Australian Government

National Health and Medical Research Council

National Health and Medical Research Council

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

September 2016

Melbourne Canberra Sydney
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ORIMA RESEARCH

Background

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

Contents

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

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

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

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

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

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

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

A. Number of HRECs

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

Table 1: Reportable HRECs by Jurisdiction

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

B. HREC membership

The minimum membership of an HREC is eight members, comprising one from each core membership category described in paragraph 5.1.30 of the National Statement. This includes two individuals assigned to each of the following categories: 'persons with current research experience that is relevant to research proposals to be considered'; and 'lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work'.

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

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

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

Additional membership

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

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

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

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

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

Institutional and non-institutional members

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

Gender balance

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

C. Administration and general operation of the HREC

Requirements of the National Statement

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

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

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

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

Reporting mechanisms

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

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

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

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

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

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

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

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

Use of the National Ethics Application Form (NEAF)

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

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

D. HREC meetings

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

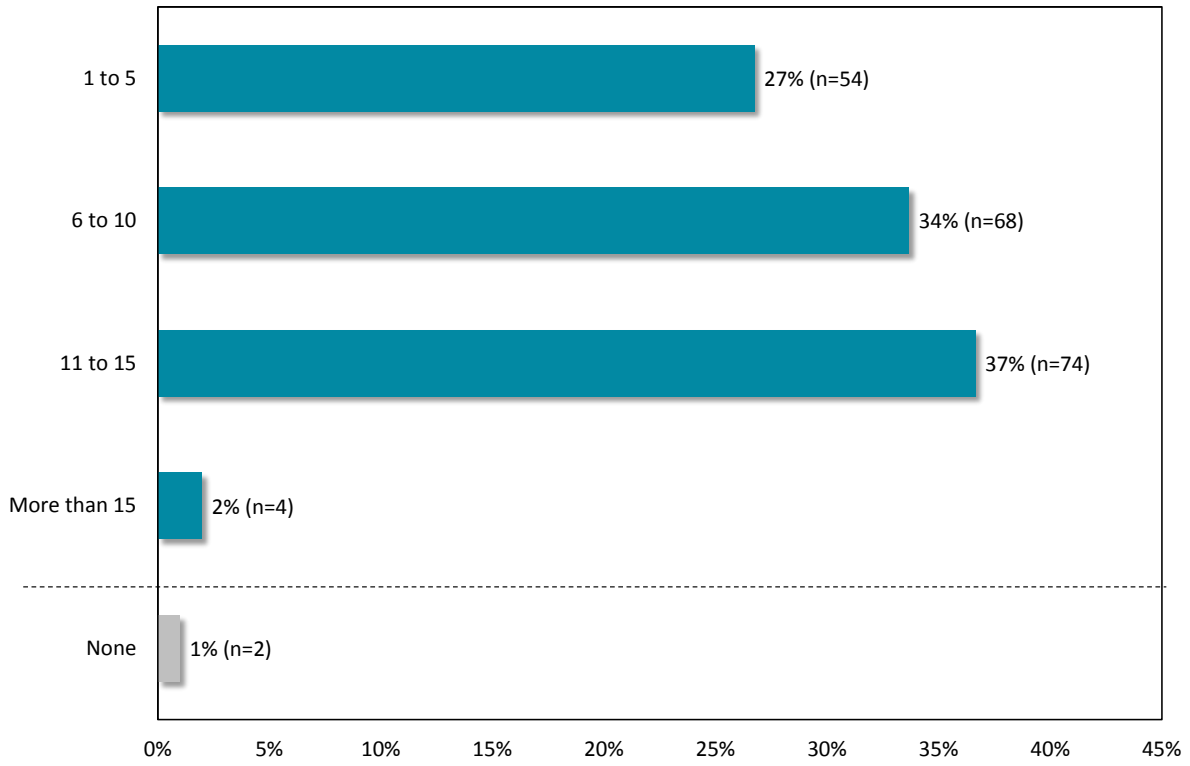
In the instances where the minimum membership was not present at all meetings, all but two HRECs (98%; n=125) reported that the Chair was satisfied, prior to a decision being reached, that the absent members who belong to the minimum membership categories received all papers, had an opportunity to contribute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

