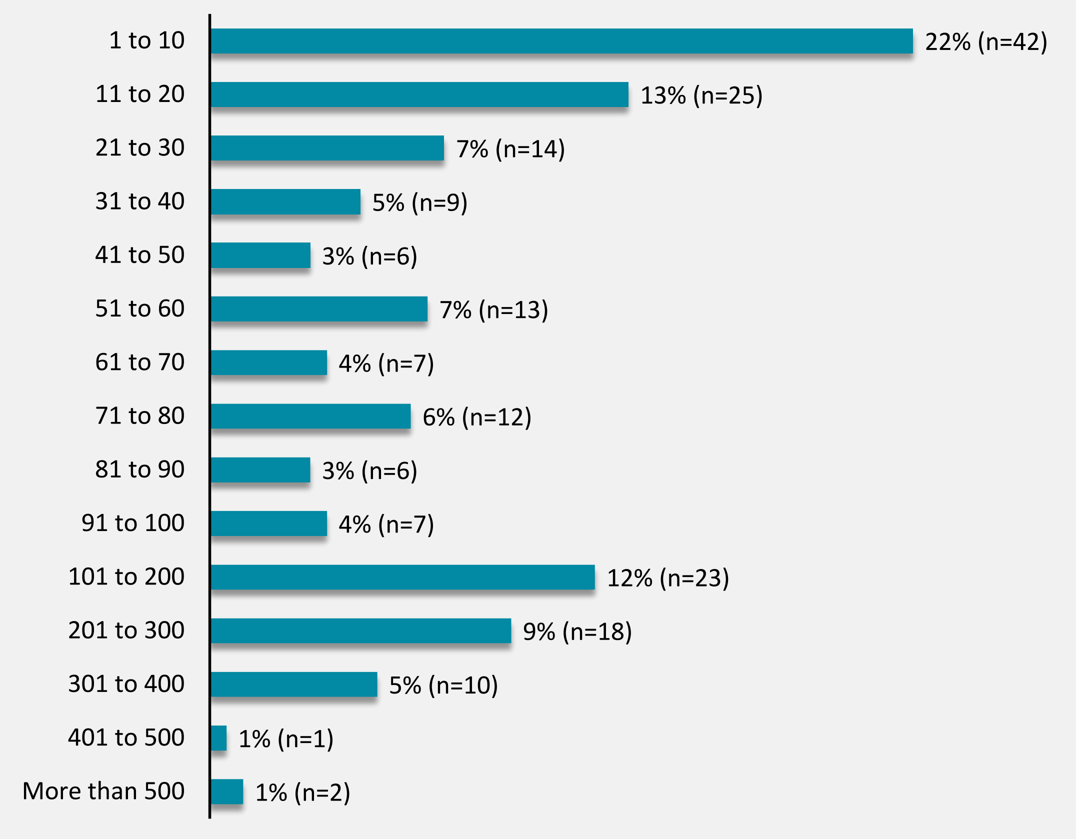
[8] ‘Accepted’ refers to accepting once or on multiple occasions.

The distribution of the number of new research proposals considered by HRECs during the reporting period is shown in **Figure 2**.

The highest number of new research proposals considered by any single HREC during the reporting period was 880 (n=1), and the lowest number was 1 (n=3). The HREC that reported considering 880 proposals met 11 times and comprised a pool of 20 members.

Figure 2: Number of research proposals considered by HRECs in 2016

Base: HRECs that considered new research proposals during the reporting period (n=195)



Types of research proposals considered by HRECs

In the 2016 reporting period, 127 HRECs (65%) considered a total of 2,155 new clinical trial[9] research proposals. In the previous reporting period (2015), 2,505 research proposals involving clinical trials were considered.

Six HRECs (3%) considered proposals involving the use of human gametes (eggs or sperm) or excess Assisted Reproductive Technology (ART) embryos during the reporting period.

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[9] The World Health Organization defines a clinical trial as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventional research that is not related to the prevention, diagnosis, treatment or management of a health condition should not categorised as a clinical trial, even if it includes randomisation or has other methodological attributes of a 'trial'. Additionally, not all clinical research proposals qualify as clinical trials.

G. Health research involving Aboriginal and Torres Strait Islander peoples

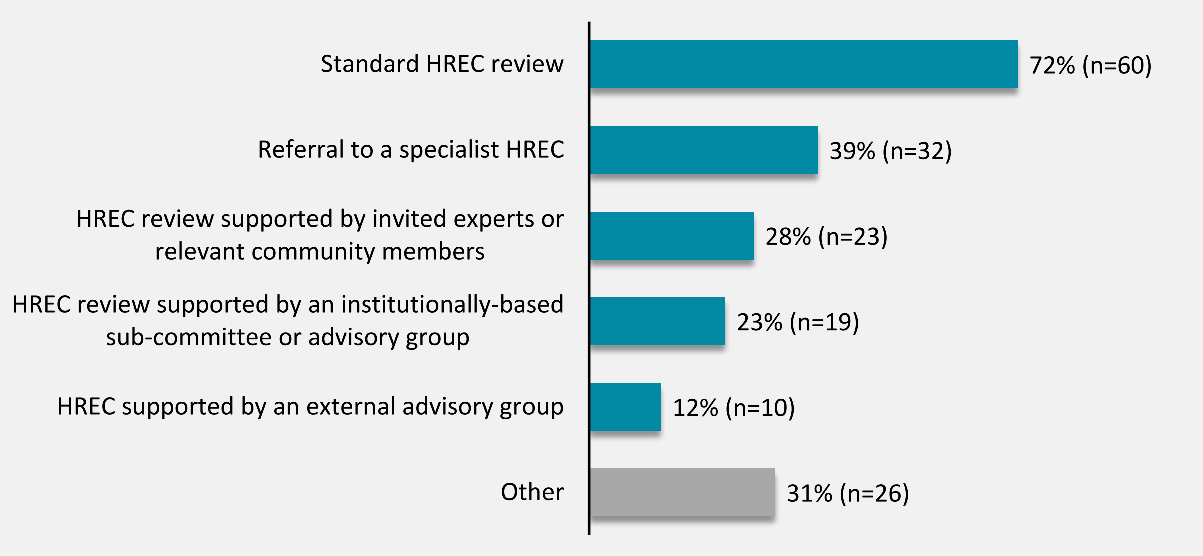
Of the 195 HRECs that considered new research proposals during the reporting period, just over two-in-five (43%; n=83) considered health related research proposals involving Aboriginal and Torres Strait Islander peoples. Of these HRECs, around nine-in-ten (92%; n=76) reported that they used the *NHMRC Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Research (2003)* in considering these health research 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 on Ethical Conduct in Human Research (2007)*; and
- NSW Ministry of Health Policy Directive '*Research – Ethical & Scientific Review of Human Research in NSW Public Health Organisations*'.

Mechanisms used by HRECs for the review of health research proposals involving Aboriginal and Torres Strait Islander peoples are shown in **Figure 3**.

Figure 3: Mechanisms used by HRECs for the review of health research proposals involving Aboriginal and Torres Strait Islander peoples in 2016

Base: HRECs that considered new health research proposals involving Aboriginal and Torres Strait Islander peoples during the reporting period, multiple responses accepted (n=83)



Just under one-third of these HRECs (31%; n=26) reported using other mechanisms for the review of health research proposals involving Aboriginal and Torres Strait Islander peoples, including[10]:

- Advice from institutional Aboriginal and Torres Strait Islander liaison staff;
- Advice from Aboriginal and Torres Strait Islander ethics advisors;
- Required evidence of community engagement and support;
- HREC is specialised in Aboriginal and Torres Strait Islander health research;
- Review sought from a specialist HREC that reviews Aboriginal and Torres Strait Islander health research; and
- Review sought from local community jury.

H. Research involving low or negligible risk

During the reporting period, over two-thirds of HRECs that considered new research proposals (70%; n=137) reported that their institution had an established alternative mechanism for ethics review (other than the HREC) for research proposals that involve low or negligible risk[11].

Of those who reported that the HREC reviews all low or negligible risk proposals, all but eight HRECs (86%; n=50) reported that the HREC had actually considered these research proposals during the reporting period.

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[10] Standard HREC review of this research may or may not include advice provided by Aboriginal and Torres Strait Islander representatives on the committee or advice provided by HREC members with extensive research experience with Aboriginal and Torres Strait Islander peoples.

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

I. Monitoring of research

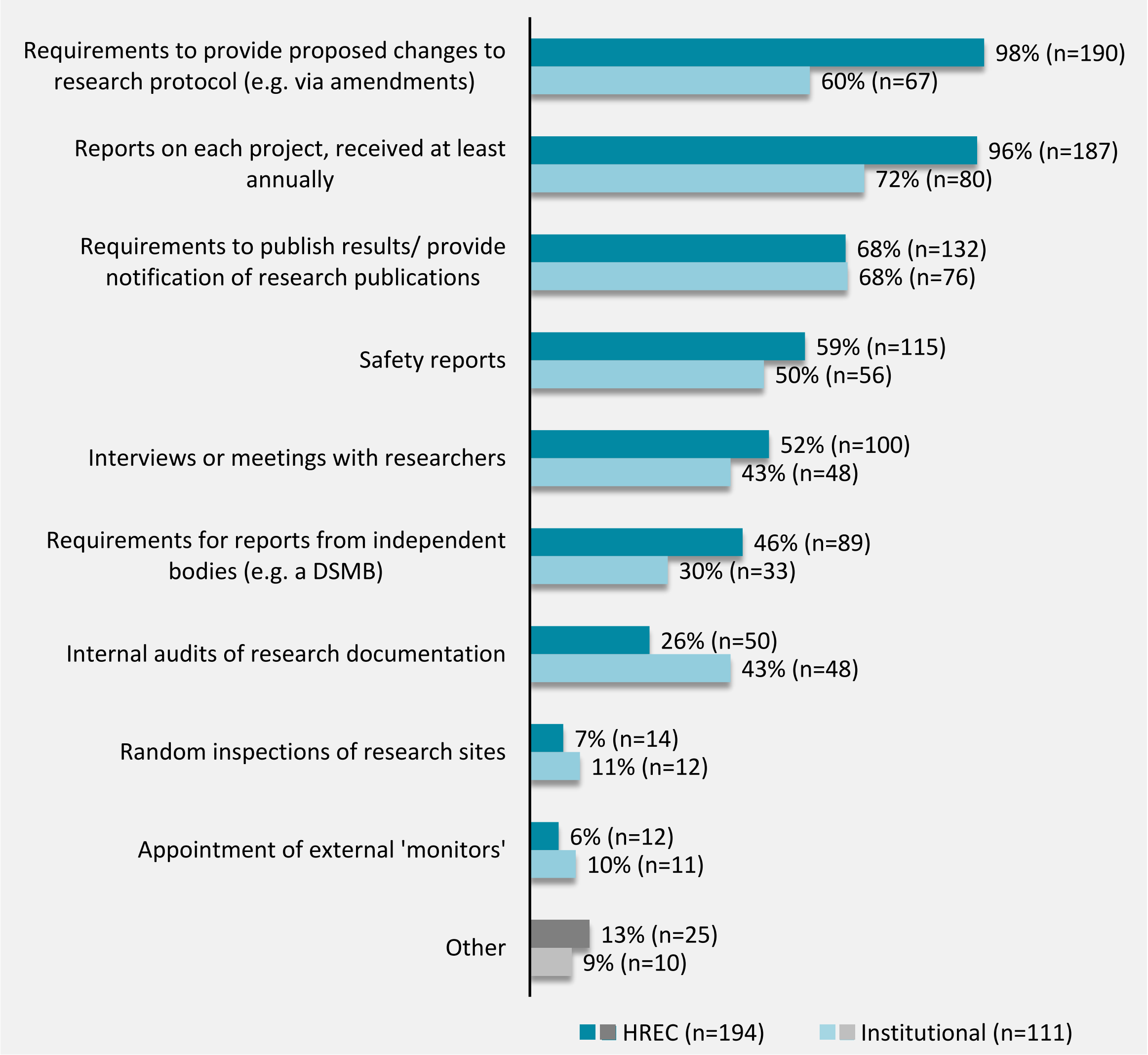
Of the 210 HRECs that submitted an annual report, all but two HRECs (99%; n=208) indicated that the institution and/or the HREC had procedures in place for monitoring approved research. Of these, all but 11 (95%; n=197) reported that the institution and/or the HREC undertook monitoring of approved research. **Figure 4** provides information on the reported monitoring processes in 2016.

The two HRECs that reported that either the HREC or the institution did not have procedures in place for monitoring approved research, reported that the HREC did not have the funding or resources to perform monitoring tasks appropriately or that monitoring approved research was not within the HREC's scope of responsibility. NHMRC will follow up with these institutions in relation to the monitoring requirements under Chapter 5.5 of the National Statement.

Figure 4 provides information on the reported monitoring processes in 2016.

Figure 4: Monitoring processes

Base: HRECs that reported that the institution and/or the HREC undertook monitoring of all approved research, multiple responses accepted (n=197)



Other processes used to monitor research included:

- Protocol deviation reports;
- Cases of research misconduct investigated by Research Integrity staff;
- Development of a database for improved accuracy of monitoring and reporting processes;
- Implementation of report templates for researchers to improve quality of information provided;
- Implementation of reporting reminders for researchers to improve timeliness of submissions;
- Introduction of start-up meetings to ensure that researchers have processes in place to appropriately follow the approved protocol;
- Quarterly reporting of clinical trials conducted under the Clinical Trials Notification (CTN) Scheme where the institution sponsored the trial;
- Requirement for researchers to provide regular progress updates and reports;
- Requirement for researchers to provide impact statements 12-18 months post-research;
- Request for researchers to provide a copy of any information sent to participants following project conclusion (e.g. statement of findings);
- Self-audits;
- Sub-committee review of complaints, breaches, and adverse events;
- Targeted visits to laboratories; and
- Training of research supervisors.

Reported reasons why the institution and/or HREC did not undertake monitoring for approved research included:

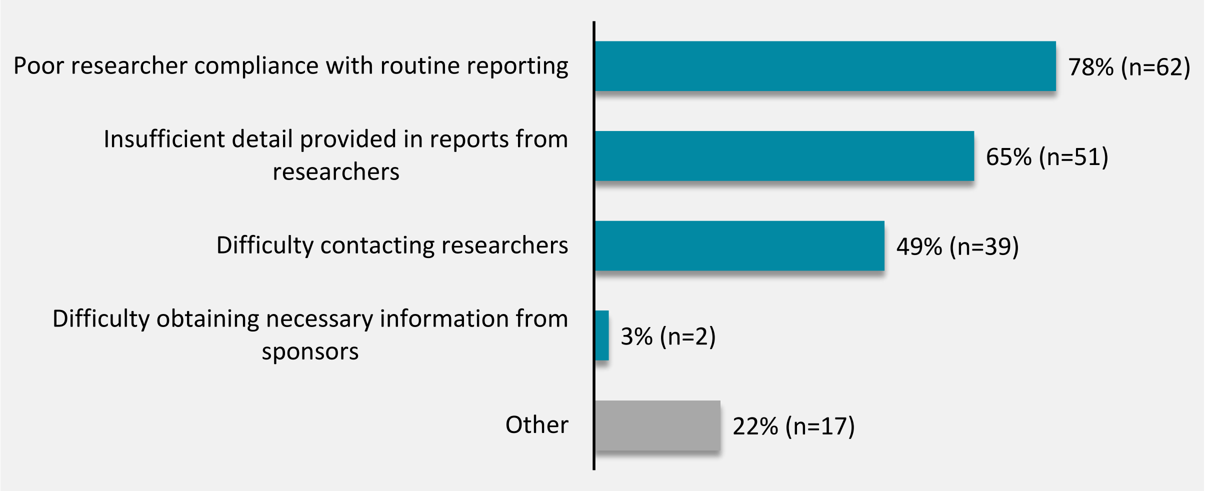
- No research was undertaken during the reporting period;
- Approved research had not yet been completed; and
- Data licensee undertakes monitoring for approved research, and provides results to the HREC.

Problems encountered in monitoring approved research

Of the 197 HRECs that undertook monitoring of approved research during the reporting period, two-in-five (40%; n=79) reported that the HREC or institution encountered problems in monitoring research. The types of problems encountered are shown in **Figure 5**.

Figure 5: Problems encountered in monitoring research

Base: HRECs that reported that they encountered problems in monitoring research during the reporting period, multiple responses accepted (n=79)



Other problems reported to have been encountered in monitoring research included[12]:

- IT systems were inadequate for managing the large number of research projects;
- Lack of a system to remind researchers when reports are due;
- Limited resources to undertake regular monitoring; and
- Organisation underwent significant restructuring.

Of the 79 HRECs that reported that they encountered problems in monitoring research, all but one (99%; n=78) 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.

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[12] Reported responses that relate only to monitoring research are represented in this report.

J. Complaints handling

Of the 210 HRECs that submitted an annual report, all but ten HRECs (95%; n=200) indicated that the institution responsible for the HREC had a publicly available procedure (i.e. on the institution's website) for receiving and handling complaints or concerns **about researchers or the conduct of approved research projects**. Nine-in-ten HRECs (90%; n=190) reported that the institution responsible for the HREC had a publicly available procedure (i.e. on the institution's website) for receiving and handling complaints or concerns **from researchers about the conduct of the HREC in consideration of their research proposal(s)**.

Reported reasons as to why the institution responsible for the HREC did not have publically available complaints procedures included:

- Complaints procedures were available on request;
- Complaints procedures were available on the institution's internal intranet;
- Complaints procedures were available via other processes (e.g. consent process, complaints discussed at HREC meetings);
- Complaints procedures will be uploaded to the institution's publicly accessible website for the next reporting period (2017);
- Complaints procedures were not publicly available due to website upgrades and/or revisions of the procedures themselves;
- The HREC did not address this matter due to a lack of resources and funding; and
- The HREC or institution does not manage the way in which this information is publicly disseminated.

Types of complaints received

During the reporting period, just under two-in-five HRECs (38%; n=80) received a combined total of 234 complaints **about researchers or the conduct of an approved research project**, while one-in-ten HRECs (10%; n=21) received a combined total of 37 complaints **from researchers about the consideration of their proposal(s) by the HREC** (see **Table 3**).

Table 3: 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	234	15
Complaints received about researchers or the conduct of an approved research project that involved Aboriginal and Torres Strait Islander peoples	8	2
Complaints received from a researcher about the consideration of their research proposal by the HREC	37	10

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

- Administrative errors;
- Availability of Participation Information Sheet;
- Behaviour of researcher;
- Concerns about questionnaire (content, language, wording);
- Concerns about reimbursement;
- Concerns about studies being undertaken without ethics approval;
- Conflict of interest;
- Consent and opt-out processes;
- Data security;
- Difficulty contacting researchers;
- Distress/ medical effects caused by research;
- Health and safety risks;
- Lack of community consultation;
- Lack of information about a study;
- Length of study;
- Limited organisational resources to support researchers;
- Modification to research methodology without prior approval from review body;
- Nature of research and research instruments;
- Participant access to research results;
- Plagiarism allegations;

- Privacy and confidentiality concerns;
- Recruitment methods (including coercion, spam, exposure of private email addresses, inclusion/ exclusion criteria, unsolicited/ unapproved recruitment, inappropriate recruitment channels, contacting deceased persons);
- Researcher response to possible adverse event;
- Time delays;
- Unapproved personnel;
- Validity, value, and purpose of research;
- Violations of approved protocol/ breaches of ethics approval; and
- Withdrawal from a research study.

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

- Difficulty finding relevant information;
- Dissatisfaction or disagreement with the HREC's feedback or decision;
- Expert review sought without consultation;
- Repeated requests for information;
- Time delays; and
- Concerns about requirements involving consultation with the Aboriginal and Torres Strait Islander community.

II. Report on the Activity of Certified Institutions' Human Research Ethics Committees for the Period 1 January 2016 – 31 December 2016

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 ethics 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 ethics 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, including the number of multi-centre reviews conducted and research categories considered. 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 2016 – 31 December 2016.

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

A. Number of certified institutions and institutional HRECs

During 2016, 45 institutions operated as certified institutions under the NHMRC National Certification Scheme. These 45 institutions included 49 HRECs (see **Table 4**). There were 46 certified institutions in the 2015 reporting period.

Table 4: HRECs by jurisdiction

Jurisdiction	Number of Certified Institutions	Number of HRECs
New South Wales	15	16
Victoria	10	10
Queensland	9	9
South Australia	6	9
Western Australia	4	4
Australian Capital Territory	1	1
Total	**45**	**49**

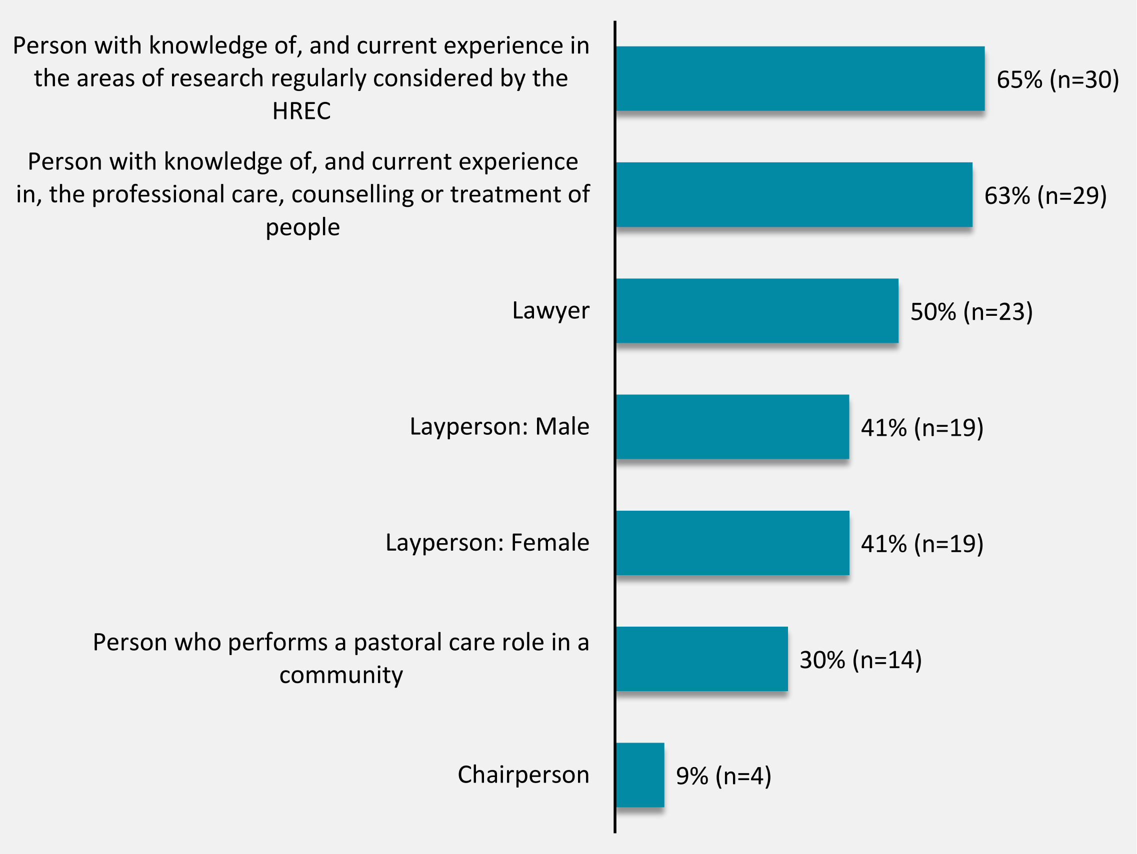
B. HREC composition

Membership

All but three HRECs (94%; n=46) reported a change to committee membership during 2016. The categories of membership in which changes occurred are shown in **Figure 6**. Three HRECs reported that they did not meet the minimum membership requirements during the reporting period[13].

Figure 6: Categories of membership in which the change occurred

Base: Certified Institutions that reported a change to committee membership, multiple responses accepted (n=46)



Sub-committee expertise

Just under two-thirds of HRECs (63%; n=31) reported that they used the expertise of a sub-committee(s) as part of their consideration of research proposals.

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[13] These HRECs reported that, during the reporting period, they did not have a member in the categories of 'lawyer' (n=2 HRECs) and 'at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people' (n=1 HREC). NHMRC is working with these certified institutions and HRECs to resolve this issue.

C. Review of multi-centre research proposals

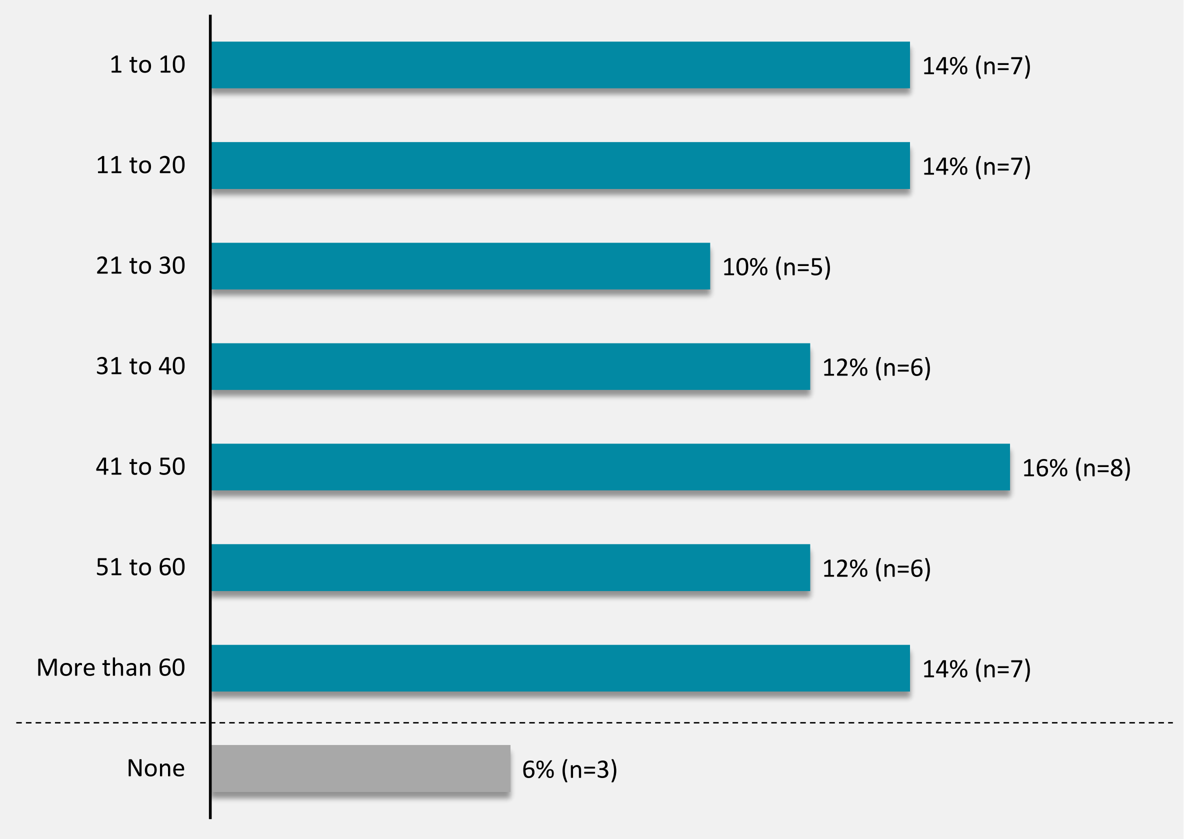
All 49 HRECs from certified institutions reported that they considered new[14] research proposals during the reporting period. Of these HRECs, all but three (94%; n=46) reported that they had reviewed new multi-centre[15] research proposals during 2016.

Number of multi-centre research proposals

The distribution of the number of new multi-centre research proposals reviewed by HRECs during the reporting period is shown in **Figure 7**.

Figure 7: Number of multi-centre research proposals reviewed by HRECs

Base: Certified institutions' HRECs that considered new research proposals (n=49)



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[14] 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.

[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.

The total number of new multi-centre research proposals reviewed during the reporting period was 1,930 (1,811 in the previous reporting period). The highest number of multi-centre research proposals reviewed by any one HREC during the reporting period was 252 (n=1) and the lowest was 0 (6%; n=3).

Of the 46 HRECs that reviewed new multi-centre research proposals in 2016, all but three (93%; n=43) reviewed proposals as the lead HREC[16]. Just under half of HRECs (46%; n=21) reviewed new multi-centre research proposals where it was not the lead HREC.

During the reporting period, around one-quarter of HRECs (24%; n=11) reported that they were aware of instances where the HREC's approval had not been accepted by another institution. Seven HRECs (14%) reported that the institution declined to accept one or more ethics approvals of multi-centre research from another certified institution. Reported reasons as to why these approvals were declined included:

- Concerns with the research study (e.g. documentation, compliance with requirements);
- Further review was required;
- Institution could not accept ethics approval from another institution that was in a different state or territory;
- Institution did not yet join the National Mutual Acceptance (NMA) scheme;
- Research study was not covered under the NMA scheme; and
- The state's health policy only allowed acceptance of ethics approvals from a public health HREC.

A list of certified institutions can be found on the NHMRC website.

Timeliness and reduced duplication

Of the new multi-centre research proposals reviewed during the reporting period:

- Around four-in-five (81%; n=1,561) were completed within 60 calendar days;
- Around three-in-five (61%; n=1,168) were intended for conduct within one state or territory only; and
- Just under two-in-five (39%; n=762) were intended for conduct in two or more states or territories.

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[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.

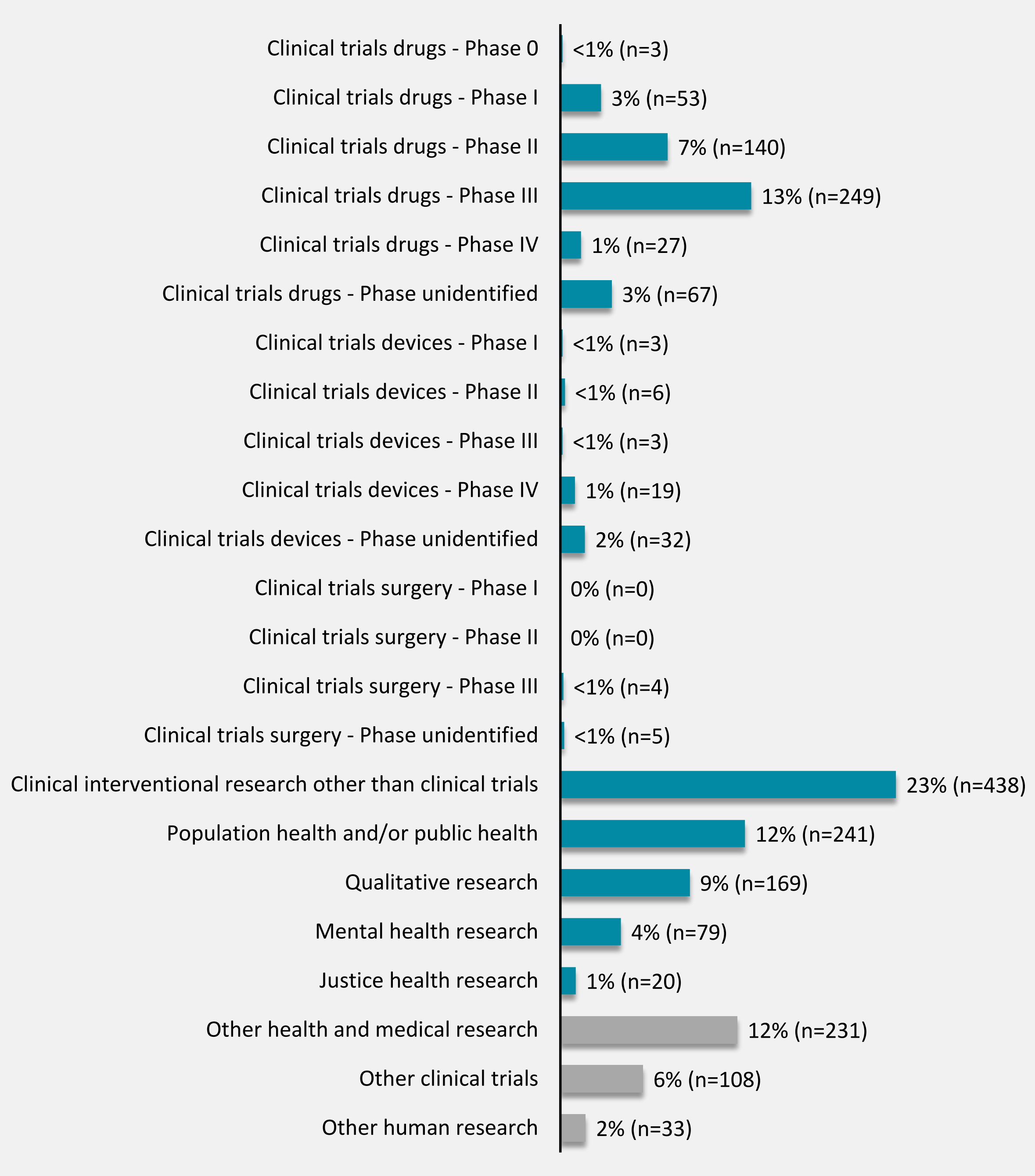
D. Multi-centre research categories considered

Types of multi-centre research categories

The distribution of the research categories considered by HRECs during the reporting period is shown in **Figure 8**.