Number of meetings

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

Figure 1: Number of meetings held by HRECs in 2015

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



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

E. Training

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

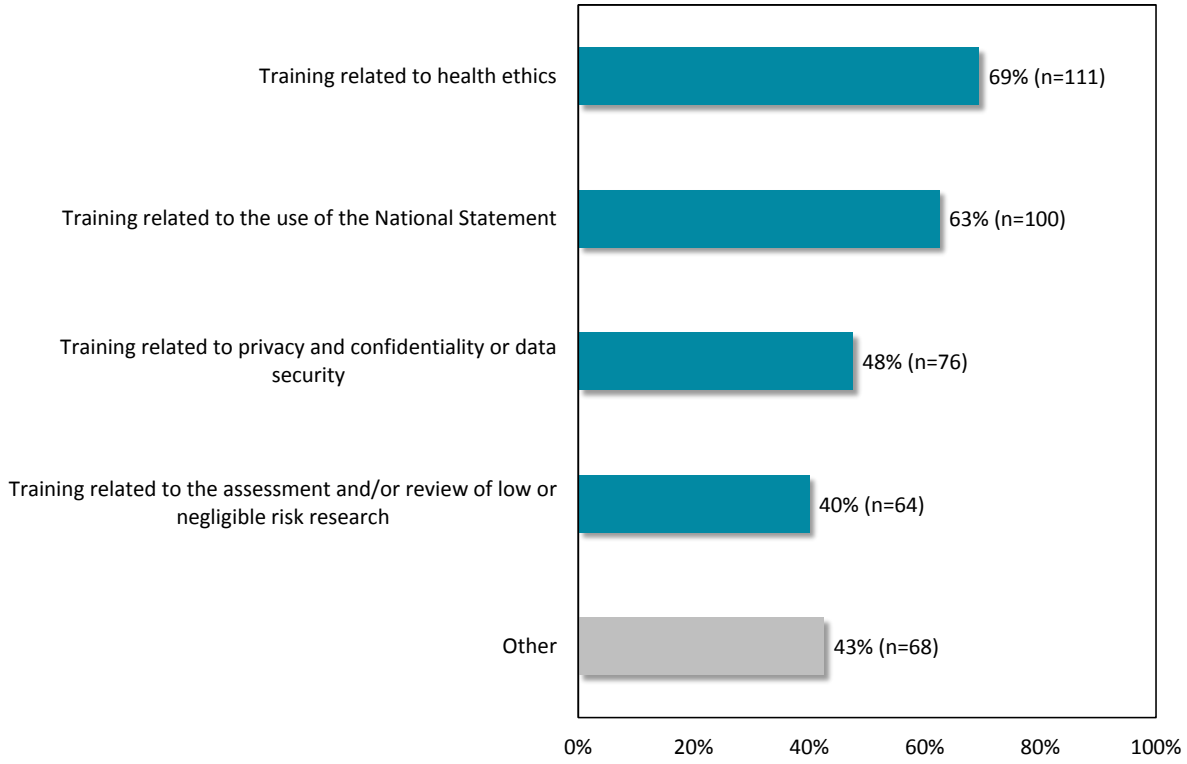
Types of training

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

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

Figure 2: Types of training undertaken by HREC members

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



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

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

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

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

F. Review of research proposals

Number of research proposals

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

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

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

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

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

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

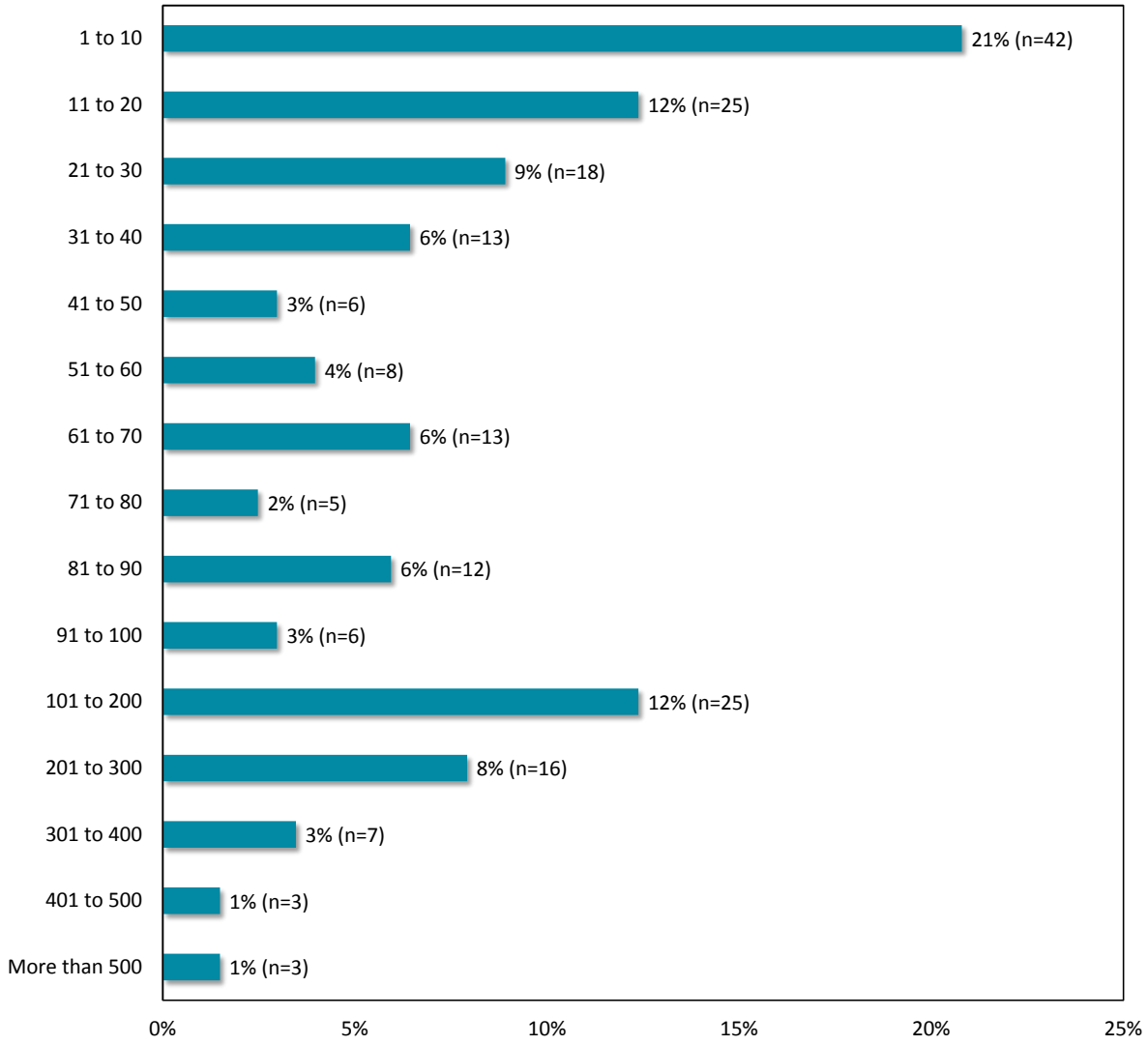
[8] As it was not mandatory for HRECs to provide this data in their reports, there were four HRECs that did not advise on the number of proposals that were denied ethical approval and will not be re-considered by the HREC.