Figure 8: Categories of multi-centre research proposals considered[17]

Base: Total number of multi-centre research proposals considered by certified institutions' HRECs (n=1,930)



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[17] Definitions for the categories of multi-centre research proposals that are included in Figure 8 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**[18] considered during the reporting period included:

- Comparative effectiveness trials;
- Observational trials; and
- Trials related to:
    - Anaesthetics;
    - Assessments;
    - Cluster-crossover design;
    - Cognitive training;
    - Dentistry;
    - Diabetes;
    - Diagnostic tests;
    - Endoscopy;
    - Epidemiology;
    - Exercise;
    - Genetics;
    - Imaging;
    - Interventions;
    - Lung screening;
    - Medical apps (internet and mobile phone);
    - Microbial analysis;
    - Nutrition;
    - Pressure dressings;
    - Probiotics;
    - Pharmacodynamics;
    - Physiotherapy;
    - Psychotherapy;
    - Radiotherapy;
    - Shared care;
    - Sleep;
    - Surgery prehabilitation;
    - Telehealth; and
    - Temperature management.

Other **health and medical research**[18] considered during the reporting period related to:

- Assessment of incidence and outcomes of specific conditions;
- Audits and evaluations;
- Bicycle training program;
- Biobanking;
- Biospecimens;

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[18] The topics listed have been self-reported by HRECs.

- Clinical research;
- Case cohort studies;
- Data analysis and linkage;
- Dietetics;
- End-of-life;
- Ethics;
- Epidemiology;
- Exercise physiology;
- Experience of care of the Aboriginal and Torres Strait Islander population;
- Follow-up studies;
- Genetics;
- Health economics;
- Health literacy;
- Health services research;
- Imaging;
- Laboratory research;
- Medical education;
- Nursing;
- Observational and longitudinal studies;
- Pharmacology;
- Pilot study;
- Quantitative;
- Registries;
- Review of health information and medical records;
- Risk and screening tools;
- Social science;
- Stepped wedge cluster randomised controlled trial;
- Surveillance; and
- Surveys.

Other **human research**[19] considered during the reporting period related to:

- Data management and linkage;
- Human resources;
- Quantitative, qualitative, and observational research;
- Registries;
- Research in the workplace;
- Service evaluation; and
- Use of human biospecimens.

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[19] The topics listed have been self-reported by HRECs.

During the reporting period, just under half of HRECs (48%; n=22) 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 2016 – 31 December 2016

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 where 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

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

management, funding or monitoring of a health service;

- where it is impracticable to seek consent; and
- where 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 2016 period; and
- Part B reports on the HREC application of the s95A guidelines during the 2016 period.

A. Application of the s95 guidelines during the period 1 January 2016 – 31 December 2016

During the reporting period, 195 HRECs considered new research proposals. Of these HRECs, one-in-ten (10%; n=19) 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 19 HRECs considered a combined 2,050 new research proposals during the reporting period. Of these, 76 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. Of these 76 proposals, all but two were reported to have had the s95 guidelines applied. The two remaining proposals were reported to have been approved by other HRECs prior to submission to the reporting HREC.

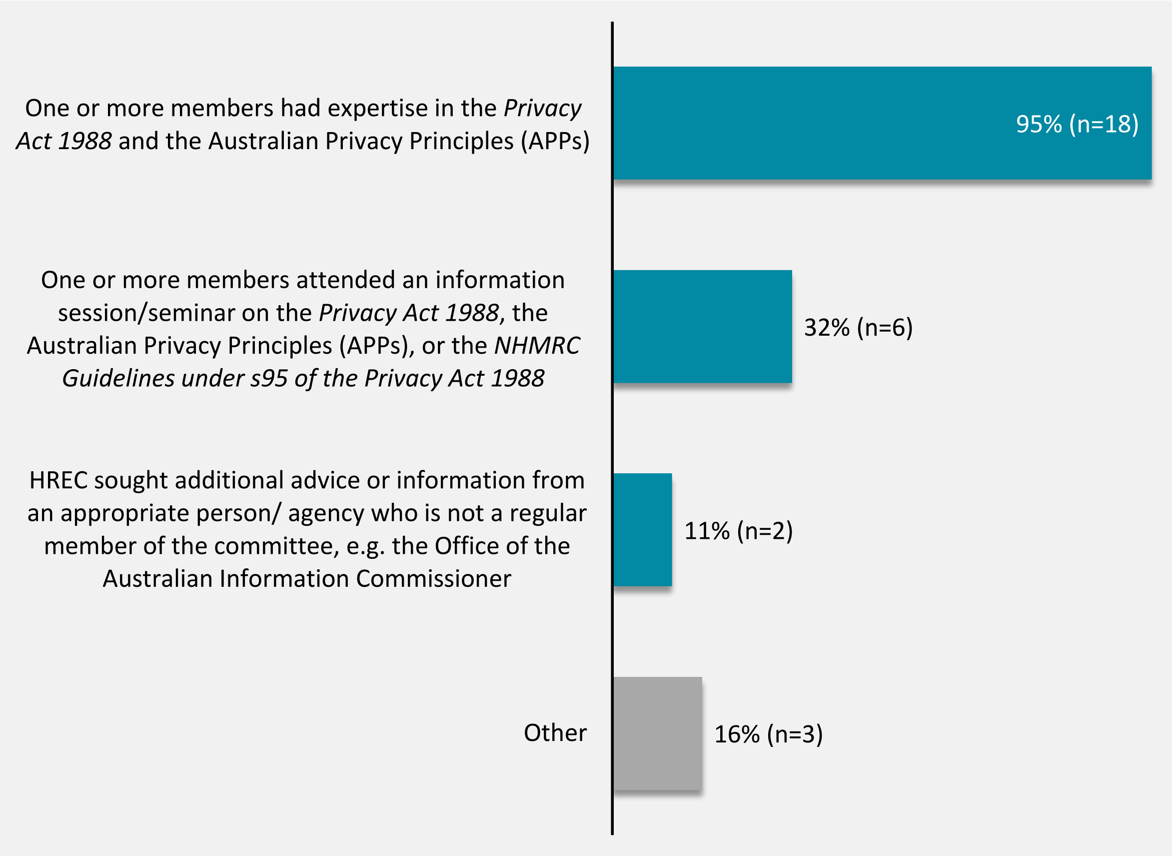
HREC assessment of expertise and understanding of privacy issues (Paragraphs 3.1, 3.2(b) and 3.4)

All 19 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 issues related to privacy.

HREC assessment of expertise and understanding of privacy issues is shown in **Figure 9**.

Figure 9: 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=19)



Other expertise included:

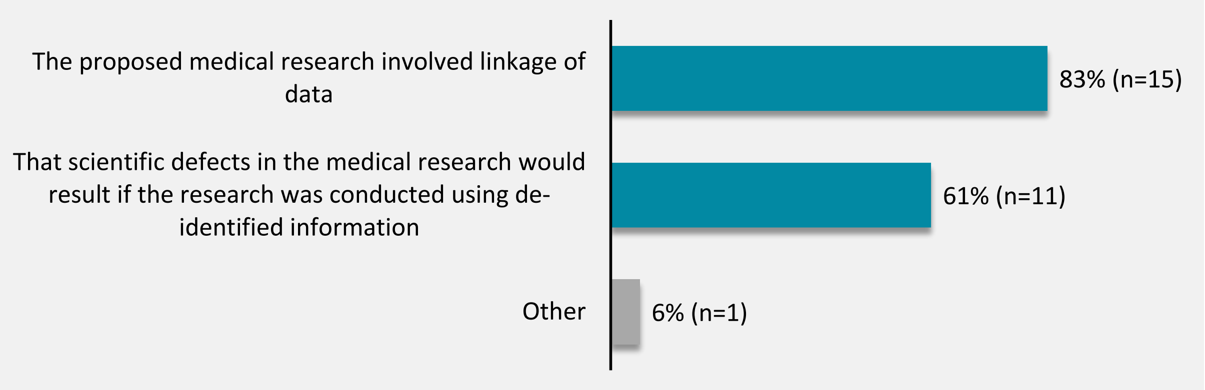
- Advice from HREC member who is a lawyer and had knowledge of privacy issues;
- Advice from institutional Privacy Officer; and
- HREC experience in assessing matters of privacy relating to health.

Personal information and consent (Paragraph 3.2(a))

Figure 10 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 10: HREC considerations with regard to identifiability of data (s95)

Base: HRECs that reported that they had applied the s95 guidelines, multiple responses accepted (n=18)

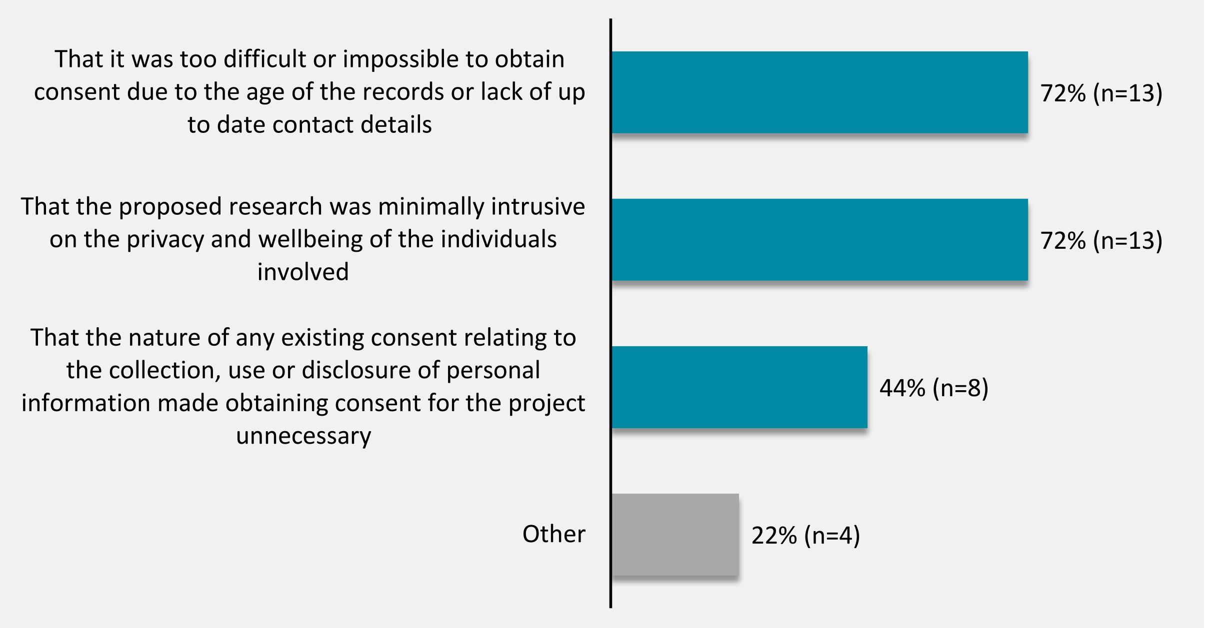


Other considerations with regard to identifiability of data included the significant public value in accessing identified information for safety reasons.

Figure 11 illustrates the issues considered by HRECs in assessing whether it was reasonable for the medical research to proceed without consent.

Figure 11: HREC considerations with regard to consent (s95)

Base: HRECs that reported that they had applied the s95 guidelines, multiple responses accepted (n=18)



Other considerations with regard to consent included:

- Deceased participants;
- Identified data used only for data linkage;
- Significant public benefit; and
- Size of the population involved (i.e. number of records).

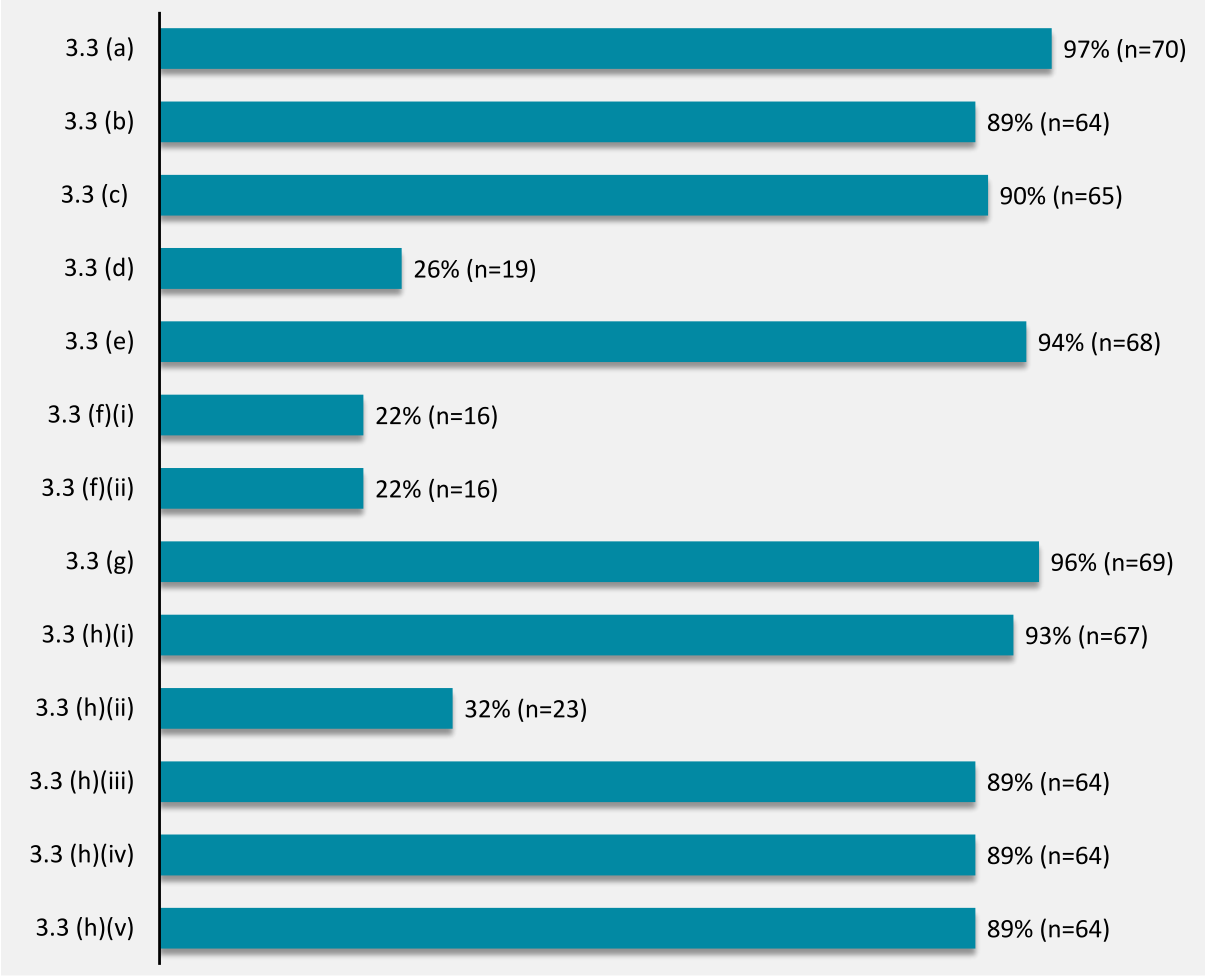
Weighing the public interest (Paragraph 3.3)

Of the 74 proposals reported to have had the s95 guidelines applied, 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 72 cases (i.e. 72 proposals were approved). There were two proposals 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. two proposals were not approved).

Figure 12 shows the matters reported to have been considered relevant in approving a research proposal under paragraph 3.3 of the s95 guidelines.

Figure 12 : Matters reported to have been considered relevant in approving a research proposal

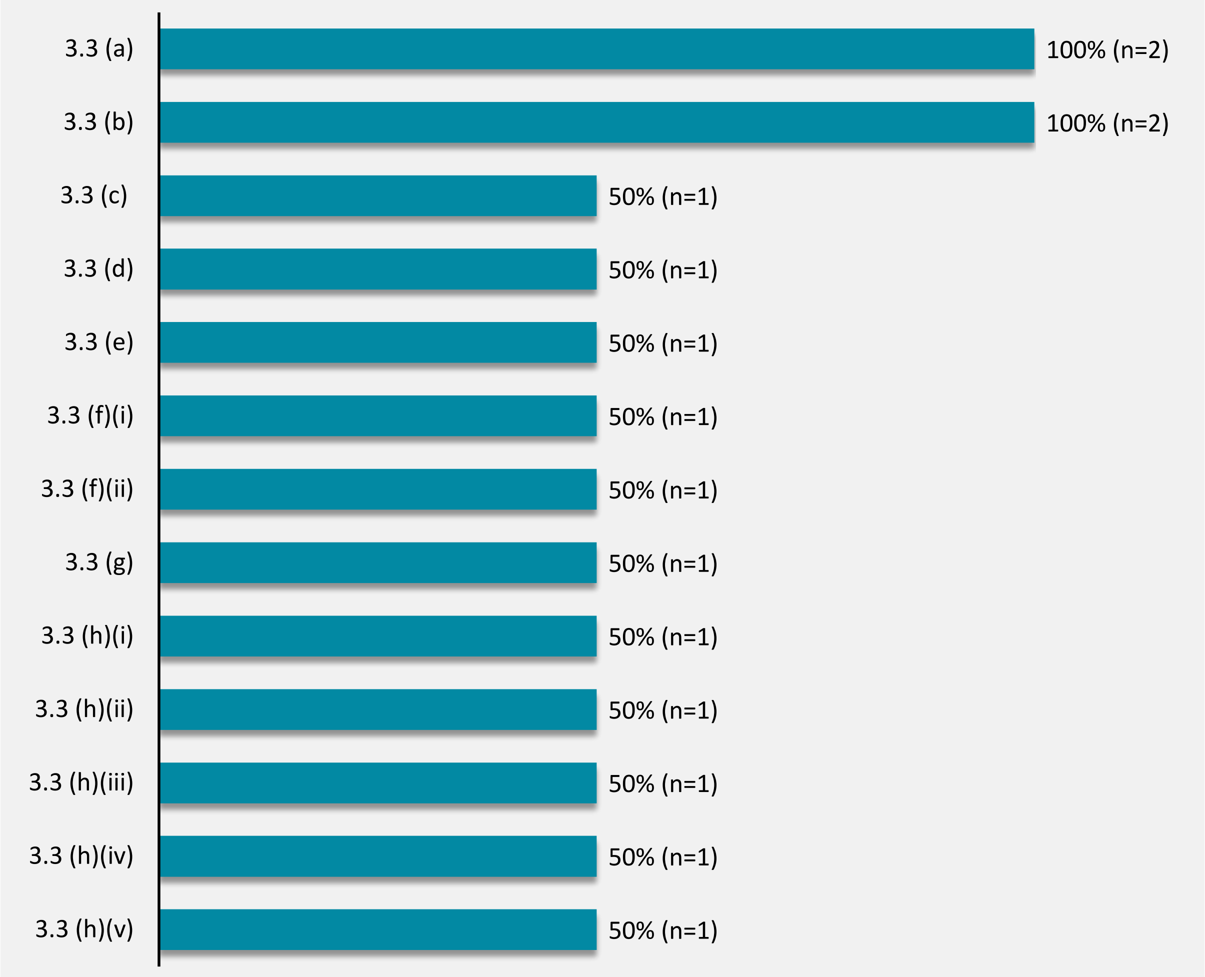
Base: Proposals for which it was determined that the public interest in the proposed medical research outweighed, to a substantial degree, the public interest in the protection of privacy, multiple responses accepted (n=72)



For the two proposals that were not approved, the matters that were reported to have been considered relevant in not approving the research proposals under paragraph 3.3 of the s95 guidelines are shown in **Figure 13**.

Figure 13: Matters reported to have been considered relevant in not approving a research proposal

Base: Proposals 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, multiple responses accepted (n=2)



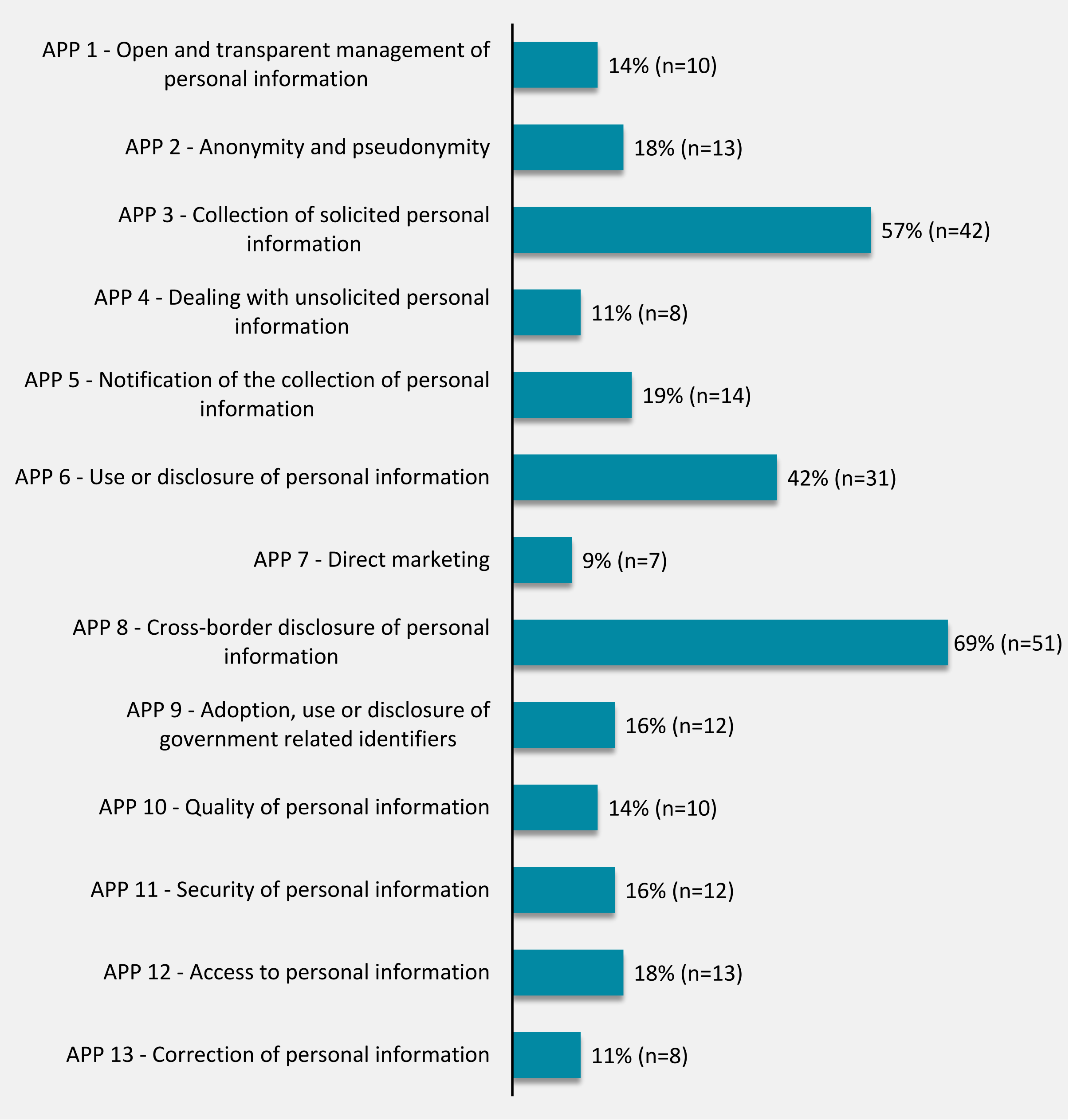
HREC assessment of relevant Australian Privacy Principles (APP) (Paragraphs 3.2(a) and 3.4)

All HRECs 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.

Figure 14 identifies the APPs which would have been infringed if not for the approval of research proposals under the s95 guidelines.

Figure 14: 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=74)



Recording and monitoring of decisions (Paragraphs 3.4 and 3.5)

Recording

All 17 HRECs which approved medical research proposals under the s95 guidelines 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 17 HRECs that approved research had procedures in place for monitoring approved research and undertook monitoring.

Just over three-quarters of the HRECs (76%; n=13) 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 2016 – 31 December 2016

Of the 195 HRECs that considered new research proposals during the reporting period, just over one-in-ten (12%; n=24) 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 impracticable to obtain consent. **Table 5** shows the types of research proposals considered within the context of the s95A guidelines.

Table 5: 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	55
The compilation or analysis of statistics relevant to public health or safety	26
The management, funding or monitoring of a health service	23
Total	**104**

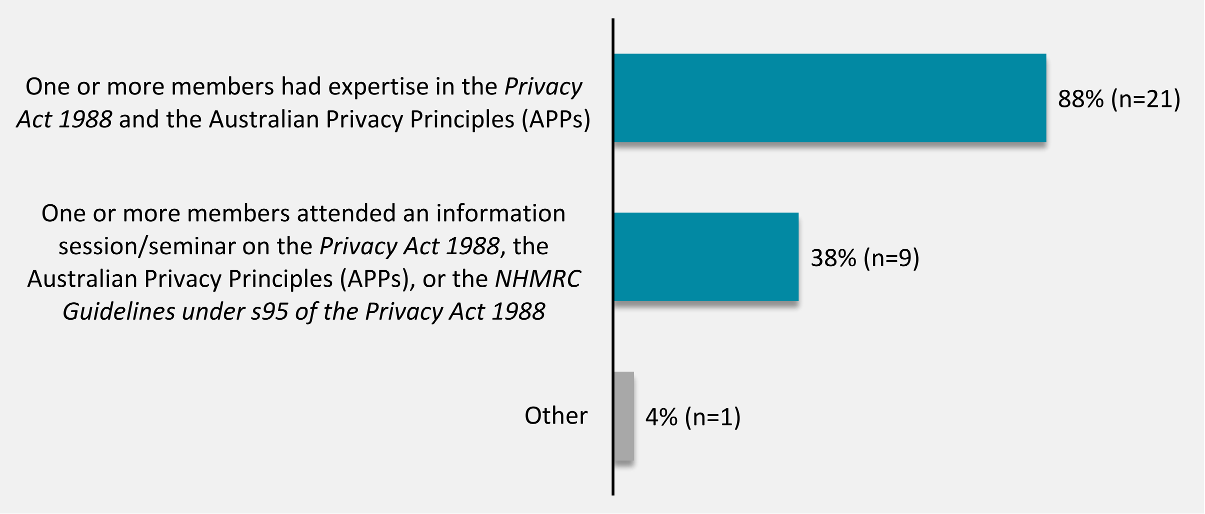
Of the 104 proposals considered within the context of the s95A guidelines, all but one were reported to have had the guidelines applied. The remaining proposal was reportedly assessed against the guidelines by another HREC, which was then accepted by the reporting HREC.

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

During the reporting period, all 24 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 15**.

Figure 15: 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=24)



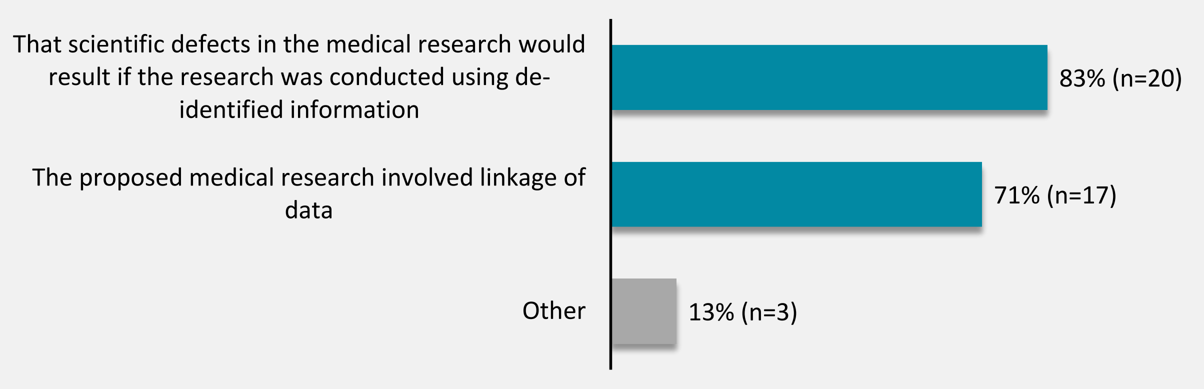
Other expertise included advice sought from a legal advisor.

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 16**.

Figure 16: 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=24)



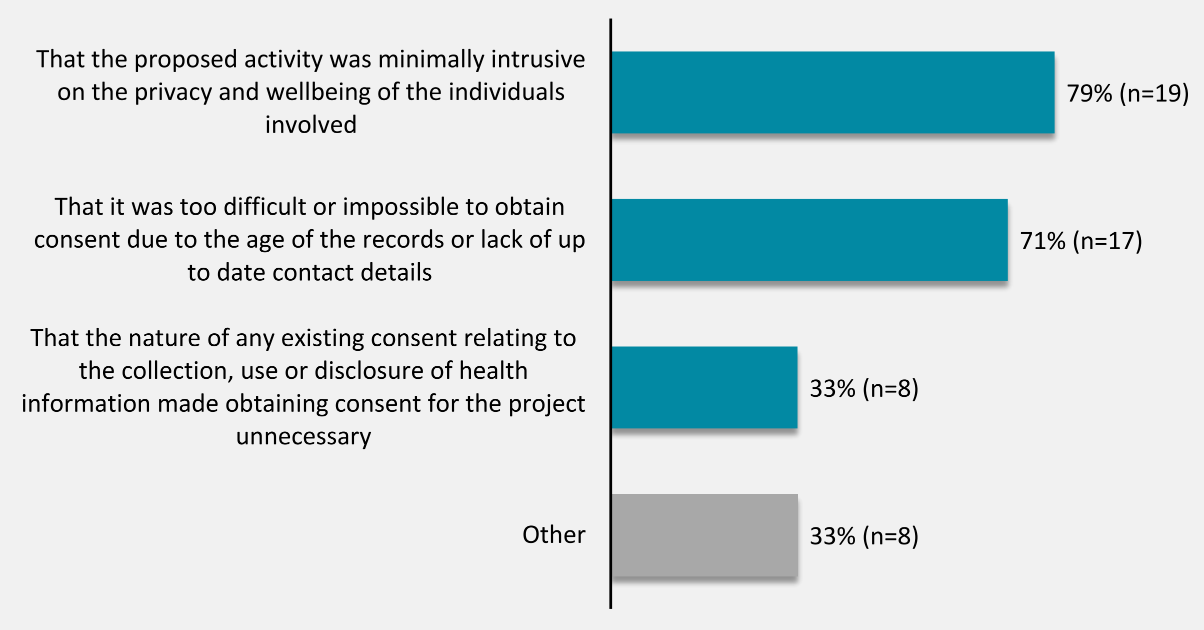
Other considerations with regard to the use of de-identified data included:

- 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;
- The study was an evaluation of a new standard of care model, which participants were not directly involved in; and
- The research carried no more than low risk for participants, and there were effective measures and safeguards taken by the researcher to protect the privacy of participants.

Figure 17 illustrates the issues considered by HRECs in deciding that it was impracticable to seek consent.

Figure 17: HREC considerations with regard to consent (s95A)

Base: HRECs that reported that they had applied the s95A Guidelines, multiple responses accepted (n=24)



Other considerations with regard to consent included:

- Accessibility of records;
- Deceased participants;
- It was impracticable to obtain consent due to the minimal information collected in the first instance;
- It was reasonable to access already collected and available data for analysis in the interest of public health and safety;
- Significant importance of obtaining all records;
- Risk of creating additional threats to privacy by having to link information in order to locate and contact participants;
- Risk of inflicting psychological, social, or other harm by contacting participants; and
- Size of the population involved (i.e. number of records).

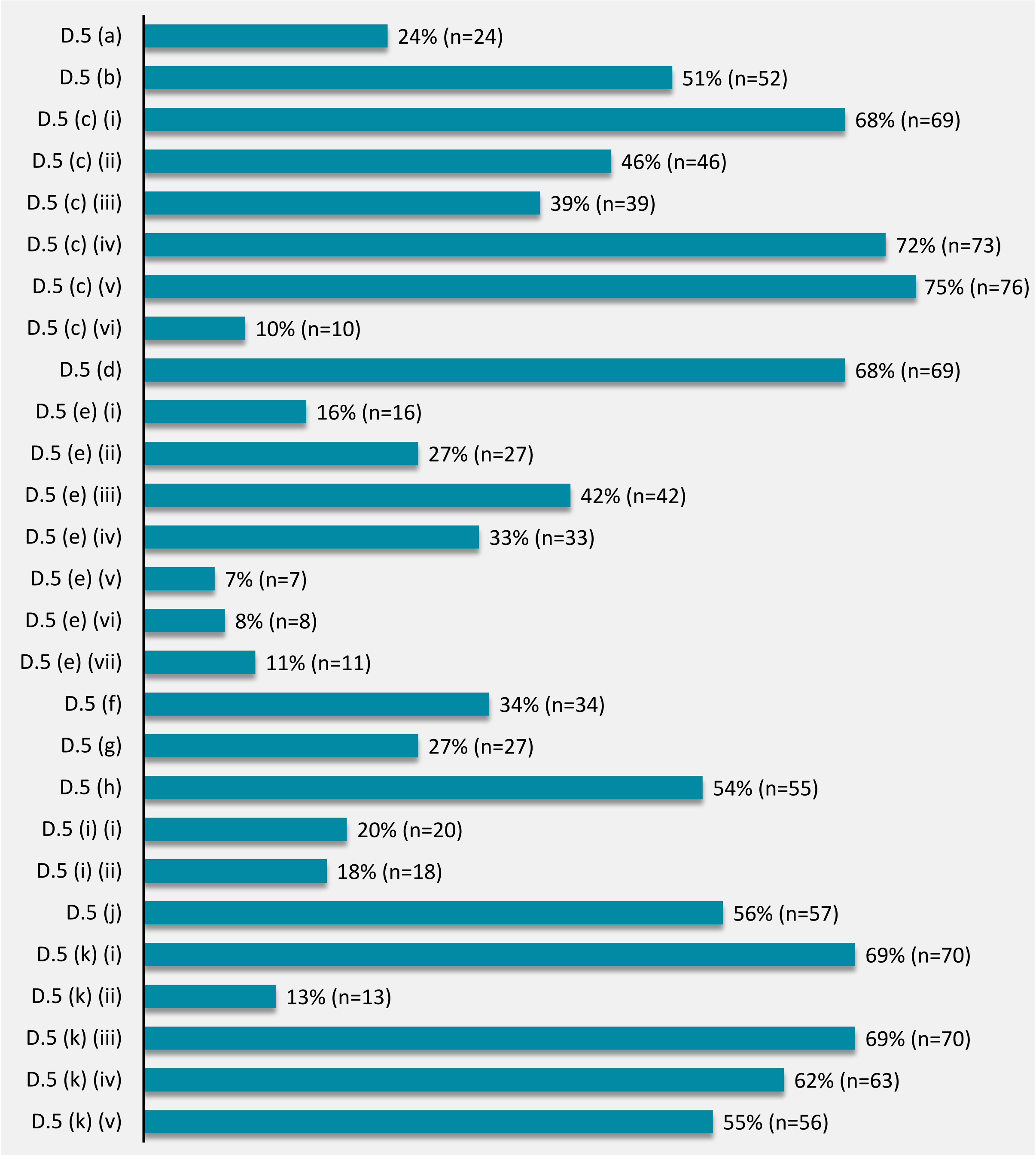
Weighing the public interest (Paragraphs D.4 and D.5)

Of the 103 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 101 cases (i.e. 101 proposals were approved). There were two proposals 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. two proposals were not approved).

Figure 18 shows the matters reported to have been considered relevant in approving a research proposal under paragraph D.5 of the s95A guidelines.

Figure 18: 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=101)



For the two proposals that were not approved, the matters that were reported to have been considered relevant in not approving the research proposals under paragraph D.5 of the s95A guidelines were D.5 (b), D.5 (c) (ii), D.5 (c) (iv), D.5 (c) (v), D.5 (e) (iv), D.5 (k) (i), and D.5 (k) (iii).

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

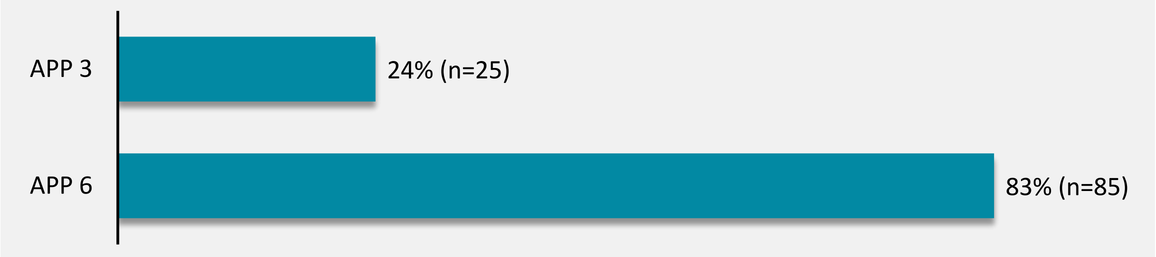
All but four HRECs reported that they had recorded the APPs which apply to proposals as required under s95A guideline D.6 (d). Reported reasons as to why the APPs were not recorded for all proposals included:

- It was determined that there were no APPs that were likely to be infringed;
- It was previous practice to record reference to Section 95A only, and the recording of the relevant APPs will be adhered to in the future; and
- Proposal was considered as a low or negligible risk (LNR) application, and had already received full ethical review and approval by another HREC.

Figure 19 identifies the APPs which would have been infringed if not for the approval of research proposals under the s95A guidelines.

Figure 19: 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=103)



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

Recording

All HRECs 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.

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 24 HRECs had procedures in place for monitoring approved research, and all HRECs also undertook monitoring for approved research.

Sixteen of these HRECs encountered problems in monitoring approved research, the most common of which were poor researcher compliance with routine reporting, as well as insufficient detail provided in reports from researchers. All but one 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% of the total number of proposals assessed by HRECs. As shown in **Table 6**, 18,039 new research proposals were reviewed by HRECs during the reporting period. Of these, only 180 proposals required application of the s95 and/or s95A guidelines. A comparison with previous reporting periods is also shown.

Table 6: Comparison with previous reporting periods – Number of proposals

Reporting period	Total proposals	Proposals reviewed which required the application of the Privacy Guidelines	
		Number	%
2016	**18,039**	**180**	**1.00**
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 7 shows that approximately one-in-five HRECs (19%; n=39) reviewed proposals or activities which may have required the 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 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	%
2016	**210**	**39**	**18.6**
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; Department of Health; Department of Social Services	National Hospital Morbidity Database (Commonwealth Department of Social Services); Name of deceased person; Sex; Date of birth; Birth status/Stillbirth flag; Date of death; Age at death; Country of birth; SLA; Indigenous status (for clerical review); Name of mother; Age of mother; Mother's date of birth; CONTENT VARIABLES (To researchers); Date of birth; Birth status/stillbirth flag; Date of death occurrence; Death of death registration; State where death was registered; Sex; Age at death; Indigenous status; Causes of death; SLA; Country of birth; Date of birth; Date of death; Age at death; SLA; Indigenous status (for clerical review); Content variables (To researchers); Year of death; Year of birth; Sex; Age at death; Indigenous status; SLA; Country of birth; Name of deceased person; Sex; Date of birth; Date of death; Country of birth; SLA; Indigenous status (for clerical review); Content variables (To researchers); Year of death registration; Sex; Age at death; Indigenous status; SLA; Country of birth; Sex; Date of birth; Date of death/Date of separation; Mode of separation/Discharge status; Age at death; Country of birth; SLA; Indigenous status (for clerical review); CONTENT VARIABLES (To researchers); Sex; Year of birth; Year of death; Age at death; Indigenous status; SLA; Country of birth.	150,000
	Australian Institute of Health and Welfare	National Death Index – Sex; Age at death; Date of death; State/territory the death was registered in; Year the death was registered in; Underlying cause of death; Code (as ICD9 codes until 1996, as ICD10 since 1997); Codes for other causes of death (as ICD10 codes since 1997).	70,000
EC00103	Australian Institute of Health and Welfare	MBS – Date of service; MBS item number; MBS item description; Provider charge; schedule fee; benefit paid; patient out of pocket; bill type; scrambled ordering provider number; scrambled rendering provider number; date of referral ; rendering provider postcode; ordering provider postcode; hospital indicator; item category; date of processing; provider specialty. PBS – date of supply; date of prescribing; PBS item number; PBS item descriptor; patient category; patient contribution; PBS Net benefit; scrambled prescriber number; form category; ATC code; ATC Name; gross price; prescriber specialty; quantity supplied. NDI – Fact of death; Date of death (date, month, year); Underlying cause of death (ICD-9/ICD-10); Other causes of death (ICD-9/ICD-10).	15,000,000
	Australian Institute of Health and Welfare	NDI – Fact Of Death; Date of Death; Underlying cause of Death; Other causes of death.	5,000
	Australian Institute of Health and Welfare	Australian Cancer Database, from 1982 to the latest available for all registered primary malignant cancers – Sex; Date of birth; Date of death; Cause of death; Tumour identification number; Date of diagnosis; ICD-O-3 topography code; ICD-O-3 morphology code; ICD-10 disease code; Most valid basis of diagnosis. National Death Index, from 1980 to the latest available – Sex; Date of birth; Date of death; Underlying cause of death; Multiple causes of death.	16,000

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[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
EC00103	Australian Institute of Health and Welfare	Medicare Benefits Schedule (MBS) – Date associated with the MBS record; Age group (5 year); sex; Location (State / Hospital & Health Service area); Provider type (public/private, hospital/other); Medicare Local/Primary Health Network; Date of referral (where relevant); Bill type (e.g. bulk bill); MBS item numbers 715 (Health Assessment for Aboriginal and Torres Strait Islander People); 701, 703, 705 & 707 (Health Assessment items); 721, 723, 729,731 & 732 (Preparation of GP Management Plan (GPMP); Coordination of Team Care Arrangements (TCA); Review of a GPMP or TCA; Contribution to a multidisciplinary care plan); 735, 739, 743, 747, 750 & 758 (Multidisciplinary case conferences); 820 – 838 (Case conference with a consultant physician); 900 & 903 (Domiciliary / Residential Medication Management Review); 10986 (Healthy kids check (>4 years) provided by a practice nurse or Aboriginal and Torres Strait Islander health practitioner); 10987 (Follow-up service provided by a practice nurse or Aboriginal and Torres Strait Islander health practitioner); 10997 (Provision of monitoring and support for a person with a chronic disease by a practice nurse or Aboriginal and Torres Strait Islander health practitioner); 10950-10970 (Allied Health Services for Chronic Disease Management); 81100-81125 (Group Allied Health Services for patients with Type 2 Diabetes); 81300-81360 (Allied Health Services for Indigenous patients who have had a health check); 11712 (Multi-channel ECG monitoring and recording during exercise); 3 to 51 (General Practitioner Attendance Items); 52 to 65 (Other non-referred attendances to which no other item applies – Group A2); 99, 104-105, 107, 108, 113 (Specialist Attendances to which no other item applies – Group A3); 110, 112, 114, 116, 119, 122, 128, 131 to 133 (Consultant Physician Attendances to which no other item applies – Group A4); 5000 to 5067 (General Practitioner After-Hours Attendances to which no other item applies); 38215 to 38246 (Selective coronary angiography); 38300 to 38318 (Endovascular Interventional Procedures (PCI)); 38480 to 38481 (Valve repair procedures); 38488 to 38489 (Valve replacement procedures); 55113, 55114, 55116 to 55119, 55120, 55122, 55123 & 55125 (Echocardiography (includes exercise and pharmacological stress echocardiography)); 38200, 38203 & 38206 (Cardiac catheterisation); 38497 to 38504 (Coronary Artery Bypass). Pharmaceutical Benefits Scheme (PBS) – Date of supply; Date of prescription; PBS item code; Anatomical Therapeutic Chemical (ATC) code and name for following medication types: B01A (Antithrombotic agents); C02D (Antihypertensives); C03 (Diuretics); C04 (Peripheral vasodilators); C08 (Calcium-channel blockers); C07A (Beta-blocking agents); C09A, C09B (ACE inhibitors); C09C, C09D (Angiotensin II antagonists); C10A, C10B (Lipid modifying agents); J01 (Antibacterials for systemic use); Generic name; Brand name; Quantity supplied; Dose/mass amount; Defined daily dose amount; Benefit category; Original or repeat script; Authority prescription; Regulation 24 status; Close the Gap (CTG) annotations.	800,000
	Australian Institute of Health and Welfare	National Death Index – date of death; state the death was registered in; underlying cause of death code; and codes for other causes of death.	400
	Australian Institute of Health and Welfare	National Death Index – date of death; state the death was registered in; underlying cause of death code; and codes for other causes of death.	600

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; state the death was registered in; underlying cause of death code; and codes for other causes of death.	1,037
	Australian Institute of Health and Welfare	PBS data – date of supply; date of prescribing; PBS item number; PBS item Description; ATC code; ATC name.	1,924
	Australian Institute of Health and Welfare	NDI – Date of death; State/territory the death was registered; Year the death was registered in; Underlying cause of death code (as ICD9 codes until 1996, as ICD10 since 1997); Codes for other causes of death (as ICD10 codes since 1997).	900,000
	Australian Institute of Health and Welfare	NDI – Date of death; Cause of death; Age at death; Sex; State/Territory of registration.	200
	Australian Institute of Health and Welfare	NDI – State/Territory of death registration; Full name; Gender; Date of Birth; Date of death; year of death registration; all causes of death (ICD codes). ACD – Full name; Gender; Date of birth; State/Territory registry case ID number; date of incidence; cancer site; histology; cause of death; date of death; geographic locator; and country of birth.	13,000
	Australian Institute of Health and Welfare	NDI – Date of death; Age at death; Area of usual residence (9 digit ASGC); Indigenous status; Mortality id; Remoteness; Sex; State of usual residence; Year of registration; Cause of death; Underlying cause of death (ICD 9 and 10); Place of occurrence; Occupation.	432,300
	Australian Institute of Health and Welfare	NDI – Fact of death; cause of death (all causes of death - underlying and other); date of death.	89
	Australian Institute of Health and Welfare	National Bowel Cancer Screening Program FOBT results – Analysis date; FOBT result [positive, negative, inconclusive/NR].	32,512
	Australian Institute of Health and Welfare	MBS listing for mammographic screening at any Queensland screening centre (MBS item numbers 59300 and 59303) between 2000 and 2005 (inclusive) – Item Number (MBS item numbers 59300 and 59303); Date of mammography (e.g. 15/06/2001); Residential postcode at time mammogram; Item Category (5 – Diagnostic imaging services); Item Group (I3 – Diagnostic radiology); Item Subgroup (10 – Radiology examination of breast/s); Screening Centre (Service Provider).	300,000
	Australian Institute of Health and Welfare	NDI – Fact of death; Cause of death (underlying cause); Date of death.	2,000
	Australian Institute of Health and Welfare	NDI – age at death; date of death; State/Territory of registration; cause of death (underlying and other). MBS/PBS – date of service/date of supply; service provider derived specialty type.	90,000
	Australian Institute of Health and Welfare	NDI – Vital status; Date of death; Cause of death (underlying cause).	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	National Diabetes Services Scheme – Date of birth; Gender; Medicare number (used to link NDSS and ACIR data); Ethnicity; Diabetes (type 1 or 2); Date of diagnosis (if available); Date of 1st insulin use (if available); Date of 1st sharps purchase; Postcode. Australian Childhood Immunisation Register – Date of birth; Gender; Rotavirus immunisation history; Date of vaccination; Number of doses received; Type of vaccine (Rotateq or Rotarix).	1,500,000
	Australian Institute of Health and Welfare	NDI – State of death registration; Postcode of usual residence on death certificate; Death registration year; Age at death; Date of death; Cause of death (primary and secondary causes); Cause of death type (coroner assessed deaths flagged). ACD – Cancer disease code; State of cancer registration; Cancer diagnosis date; Age at diagnosis; Topography code; Histology code; Date of death; Basis of diagnosis.	4,793
	Australian Institute of Health and Welfare	NDI – Date of death; Underlying cause of death; Other cause of death.	5,000
	Australian Institute of Health and Welfare	NDI – Date of Death; Cause of Death; Secondary or related cause of Death.	1,600
	Australian Institute of Health and Welfare	NDI – Death status; Date of death; State/territory of death registration; Year of death was registration; Underlying cause of death code (as ICD9 codes until 1996, as ICD10 since 1997); Codes for other causes of death (as ICD10 codes since 1997).	50,000
	Australian Institute of Health and Welfare	NDI – fact of death; date of death; state of registration of death; cause of death data (underlying cause of death & multiple causes of death variables); postcode.	1,100
	Australian Institute of Health and Welfare	NDI – Date of death; Underlying cause of death; Multiple causes of death. ACD – Cause of death; Tumour identification number; Date of diagnosis; ICD-O-3 topography code; ICD-O-3 morphology code; ICD-10 disease code; Most valid basis of diagnosis.	16,000
	Australian Institute of Health and Welfare	NDI – Sex; Age at death; Date of death; State/territory in which the death was registered; Year the death was registered in; Underlying cause of death code (ICD10); Codes for other causes of death (ICD10).	100,000
	Australian Institute of Health and Welfare	NDI – fact of death; underlying cause of death; all other causes of death.	250

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	Linkage service provided by AIHW as an integrated linkage authority Emergency Department Data – Encrypted Project ID; Campus code; Month and Year of Presentation; Length of Stay; Diagnosis (ICD-10 AM codes); Time to Treatment; Type of visit; Triage category; Age; Sex; Statistical Local Area of residence; Country of Birth; Interpreter Required; Preferred Language; Compensable status; Departure Status; Visa Category and Effective Date; Date of Arrival in Australia. Admitted Patient Data – Encrypted Project ID; Campus code; Month and Year of Admission; Length of Stay; Diagnosis (ICD-10 AM codes); Procedures; Diagnosis Related Group (DRG); Weighted Inlier Equivalent Separation (WIES); Age; Sex; Statistical Local Area of residence; Country of Birth; Admission Type; Care type; Interpreter Required; Preferred Language; Patient type; Departure Status; Separation Referral; Visa Category and Effective Date; Date of Arrival in Australia; Language proficiency.	1,600,000
	Australian Institute of Health and Welfare	Linkage using Project person number NDI – Date of death; Age at death; Age group; Area of usual residence (9 digit ASGC); Mortality id; Remoteness; Sex; State of usual residence; Year of registration (of death); Underlying cause of death (ICD 9 and 10); Cause of death; Cause of death number; Place of occurrence. Hospital data – Age; Age group; Sex; Patient postcode; State of residence; Country of usual residence; Marital status; Source of referral; Stay number (encrypted); Episode start date (Date); Episode end date (Date); Diagnosis codes; Procedure codes; Procedure date (Date); Mode of separation; Hospital type (Public/Private); Emergency status; Hours in ICU; Hours on mechanical ventilation; Major Diagnostic Category; Qualified bed days; Referred to on separation. MBS – Age at date of service; Sex; Postcode; Date of service; Date of processing; Medicare item numbers; Aggregate Item number; Method of payment; Amount Fee Charged; Amount of Benefit Paid; Amount of Gap Benefit Paid; Schedule fee; Physical Modifier; Age Modifier; Emergency Modifier; Service provider number; Servicing Provider Postcode; Servicing Provider Practice Location; Referring/requesting provider number; Referring/requesting provider practice location; Referral Date; Hospital indicator; Provider specialty; Line type; Service type. PBS – Age; Sex; Postcode; Payment Category Code; Card type; Regulation 24 Indicator; Date of prescription; Date of supply; PBS item number; Number of prescriptions; Quantity of the item supplied; Scrambled Pharmacy ID; Pharmacy State; Postcode of location of pharmacy; Scrambled Prescriber ID; Hospital identifier; ATC code; ATC name.	400,000

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	NDI – Date of death (month and year only); Underlying cause of death code; All other causes of death codes; State of death registration; Year of death registration. Admitted patient care data: ♦ Establishment data – State or territory and name and location of the hospital; Administrative data; Funding source. ♦ Length of stay data – Admission and separation date (month and year only); Length of stay; Leave days; Same day flag (to indicate separation/discharge on the same day as admission). ♦ Clinical and related data – Urgency of admission; Principal diagnosis (the diagnosis established after study to be chiefly responsible for occasioning the patient's episode of care in hospital); Additional diagnoses (for example, co-existing conditions and/or complications);Procedures (surgical and non-surgical); Major Diagnostic Category (MDC) and Australian Refined Diagnosis Related Group (AR-DRG); Care type (for example acute, rehabilitation, palliative, newborn); Admission mode; Separation mode (status at separation: discharge/transfer/death and place to which person is released); External causes of injury or poisoning, place of occurrence of external cause and activity when injured; Hospital in the home days; Condition onset flag. Outpatient care data: ♦ Establishment data – State or territory and name and location of the hospital; Administrative data; Funding source; Service request received date (month and year); Service request source. ♦ Clinical and related data – Clinic type; Care type; Group session indicator; Multiple provider indicator; Delivery mode and setting. Non-admitted patient emergency department care data: ♦ Establishment data – State or territory and name and location of the hospital. ♦ Administrative data – Transport mode (arrival); Type of visit to emergency department; Waiting time (to commencement of clinical care); Funding eligibility indicator (Department of Veterans' Affairs); Compensable status. ♦ Length of stay data – Physical departure time and date (month and year only); Presentation time and date(month and year only); Clinical care commencement time and date (month and year only); Episode end time and date (month and year only). ♦ Clinical and related data – Principal diagnosis, code; Additional diagnosis; Diagnosis classification type; Urgency related group major diagnostic block, code; Urgency related group, URG (v1.3) code; Triage category.	35,000,000

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	**(CONTINUED)** MBS data – Date of processing (month and year only); Date of service (month and year only); Date of referral (month and year only); MBS (base) item code; MBS (aggregate) item code; Hospital indicator; Line type (e.g. valid, adjustment, substantiation); Service type (e.g. patient claim, bulk bill or simplified bill); Number of services; Fee charged to patient ($); Schedule fee for MBS item claimed ($); Benefit paid ($); Medicare Safety Net benefit paid ($); Extended Medicare Safety Net benefit paid ($); Unique patient identifier, de-identified; Unique provider number for service provider, de-identified; Service provider practice location; Postcode of service provider; Registered specialty of service provider; Unique provider number for referring provider, de-identified; Referring provider practice location. PBS Data – Date of processing (month and year only); Date of supply (month and year only); Date of prescription (month and year only); PBS item code; Patient category (e.g. general ordinary, general safety net, concessional ordinary); Under co-payment flag; Form type code (used to identify repeats and authority prescriptions); Drug type code (used to identify highly specialised drugs); Streamlined authority code (used to identify reason or indication for prescription); Unique hospital identifier (used to identify items dispensed in hospitals), de-identified; Number of scripts dispensed; Patient contribution amount ($); Benefit amount ($); Quantity of PBS item supplied (used when calculating Defined Daily Dosage, DDD); Number of authorised prescription repeats; Number of times previously supplied (i.e. from prescription with repeats); Derived major speciality of prescriber.	35,000,000
	Australian Institute of Health and Welfare	NDI – Date of death; Year of death registration; State/territory of registration of death; All Causes of death.	245
	Australian Institute of Health and Welfare	NDI – Death Status; Date of Death; State/Territory of death; Underlying cause of death code; Codes of other causes of death.	1,400
	Australian Institute of Health and Welfare	NDI – Date of Death; State/Territory of death; Year of death registration; Underlying cause of death code; Codes of other causes of death.	1,000
	Australian Institute of Health and Welfare	NDI – age at death; sex; date of death; State/Territory of registration; registration number; cause of death and all other causes of death mentioned on the death certificate.	550
	Australian Institute of Health and Welfare	NDI – Date of death; Year of death registration; State/territory of registration of death; Cause of death code; Codes for other causes of death.	31,000

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	NDI – Date of death; Underlying Cause of Death Diagnosis Code AND ICD-10 version; Other cause of death diagnosis code and ICD-10 version; State/territory the death was registered in; Location variable. ACD – Country of birth; Date of death (dd/mm/yy); Age at death; Cause of death; Tumour-level attributes; Tumour identification number (assigned by the state/territory); Date of diagnosis; Date of diagnosis accuracy indicator; Age at diagnosis; ICD-O-3(a) topography code; ICD-O-3(a) morphology code; ICD-10(b) disease code; Most valid basis of diagnosis; Geographic location of residence at diagnosis according to the 2011 Statistical Area Level 2 (SA2); State/territory of usual residence at diagnosis. MBS – Date of Service; MBS item number; Hospital indicator; Beneficiary level; Provider scrambled ID; Provider practice location identifier; Geographic Provider location according to the 2011 Statistical Area Level 2 (SA2 Code)*; Provider specialty. PBS – Date of Supply; Item code; ATC code; Generic name; Brand name; Drug form and strength; Quantity dispensed; Original or repeat prescription; Beneficiary level; Authority reason code; Prescriber scrambled ID; Prescriber location according to the 2011 Statistical Area Level 2 (SA2)*; Prescriber type; Pharmacy scrambled ID; Pharmacy location according to the 2011 Statistical Area Level 2 (SA2).	2,000,000
	Australian Institute of Health and Welfare	PBS – Date of processing; Date of supply; Date of prescribing; PBS item number; Drug name; Form and strength; ATC code; Patient category; Under co-payment indicator; Form category; Number of scripts; Patient contribution; Net benefit; Pharmacy identifier (scrambled); Pharmacy postcode; Prescriber number (scrambled); Prescriber postcode; Prescriber major specialty. MBS – Date of processing; Date of service; Date of referral; MBS item number; MBS item description; MBS item category; Broad type of service; Hospital indicator; Bill type; Number of services; Fee charged; Schedule fee; Benefit paid; Service provider number (scrambled); Servicing provider postcode; Servicing provider registered specialty.	1,000,000
	Australian Institute of Health and Welfare	Medicare Benefits Scheme (MBS), requesting data from 2005-2016 (We require data from 5 years before the commencement of the STAND FIRM trial (2010) to confirm if participants took up a CDM plan due to the intervention) – MBS item number (Only for MBS items 721, 723, 725, 727, 729, 731 and 732); MBS item description; Date of service. National Death Index (NDI), requesting data from 2010-2016 – Date of death; State/territory the death was registered in; Underlying cause of death code; Codes for other causes of death. Pharmaceutical Benefits Scheme (PBS), requesting data from 2005-2016 (We require data from 5 years before the commencement of the STAND FIRM trial (2010) to see if participants had a change in their prescribed secondary prevention medications due to the intervention and use of CDM plan) – ATC code (Only for medications beginning with the following ATC codes: B01 and C (Antithrombotic agents and Cardiovascular system)); PBS item number (should correspond with those specified by the aforementioned ATC codes); Drug name; Form and strength; Date of supply; Date of prescribing; Form category.	570
	Australian Institute of Health and Welfare	National Death Index – Fact of death (date of death); Cause of death (all causes of death).	150

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 – Registration No.; Registration Date; Diagnosis Date; Diabetes type; State/territory of usual residence; Postcode; Date of birth; Sex; Indigenous status; Doctor-Insulin required; Insulin Type – Injection; Insulin Type – Pump; Date of first insulin injection; Non-Insulin Injectable Allowed; Date first non-insulin injection; Diagnosis Date; Time since first insulin injection; Status; Status Reason Code; Member of GDM register; Derived date of first insulin purchase from NDSS sales data; Derived diabetes type recorded at first insulin purchase from NDSS sales data; Derived flag to indicate insulin, byetta only or no purchase record from NDSS sales data; Derived flag to indicate insulin pump consumable or reservoir purchase from NDSS sales data; Derived date of first insulin pump consumable or reservoir purchase from NDSS sales data. NDI – Date of death; Documented error flag; National death index link weight. PBS – Date of birth; Sex; Postcode; Payment Category Code; Card type; Date of prescription; Date of supply; PBS item number; Number of prescriptions; Quantity of the item supplied; ATC code; ATC name.	418,937
EC00109	Australian Hearing	Name; address for correspondence; servicing hearing centre; the three-frequency average hearing threshold; type of loss; and make/model of hearing aids (if applicable).	50-100
	Australian Hearing	Name; suburb; age; hearing loss; phone number.	100-200
	Australian Hearing	Name; address for correspondence; servicing hearing centre; age; hearing thresholds; and make/model of hearing aid(s).	50-100
	Australian Hearing	Name; date of birth; hearing thresholds; hearing devices; presence of disabilities; and contact details.	50-100
EC00130	Australian Institute of Health and Welfare	Mortality and its etiology recorded for any of the participants within the study cohort.	1,500
	Department of Human Services	Number of children in the study's participant group who went on to continue with their routine immunisation schedule, and if the vaccines were received on time.	50-100
EC00153	Department of Health	Bowel Cancer Screening Program Register	200
	Australian Institute of Health and Welfare; Department of Health; Department of Human Services	National death index; Medicare benefits scheme; pharmaceutical benefits scheme.	3,200-3,300
	Australian Institute of Health and Welfare	National Death Index – Age at death; Date of death; State/territory the death was registered in; Year the death was registered in; Underlying cause of death code (as ICD9 codes until 1996, as ICD10 since 1997); Codes for other causes of death.	90,000 – 110,000
	Australian Institute of Health and Welfare; Department of Health; Department of Human Services	Australian Cancer database; National Death Index; National Bowel Cancer Screening Program Register; National HPV Vaccination Program Registry; Medicare Data.	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
EC00153	Australian Institute of Health and Welfare	National Death Index – To obtain mortality risk statistics for each cardiac abnormality studied (the "master database")	450,000
	Department of Education	Naplan	14,000
	Australian Institute of Health and Welfare	Death Index	3,500-4,000
EC00195	Department of Health	Name (first, middle, last); Street Address (unit number, street number, street name); Suburb or Town; Postcode; State; Email address; Gender; Age (either age category or date of birth).	1-28,200
EC00215	Australian Institute of Health and Welfare; Department of Health; Department of Human Services	AIHW – Register of cancer cases; register of deaths. Department of Health – Bowel screening data; HPV vaccination data. Department of Human Services – Name and address records to update HPV vaccination data.	Approximately 5 million
EC00217	Australian Institute of Health and Welfare	National Hospital Morbidity Database (NHMD) – Records collected will be those relating to hospital admissions & stay; relevant diagnosis & care provided (cardiac procedures/interventions); discharge information; & personal identifying information to accurately link records with existing records.	30
EC00227	Australian Institute of Health and Welfare; Department of Education; Department of Health; Australian Curriculum	AEDC physical health and wellbeing score; AEDC social competence score; AEDC Emotional maturity score; AEDC Language and cognitive skills score; AEDC Communication skills and general knowledge score; Year 3/6/7/9 Reading Score; Year 3/6/7/9 Persuasive writing score; Year 3/6/7/9 Spelling score; Year 3/6/7/9 Grammar and punctuation score; Number of billed GP attendances per annum; Number and date of billings for mental health care plans; Number and date of billings for asthma cycle of care; Dispensing of pharmaceuticals; Year of death; Primary cause of death.	989,686
EC00243	Australian Institute of Health and Welfare; Department of Health	Routinely collected registry information regarding the following: infectious diseases notifications; deaths; liver cancer diagnoses; hospitalisations; data regarding provision of testing, management and treatment of hepatitis B and C.	Not specified
EC00262	Department of Health	These datasets will contain personal identifying information only (names, addresses, dates of birth) and will not contain any health/clinical information. Participants are included in the CDL project via the datasets of data custodians who participate in the PHRN through the provision of their demographic data for linkage of approved research projects.	As the research involves improving linkage methods for population research, whole-of-population datasets will be targeted. Individual datasets for hospital, emergency and death will be sought (in-principle support from WA and NSW)

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
EC00304	Australian Institute of Health and Welfare	Australian Cancer Database – Surname; given names; date of birth; sex; postcode; date of cancer diagnosis; age at diagnosis; bases of diagnosis; topography; histology; breast tumour size; postcode. National Death Index – surname; given names; date of birth; sex; underlying cause of death; other causes of death.	Australian Cancer Database: 2.5 million records. National Death Index: total number of records not specified.
	Australian Institute of Health and Welfare	National Death Index – date of death; and principal/underlying causes of death.	88,000
EC00337	Australian Institute of Health and Welfare; Department of Human Services	Medicare – address; names; sex; DOB; post code. Australian Cancer Database – name; DOB; sex; date of diagnosis; international classification of disease ICD-10 code; state/territory of usual residence at diagnosis; date of death; cause of death; post code. National Death Index – name; sex; DOB; address; date of death; cause of death.	Not provided
	Australian Institute of Health and Welfare	National Death Index – Vital statistics (alive or dead); names; DOB; postcode.	National study – not provided
EC00397	Australian Red Cross Blood Service	Blood samples	100-500
	Australian Red Cross Blood Service	Blood samples	250-300
EC00410	Australian Institute of Health and Welfare; Department of Health; Department of Social Services	Data Linkage Centre performed linkage and provided researchers with the data items. AIHW – National Death Index: Sex; Age at Death; Year Of Death occurrence & registration; Country Of Birth; SLA; Indigenous Status; cause of death. AIHW – National Hospital Morbidity Database: Sex; Age at Death; Year Of Death; Country Of Birth; SLA; Indigenous Status. Dept of Health – Hospital Emergency Department Database: Sex; Age at Death; Year Of Death; Country Of Birth; SLA; Indigenous Status. Dept of Social Services – Residential Aged Care Database: Sex; Age at Death; Year Of Death; Country Of Birth; SLA; Indigenous Status.	Approx. 150,000 death records per year (Indigenous and non-Indigenous) – includes 2,500-3,000 records of Indigenous deaths
	Australian Institute of Health and Welfare	National Death Index – Sex; age at death; date of death; state/territory the death was registered; year of death registration; cause of death code (ICD9 or ICD10); codes for other causes of death.	Approx. 70,000

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	SchoolID School identifier; StudentID Student identifier; ClassTypeA_1 Multi-year class; ClassTypeB Child repeating this grade; ClassTypeC Dual placement; ClassTypeD Number of terms attended; Tmsch In school for less than one month; Gender Sex of child; AgeCat Age categories; SpecialNeeds Special needs status; ATSI Indigenous; ESL English as a second language; Lang Speaks language other than English; PlaceOfBirth Place of birth; State State; LGA Local Government Area; SLA Statistical Local Area; A7 Well coordinated; A9 Manipulates objects; A10 Climbs stairs; A11 Level of energy; A12 Overall physical; B3 Tells a story; B4 Imaginative play; B38 Special athletics/dance; C1 Overall social/emotional; C2 Gets along with peers; C3 Cooperative; C4 Plays with various children; C5 Follows rules; C6 Respects property; C7 Self-control; C8 Respect for adults; C9 Respect for children; C10 Accept responsibility; C11 Listens; C12 Completes work on time; C13 Independent; C16 Curious; C20 Independent solve problems; C23 Adjust to change; C24 Knowledge about world; C25 Tolerance for mistake; C26 Help hurt; C32 Invite bystanders; PHYS Physical health and wellbeing; SOC Social competence; EMOT Emotional maturity; LANGCOG Language and cognitive skills; COMGEN Communication and general knowledge; PHYSCategory Vulnerable – Physical health and wellbeing; SOCCategory Vulnerable – Social competence; EMOTCategory Vulnerable – Emotional maturity; LANGCOGCategory Vulnerable – Language and cognition; COMGENCategory Vulnerable – Communication; DV1 Vulnerable - One or more domains; DV2 Vulnerable - Two or more domains; Ontrack0 On track on no domains; Ontrack1 On track on one or more domains; Ontrack2 On track on two or more domains; Ontrack3 On track on three or more domains; Ontrack4 On track on four or more domains; Ontrack5 On track on five domains; PHYS_1 Physical readiness for school day; PHYS_2 Physical independence; PHYS_3 Gross and fine motor skills; SOC_1 Overall social competence; SOC_2 Responsibility and respect; SOC_3 Approaches to learning; SOC_4 Readiness to explore new things; EMOT_1 Prosocial and helping behaviour; EMOT_2 Anxious and fearful behaviour; EMOT_3 Aggressive behaviour; EMOT_4 Hyperactive and inattentive behaviour; LANGCOG_1 Basic literacy; LANGCOG_2 Interest literacy/numeracy and memory; LANGCOG_3 Advanced literacy; LANGCOG_4 Basic numeracy; COMGEN_1 Communication skills and general knowledge; PHYS_1_Vuln Vulnerable – Physical readiness for school day; PHYS_2_Vuln Vulnerable – Physical independence; PHYS_3_Vuln Vulnerable - Gross and fine motor skills; SOC_1_Vuln Vulnerable – Overall social competence; SOC_2_Vuln Vulnerable - Responsibility and respect; SOC_3_Vuln Vulnerable – Approaches to learning; SOC_4_Vuln Vulnerable - Readiness to explore new things; EMOT_1_Vuln Vulnerable – Prosocial and helping behaviour; EMOT_2_Vuln Vulnerable - Anxious and fearful behaviour; EMOT_3_Vuln Vulnerable – Aggressive behaviour; EMOT_4_Vuln Vulnerable – Hyperactive and inattentive behaviour; LANGCOG_1_Vuln Vulnerable – Basic literacy; LANGCOG_2_Vuln Vulnerable – Interest in literacy/numeracy and memory; LANGCOG_3_Vuln Vulnerable – Advanced literacy; LANGCOG_4_Vuln Vulnerable – Basic numeracy.	25,675

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	Department of Health	Medical Benefits Schedule (MBS) Variables – Date of registration; 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 or referred; Person ID number (De-identified); Case number; Scrambled practice number; Patient age at time of service; Postcode of residence of patient (as at date of service); Gender; Indigenous Status; Year of birth; Person ID number; Date of registration in WA with Medicare (if available). Medicare Registration Variables – Year of birth; Person ID number (De-identified); Gender; Indigenous status; Postcode at year of enrolment; Date of registration in WA with Medicare (if available). NDI variables – Person ID number (de-identified); Sex; Date of death; Registration year; State / territory where death registered; Underlying cause of death; Other causes of death; Indigenous status; Marital status; Region of address at time of death.	Exact numbers will only be known after data provided (estimate 2 million)
EC00448	Australian Institute of Health and Welfare	National Death Index – probabilistic matching of surname; first name; second name; sex; date of birth; date of death.	50-150 per year

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	Australia and New Zealand Dialysis and Transplant Registry; National Organ Matching System	Age/ hypertension; gender; cause of death; type (LD vs DD, ECD vs nonECD; DBD vs DCD); race; BMI; Diabetes/CVD/CVA/PVD/chronic lung disease at entry and last follow up; Ischaemic time; time on dialysis; Pretransplant dialysis modality (preemptive,PDPD, PDHD, DHD, HDPD); Induction therapy; PRA; previous grafts; Past history of malignancies; HLA matching; Transplant centre, era/state or country; Donor/recipient ABO blood group; molecular typing; Post transplant; DSA monitoring; Pre transplant; immunological characterisation; cross matching results for any given donor kidney; Unacceptable HLA mismatches (approved antibodies); Top 30 allocation scores for any given donor kidney (matching history); Rankings at which kidneys were transplanted (does not necessarily indicate who was offered); Donor and recipient centres.	15,000
	ANZICS-CORE Adult Patient Database	Age; Gender; Admission type (elective vs. emergency); ICU admission source (i.e. ED vs. ward vs. theatre vs. other hospital); Chronic APACHE comorbidities; APACHE-III admission diagnosis[33]; Illness severity based on the on the APACHE-II and III scores and risk of death; "ANZ Risk of Death" models score[33].	25,360
EC00112	Paraquad NSW; The Paraplegic and Quadriplegic Association of South Australia	Contact Information: Surname (including maiden names, where appropriate); Given names (up to three given names); Date of birth; Address. Basic demographic data includes: Gender; Country of birth, Ethnicity, Aboriginal or Torres Strait Islander person, Marital Status, Accommodation type, Urban Vs Rural/Regional, Highest level of education, Employment status, Occupation. Minimal injury information includes: Date of SCI, Aetiology of Spinal Cord Injury (SCI), Neurological lesion level, American Spinal Injury Association Impairment Scale (AIS) grade, Compensation status and type.	10,000
EC00113	The Chris O'Brien Lifehouse	Patient demographics; diagnosis; tumour characteristics; tumour type; tumour size; pathology reports (margins excised).	100 records
	The Chris O'Brien Lifehouse	Demographic information; treatment information; Biochemistry; outpatient assessments; hospital admissions; histopathology reports.	20 records
	The Chris O'Brien Lifehouse	Patient demographic information; treatment information; medication use; treatment outcomes.	Records between 1 Oct 2014 - 1 June 2015 and 1 July 2015 - 1 April 2016
	The Chris O'Brien Lifehouse	Tumour and patient characteristics; diagnosis and treatment outcomes.	Patient records between June 2006 - June 2016
	The Chris O'Brien Lifehouse	Demographic information; clinical indicators; dosimetry information; outcome measures.	80 records

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	The Chris O'Brien Lifehouse	Patient characteristics; medical history; cancer details; surgical history.	Records of women between 2011-2016
	The Chris O'Brien Lifehouse; Meditech	Tumour histopathology; radiology reports; patient demographics; medical history.	50-100 records
	The Chris O'Brien Lifehouse; GP consulting room	Procedures details; pre and post procedure symptoms; outcomes; hospital stay; complications; patient demographics.	Records between 2014-2016
	The Chris O'Brien Lifehouse	Patient details; disease and treatment and biometric characteristics.	15 patients
	The Chris O'Brien Lifehouse	Patient details, disease and treatment characteristics.	Nov 2013 - Nov 2016
EC00118	Chris O'Brien Lifehouse	Demographic information; performance status; treatment details; tumour pathology results; imaging results; length of stay; cause of death; date of death.	50-100
	Private rooms of vascular surgeons	Demographic information; diagnosis and co-morbidities; medications; prevalence of AV fistula surgical interventions; characteristics of fistulas.	50-100
	Private rooms of Gastroenterologists	Demographic information; Inflammatory Bowel Disease (IBD) Sub type; IBD Phenotype.	50
	General practitioner practices	Survival; vital status; cause of death; relapse; second cancer rate; co-morbidities; prognostic factors.	6
	Chris O'Brien Lifehouse; Northern Cancer Institute	Demographic information; type of mesothelioma; performance status; treatment; past medical history; date of death or last follow-up.	30
	Private neurology practices, including Sydney Neurology	Demographic information; clinical and MRI findings; treatment; prognostic factors; relapse on treatment.	1-50
EC00141	Palliative Care Outcomes Collaboration (2014) Australian Health Services Research Institute (AHSRI), University of Wollongong	Patient Demographics; Setting of care for each palliative care episode and Corresponding patient needs and clinical condition.	50-100
EC00145	ReachOut.com	Individual forum posts by both participants and moderators, including textual content, user names, creation times, and structure of how these posts are organised (i.e. thread structure); Annotations for a sample of posts, that identify them as red (very concerning), amber (moderately concerning) or green (unconcerning).	~60,000 forum posts made by ~2,000 distinct authors. Of these, ~1,500 will be annotated by whether or not they are concerning.

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	The Sydney Medically Supervised Injecting Centre	Demographics: gender; age; level of education; housing status; prior imprisonment; main source of income. Drug use history: age at first injection; recent public injecting; injecting frequency; drugs injecting in the last month; smoking status; overdose history; drug to be injected at the site. Drug treatment history. MSIC service utilisation (number of visits). Self-reported health issues (do you have any health/medical issues, Septicaemia, hepatitis B, hepatitis C, HIV, endocarditis (heart infection), asthma, lung problems, heart problems, abscesses (skin infections), epilepsy, diabetes, other (specify)). Prescribed medications. Mental state and prior prescription of psychiatric medications.	15,000
EC00153	Aboriginal Community Controlled Health Services	Communicare, Medical Director, MMEx, Best Practice, Ferret and pathology services (including PathWest, Clinipath, Westerns, SA Pathology, Pathology QLD) used by the individual health centres. Quantitative STI testing and clinical management data: 1. Patient consultation data and associated demographics (including reason for visit, symptoms, laboratory test requested, age, sex and gender) 2. Episodes of STI management and related diagnosis of STIs, presumptive treatment, follow up and contacts identified and treated. 3. Laboratory test results.	30-33
	Tabbot	Tabbot Database – Clinical outcomes and complications: Numbers of contacts-virtual visits; Referral to support service e.g. Domestic violence; Contraception history and recommendation; Health history; Date of birth; General location remote/ rural/ regional area.	8-10
	Miwatj	Clinical records	50-100

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	The Australian & New Zealand Society of Cardiac & Thoracic Surgeons	National cardiac surgery database – Gender; Age; Suburb; State; Indigenous status; Insurance; Smoking history; Current smoker; Estimated glomerular filtration rate (eGFR); Family history of CAD; Diabetes; Diabetes – control; Hypercholesterolaemia; Renal – last pre-op creatinine level; Renal – dialysis; Renal – transplant; Hypertension; Cerebrovascular disease; Cerebrovascular disease – type; Cerebrovascular disease – when; Peripheral vascular disease (PVD); Respiratory disease; Respiratory disease – type; Infective endocarditis; Infective endocarditis type; Immunosuppressive Rx; Myocardial infarction (MI); MI – Type; Myocardial infarction – when; Treatment of angina – GTN; Treatment of angina – heparin; Treatment of angina – heparinoids; Angina – type; History of congestive heart failure; CHF at Current admission; Cardiogenic shock; Resuscitation; Arrhythmia; Arrhythmia type – atrial; Arrhythmia – atrial type; Arrhythmia type – heart block; Arrhythmia type – ventricular; Arrhythmia type – other; Permanent pacemaker in situ; Medications at time of surgery – inotropes; Medications at time of surgery – nitrates; Medications at time of surgery – anticoagulation therapy; Medications at time of surgery – steroids; Aspirin or other anti-platelet therapy – aspirin; Aspirin or other anti-platelet therapy – clopidogrel; Aspirin or other anti-platelet therapy – IIb blockade; Aspirin or other anti-platelet therapy – Aggrostat; Aspirin or other anti-platelet therapy – Other; Previous cardiothoracic intervention; Types of previous surgery – CABG; Types of previous surgery – off-pump CABG; Types of previous surgery – valve; Types of previous surgery – other cardiac; LVEF Method; EF; EF Estimate; Left main stenosis >50%; Number of diseased coronary systems; Status; Coronary artery bypass; Valve surgery; Other cardiac surgery; LV Aneurysm; VSD (Acquired); ASD; Trauma; Other; LVOT Myectomy for HOCM; LV Rupture Repair; Pericardiectomy; Pulmonary; thrombo-endarterectomy; Left ventricular; reconstruction; Pulmonary embolectomy; Cardiac tumour; Cardiac transplant; Other congenital; Permanent LV epicardial; Lead; Atrial arrhythmia surgery; Atrial arrhythmia; Aortic procedure; Aortic aneurysm; Aortic aneurysm type – ascending; Aortic aneurysm type – arch; Aortic aneurysm type – descending; Aortic aneurysm type – thor/abd; Aortic dissection; Aortic dissection – type; Aortic dissection – when; Acute traumatic aortic transection; Other non cardiac procedure; Carotid endarterectomy; Lung resection; Other vascular surgery; Other thoracic surgery; Other; Aortic valve procedure; Aortic valve prosthesis – implant – type; Aortic valve prosthesis – explant – type; Aortic stenosis; Aortic regurgitation / insufficiency; Aortic valve pathology/aetiology; Mitral valve procedure; Mitral valve prosthesis – implant – type; Mitral valve prosthesis – explant – type; Mitral regurgitation / insufficiency; Mitral valve pathology / aetiology; Tricuspid valve procedure; Tricuspid valve prosthesis – implant – type; Tricuspid valve prosthesis; Tricuspid regurgitation / insufficiency; Tricuspid valve pathology / aetiology; Pulmonary valve procedure; Pulmonary valve prosthesis – implant – type; Pulmonary valve prosthesis – explant – type; Pulmonary regurgitation / insufficiency; Pulmonary valve pathology / aetiology; Blood bank products – RBC; Blood bank produces – Non RBC; Perioperative transfusion – bank RBC; Perioperative transfusion – platelets; Perioperative transfusion – Novo 7; Perioperative transfusion – FFP; Peroperative transfusion – Cryo; ICU admission – Date/time; ICU discharge – Date/time; Readmitted to ICU; Reintubation; Reintubation – Date/time; Re-extubation – Date/time; ICC lost; Return to theatre; Re-op valve dysfunction; Re-op bleeding/tamponade; Re-op graft occlusion; Re-op deep sternal infection; Re-op other cardiac; Re-op other non cardiac; New renal failure; Haemofiltration;	3,080-3,085

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	The Australian & New Zealand Society of Cardiac & Thoracic Surgeons	**(CONTINUED)** Highest post-op creatinine level; Peri-operative AMI; Peri-operative cardiogenic shock; Cardiac inotrope use – for low cardiac output syndrome; Cardiac inotrope use – for low SVR syndrome; New cardiac arrhythmia; New heart block; New other brady-arrhythmia; Cardiac arrest; New atrial arrhythmia; New ventricular tachycardia; Stroke permanent; Stroke transient; New continuous coma >=24 hours; Prolonged ventilation >24 hours; Pulmonary embolism; Pneumonia; Re-intubation and ventilation; Deep sternal wound infection; Deep thoracotomy wound infection; Septicaemia; Aortic dissection; Acute limb ischaemia; Multi-system failure; Discharge; Mortality – Date; Mortality – Location; Mortality – Primary cause; Morality – Subsequent case; Elective day of surgery admit (DOSA); Surgery date; Operation number; Verified comment; Discharge date.	3,080-3,085
	Western Diagnostic Pathology	Serology test results relating to HBV and HCV.	60,000
EC00171	HAMBS – Hospital and Medical Benefits System	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 (ICD10AM); Procedures that were performed on the patient, coded in the Australian Classification of Health Interventions (ACHI), the Diagnosis Related Grouping (CRG) and the Medical Benefits Schedule number; Medical, prostheses and hospital benefits billed to the insurance fund.	1,000,000
EC00172	Novartis Australia – the Clozaril Patient Monitoring System (CPMS); Hospira – the Clopine Connect system	Demographic data – Name; age; gender. Clinical data –Diagnosis; Clozapine start date and end date; final dose; reason for discontinuation; duration of treatment; mental health act status at the time of initiation; management type: Community or Shared care; premorbid Health (hypertension; diabetes mellitus; hypercholesterolemia; body mass index; cardiac abnormalities; smoking status; respiratory abnormalities; seizure history).	400-470
EC00182	St Vincent's Private Hospital, Toowoomba; St Andrew's Private Hospital, Toowoomba.	Name and contact details	65
	Cherbourg Health Action Group – Community	Survey of Oral Health practices	30
	St Andrew's Private Hospital, Toowoomba	Medical Records	100
EC00234	Bendigo Primary Care Centre	Patient health record information including patients' age; number and type of chronic diseases; frequency of utilisation of services at Bendigo Primary Care Centre; 75 year old check status; living status; language and ethnicity. Where available, mental health and well being scores will be recorded.	Approximately 1,000 records

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
EC00235	Various private pathology providers, e.g. Melbourne Pathology, Healthscope, Dorevitch	Blood test results, if not available from Peter Mac Pathology service or Peter Mac medical record.	1-200 (depends on how many patients had bloods tests done at private pathology provider, instead of Peter Mac Pathology)
	Various private pathology providers, e.g. Melbourne Pathology, Healthscope, Dorevitch	Archived tissue samples	1-150 (depends on how many patients had tissue samples tested by a private pathology provider, instead of Peter Mac Pathology)
EC00242	The Avenue Private Hospital	CT scans	70
	The Avenue Private Hospital	Length of stay in hospital	200
EC00263	The Peri-operative Department at Bethesda Private Hospital / Healthcare	The information to be sought includes the documentation of post operative pain management and intervention to the patient as documented by the nurse on that day of surgery only.	Up to 50 medication and pain management charts will be collected and observed from medical records
	RSL Menora WA, which is a non- profit RACF organisation	The information that will be sought from this facility is the Incident Management Records of 2015. The date, time and URN of the selected Incident Management Record will be collected.	The estimated number of records that will be accessed is 100
	Joondalup Health Campus	Nursing documentation of pain assessments; ICU flow chart in the medical records.	Approximately 30
	The Royal Flying Doctor Service	Information pertinent to snake bites	78,000 clinical records
	The audit will be conducted at Juniper Hillcrest in Geraldton	The information to be collected includes: resident's date of admission and date of death, place of death, formal diagnosis of dementia, religious and cultural background. Care plans and progress notes, training records will be used to obtain the information. In addition, the facility`s palliative care policy and evidence of on going education to staff will be obtained.	Approximately 60-70 records will be accessed
EC00267	1601: Joondalup Health Campus	Patient demographics; referral date; clinic attendance; weight change.	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
EC00267	1603: Joondalup Health Campus	Medical history; presenting complaint; diagnosis; treatment information; disease risk factors; medical management.	100
	1610: Joondalup Health Campus	Patient demographics; medication; LOS.	150
	1611: Joondalup Health Campus	Pain episodes; analgesia; pain assessment.	30
	1615: Joondalup Health Campus	Patient demographics; admitting diagnosis; co-morbidities; nutrition data; hospital stay data; vital status; outcome data.	100
	1616: Joondalup Health Campus	Patient demographics; co-existing illnesses; severity of illness; source and type of clinical specimens; test results; treatment; medications; outcomes.	40
	1617: Joondalup Health Campus	Discharge details; hospital stay.	50
	1618: Joondalup Health Campus	Patient demographics; admission details; patient experience; post-operative complications; QOL measures.	Number of records not yet available
	1621: Joondalup Health Campus	Patient demographics; admission details; diagnosis; medications; test results; complications; procedures; medical history; risk factors.	60
	1623: Joondalup Health Campus	Patient demographics; LOS; procedure details; complications; outcomes; readmission rates.	200
	1625: Joondalup Health Campus	Diagnosis and appropriateness; exclusion criteria; discharge; medication; laboratory results.	50
	1632: Joondalup Health Campus	Patient demographics; procedure and indications for; personnel; medications; complications; patient satisfaction.	450-500
	1633: Joondalup Health Campus	Patient demographics; history; procedure details; outcomes.	600
	1634: Joondalup Health Campus	Patient demographics; procedure; obstetric parameters.	100
	1638: Joondalup Health Campus	Patient demographics; indications for surgery; outcomes; LOS.	70
	1639: Joondalup Health Campus	Patient demographics; laboratory results; clinical observations; personnel involved; procedure details and outcome.	70-120
	1644: Joondalup Health Campus	Patient demographics; presentation date; symptom incidence; medications; symptoms; risk factors; LOS; disease progression.	1,200
	1647: Joondalup Health Campus	Patient information; admission; assessment; treatment; discharge; follow-up.	1,200
	1648: Joondalup Health Campus	Post-operative screening and care	100
	1649: Joondalup Health Campus	Patient demographics; medical history; tests/monitoring; medications.	5,000-10,000

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
EC00286	St John of God Subiaco Hospital, and private consulting suites of Dr Jason Tan and Dr Stuart Salfinger	Medical history, demographic data, operation records, anaesthetic records, histopathology specimen reports, inpatient progress notes, observation and medication charts and correspondence from the treating specialist. Online data will also be accessed from SJGHC WebPas specifically relating to transfer of patients in and out of theatre and the duration of theatre operating time.	100
EC00302	Calvary Wakefield Hospital	Medical history and care during the hospital for the coronary angiogram/PCI including: medications, risks factors, previous cardiac tests and results of the coronary angiogram/PCI procedure.	Approximately 100 per year
EC00315	St Vincent’s Private; Cabrini Health	Demographic details (age, DOB, address); Clinical information about disease (stage, treatment provided) and critical information for risk adjustment; Date of death/discharge; Complications.	1,000 cases per year across participating sites (which includes sites other than the private sector organisations specified)
	Residential Care Facilities (Royal Freemasons: Coppin House; Jewish Care: Gary Smorgan House, Smorgan Nursing Home, Montefiore homes; Aged Care Services Australia Group (ACSAG): Central Park, Eleanora Nursing Home; Emmy Monash Aged Care; Abberfield Aged Care; Regis Aged Care – Regis Seaside Manor; Menarock Aged Care Services – Rosehill Aged Care	Medications and medical care details	300
	Cabrini Health; Geelong Private Hospital; Maryvale Private Hospital; Masada Private Hospital; Mildura Private Hospital; St John of God Health Care	Demographic details (name, age, DOB, address); Clinical information about disease (stage and details of diagnosis); Prostate cancer treatment provided (brachytherapy, radiotherapy, surgery and hormone therapy) and critical information for risk adjustment; Date of death/discharge; Complications.	5,000 per year
EC00332	Mater Private Intensive Care Unit, Mater Misericordiae Ltd	Skin assessment; Medical charts.	355
	Mater Centre for Neurosciences, Mater Misericordiae Ltd	Medical Charts	153

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	Matrix (the maternity clinical database), Mater Misericordiae Ltd; Mater Central Data Repository (which house a copy of Matrix data and other clinical and non-clinical data systems), Mater Misericordiae Ltd	Medical history	Approximately 12,000 records
	Mater Misericordiae Ltd at Mater Mothers' Hospital, Mater Mothers' Private Brisbane, Mater Mothers' Private Redland; Mater Misericordiae Hospital Rockhampton; Mater Misericordiae Hospital Mackay; Mater Misericordiae Hospital Gladstone	Medical databases	up to 5,000 approximately
	Mater Hospital Brisbane, Mater Misericordiae Ltd	Medical Charts	100-150
	Mater Misericordiae hospital Bundaberg; Mater Misericordiae hospital Gladstone; Mater Misericordiae hospital Rockhampton; Mater Misericordiae hospital Mackay	Medical Charts	400
	Mater Misericordiae Ltd	Medical Charts	33
	Mater Misericordiae Ltd	Medical databases; Cerebral Palsy Registers.	Approximately 700
	Mater Misericordiae Ltd; Australian Cerebral Palsy Registers	Medical Charts; Medical Databases	Approximately 700
	Mater Mothers' Hospital, Mater Misericordiae Ltd	Medical Charts	Approximately 1,500
	Mater Mothers' Hospital	Medical Charts	Approximately 31,250
	Mater Mothers' Hospital, Mater Misericordiae Ltd	Mater Health Matrix Database	20,000 to 30,000
	Mater Mothers' Hospital, Mater Misericordiae ltd	Medical Charts; Medical Databases	Approximately 2,000

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 Hospital Brisbane, Mater Misericordiae Ltd; National Joint Replacement Registry	Medical Charts	59
	Mater Pathology and Mater Hospital Brisbane, Mater Misericordiae Ltd	Medical Database	1,300
	Mater Cancer Care Centre, Mater Misericordiae Ltd	Medical Charts; Medical Databases.	120
	Mater Hospital Brisbane, Mater Misericordiae Ltd	Medical Databases	120
	Health Information, Mater Misericordiae Ltd	Medical Database	1
EC00337	Private GP Clinics	Patient name, age, sex, current and past medications, medical history, social history (whether the patient lives alone or has a carer, smoking status, alcohol usage), town/city of residence, kidney function tests, liver function tests if applicable and relevant points about their use of antithrombotics. Patients will be de-identified after the interviews have taken place. In addition the age and training level of the doctor will be recorded.	100, 20 Different GP Clinics
	Angus Thompson, Accredited Home Medicines Review (HMR) Pharmacist	Basic patient demographics of age and gender. Information (e.g. drug, dose, frequency) on use of proton pump inhibitors and other drugs that may increase risk of hypomagnesaemia (e.g. diuretics). Information from pathology tests relevant to area of study i.e. magnesium levels. Information (e.g. formulation, dose, frequency) on use of magnesium supplements.	300-400
	Dr Jonathon Mulfords Private Rooms	Patient demographics (Age, sex, height, weight, BMI) and region of Arthroplasty; Use of Tranexamic Acid; Transfusion required or not; Number of blood tests (including value of Pre and post operative haemoglobin and UEC).	Not Provided. Inclusion criterion for this study is: All who underwent Primary Total Knee or Hip replacement in Launceston General Hospital, North West Regional Hospital or St. Luke Private Hospital from 01/01/2010 – 01/01/2016

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	Private Practising Neurologists (TAS)	Data being collected will include patients gender, date of birth, postcode, diagnosis, dates of visitations, clinical symptoms at each visitation including sensory and motor symptoms, electrodiagnostic results from nerve conduction studies, treatment details and relevant medical history.	250
EC00399	Riverina Cardiology, Wagga Wagga	Result of Computed tomography coronary angiography (CTCA), patient outcomes at 12 months (mortality, myocardial infarction, diagnosis of Coronary Artery Disease by other means, further cardiac imaging); basic demographics including age and gender.	Approximately 400-600
	Medibank Health Solutions (Previous private provider for Southern NSW LHD mental health help line)	Monthly telephone triage calls; Monthly ED presentations; number of unplanned ED presentations; number of planned ED presentations; triage category.	Approximately 25,000
EC00422	Brightwater Care Group	Data items for linkage – Enc_Per_ID; Client ID / URN; LastName; SecondName; FirstName; Preferred name; Gender; DateOfBirth; AboriginalTSI; Address1; Address2; City; State; Zip; Country; PreviousPostcode; PreResAddress2; PreResCity; PreResState; OnElectRoll; Referral Date; Admission date. Data items for research – ABI (Yes/No); Aboriginal/TSI; Accommodation/housing details; Additional Diagnoses; Admission date; Admission FIMFAM (Total); Admission MPAI-4 (Total); Admitted from; Age; Age at entry / on admission; Barthel Score; Blood borne disease status; Cause of injury; Comorbidities (not the same as secondary diagnosis); Concessional / Fee Waiver; Cornell score; Country of Birth; Criminal history; Cultural Background; Date of Birth; Date of injury; Dependent children; Discharge date; Discharge destination/Post Code; Discharge FIMFAM; Discharge MPAI-4; Drug and alcohol history (yes / no) drop down – intravenous, recreational, etc.; DVA Card colour; Employment status at time of injury; Ethnicity; FimFam Assessment dates (other); FimFam Assessment scores (other); Funding package; Gender; Guardianship and Administration status; Health Fund; Highest educational level; Homeowner status; Hospital admission date; Hospital discharge date; Language Spoken; Marital status; Mini-mental score; Mobility Status; MPAI-4 Assessment dates (other); MPAI-4 Assessment scores (other); Northwick Park Care Needs Assessment (admission); Northwick Park Care Needs Assessment (discharge); Occupation prior to injury; PAS score; Pension Type; Postcode of last residential address; Preferred Language; Primary diagnosis on referral; Program; Referral Date; Referral source; Referral source (Other); Religion; Smoker; State of Aust.	17,000
	St John of God Pathology and Western Diagnostic Pathology	St John of God Pathology – labtrackid; umrn; sex; dob; location; doc; toc; lab_number; troponin_i; troponin_t; ck; ck_mb; glucose; ghb; ldl; hdl; triglcyerides; cholesterol; fast_flag; creatinine; egfr; hb; wcc; haem_flag; hospital. Western Diagnostic Pathology – Ultra patient unique identifier; MRN; Sex; Date of birth; Location; Admission diagnosis - Not available; Admission date - Not available; Separation dates - Not available; Date of collection; Time of collection; Lab number; Troponin I result; Troponin T result; CK result; CK-MB result; Blood glucose (fasting) result; Glycosylated haemoglobin result; LDL result; HDL result; Triglycerides result; Total cholesterol result; Fasting flag; Serum creatinine result; eGFR; Haemoglobin result; White cell count result; Haemolysis flag; Hospital site - Our collection centre code if an inpatient - denotes hospital.	13,000

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
EC00422	Intellectual Disability Exploring Answers (IDEA)	ID_level; Heber1; Heber2; Heber3; sex; dob; Source of ascertainment.	22,000
	St John of God Pathology; Australian and NZ Dialysis and Transplant Registry (ANZDATA); Clinipath; Western Diagnostic Pathology; Perth Pathology	St John of God Pathology – Postcode (at test date); Test date; Serum Creatinine where eGFR <60; Age (MMYYYY); Gender. ANZDATA – Postcode; Start date of dialysis and or transplant date; Age (MMYYYY); Gender. Clinipath – Unique record ID; Postcode (at test date); Test date; Serum Creatinine where eGFR <60; Age (MMYYYY); Gender. Western Diagnostic Pathology – Unique record ID; Postcode (at test date); Test date; Serum Creatinine where eGFR <60; Age (MMYYYY); Gender. Perth Pathology – Unique record ID; Postcode (at test date); Test date; Serum Creatinine where eGFR <60; Age (MMYYYY); Gender.	2,100,000
	Joondalup Health Campus	Admission age; Sex; Admission status; Care type; Subset admission date; Subset separation date; Mode of separation; Subset date of birth; Marital status; Employment status; Interpreter service; Language; Country/State of birth; State/Territory of residence; Length of stay; Source of referral- location; Source of referral- professional; Source of referral- transport; Insurance status; Total leave days; Number of leave periods; Days of psychiatric care; Days of Hospital in the Home care; Days in Intensive Care Unit (ICU); Hours in ICU; Principal diagnosis; Co-diagnosis; Additional diagnoses; Principal procedure; Additional procedures; External cause of injury; Activity code; Place of occurrence; Admission date; Separation date; Additional procedure dates; Mental health legal status; Diagnostic Related Group (DRG);Grouper version; Major Diagnostic Category (MDC); Grouper version.	1,012
	Intellectual Disability Exploring Answers (IDEA)	ID_level; Heber1; Heber2; Heber3; sex; dob; Source of ascertainment.	640,000
	SilverChain	Date of visit; Time of visit; Duration of visit; Service type code; Service from date; Service to date; Visit type code; Provider type; Temporary change in care (including to date, from date and reason); Service holds (including to date, from date and reason).	80,000

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
EC00422	Busselton Health Study	Drink alcohol ever; alcohol consumption amount; alcohol consumption level, self rated; when started drinking; when stopped drinking; cholesterol total; cholesterol hdl; cholesterol ldl; triglyceride; glucose fasting; alanine aminotransferase; albumin; alkaline phosphatase; bilirubin; c-peptide fasting (& 1 hour in 1978); calcium; creatinine; ggt; iron; protein total; transferrin & transferrin saturation; uric acid; systolic bp; diastolic bp; height; weight; history of high cholesterol; history of high triglyceride; history of hypertension; history of stroke; Rose angina questionnaire; Rose MI questionnaire; dob; sex; marital status; married when; occupation; country of birth; when arrived in Aust; diabetes ever or now; diabetes ever treated for; diabetes treatment type; diabetes treated by diet; on a special diet now; changed diet last n yrs; changed diet reason; bran; bread; butter/margarine; cheese, eggs; coffee, tea; cream, ice cream, yoghurt; fish; fruit; meat; milk; vegetables; salt added; snacks; soft drinks; sugar, honey; type of water; number hospital adms last year; when last saw doctor; changed exercise last 3/5 yrs? ; changed exercise reason; exercise hours per week; hours light, mod, vig activity at home, work, leisure; white cell count; eosinophil; basophil, lymphocytes, monocytes, neutrophil; red cell count; red cell distribution width; platelet count; haematocrit; haemoglobin; mean cell haemoglobin, MCH concentration; mean cell volume; angina; diabetes; high cholesterol; high triglicerides; hypertension; myocardial infarction, heart attack mean platelet volume; other chest problem/trouble; reflux oesophagitis; stroke; transient ischaemic attack; ulcer; all drugs currently used (detailed); diabetes – tablets; diabetes – insulin; hrt; hrt (detailed); hypertension trt; oral contraceptives; ulcer & anti-inflammatory drugs; occupation; history of dusty job; work hours light, moderate & vigorous activity; exposed to tobacco smoke at work; smoked ever; when started/stopped smoking; tobacco consumption weekdays & weekends; ets at home (smokers in household); ets at work; ulcer, ever had and type; ulcer details (how diagnosed,etc); heartburn; indigestion; reflux oesophagitis; family history of ulcers; stroke; cerebral haemorrhage/cerebral thrombosis; transient ischaemic attack; neurological symptoms (inc speech loss,numbness..); weight measured at clinic; weight changed last 12 months and reason; weight at age 20; on HRT now; which HRT.	4,687
EC00445	The ACH Group (SA); Hammond Care (NSW); Sir Moses Montefiore Jewish Home (NSW)	Site/service; Client gender; Client age; Client living situation; Severity of dementia as indicated by cognitive assessment tool score; Duration of service; Number of face-to-face consultations; Number of phone calls to client/carer; Assessments undertaken; Intervention approaches used; Environmental modification advice; Prescription of assistive devices or equipment; Education about dementia (for the person with dementia); Education about dementia (for the carer); Carer coping strategies; Case management; Placement/respite processes; Aged Care Assessment applications; Referral to other services; Teaching compensatory strategies for basic ADLs; Use of strategies to enhance memory; Assisting clients choice and use of meaningful activities; Rehabilitation for comorbidities (e.g. falls); Teaching compensatory strategies for instrumental ADLs; Behavioural management approaches; Functional mobility training; Social activities; Leisure activities; Reminiscence therapy; Driving cessation advice/transport options; Psychosocial support (e.g. counselling); Cognitive retraining; Validation therapy; Reality orientation; Teaching compensatory strategies for community activities; Creative media (dance, drama, music, art); Outings (e.g. museum, clubs); Exercise/tai chi/yoga; Other commonly used interventions; Perceptual retraining; Stress management/relaxation training; Snoezelen.	100

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
EC00451	Private neurologists from North Queensland, Hunter/Newcastle region, Geelong region and Tasmania	Patients' gender, date of birth, postcode, diagnosis, dates of visitations, clinical symptoms at each visitation including sensory and motor symptoms, electrodiagnostic results from nerve conduction studies, treatment details and relevant medical history.	Up to 250 records