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

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

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

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

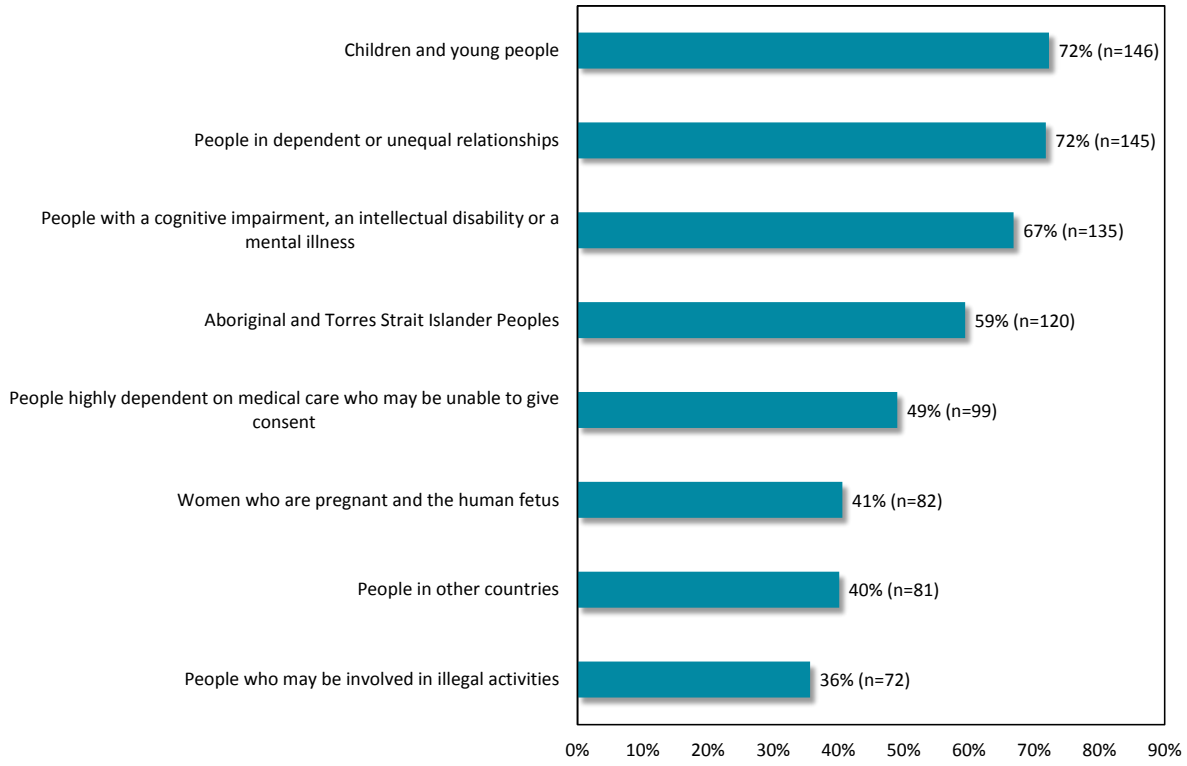


Types of research proposals considered by HRECs

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

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

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



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

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

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

G. Health research involving Aboriginal and Torres Strait Islander Peoples

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

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

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

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

Table 3: Research involving Aboriginal and Torres Strait Islander Peoples

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

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

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

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

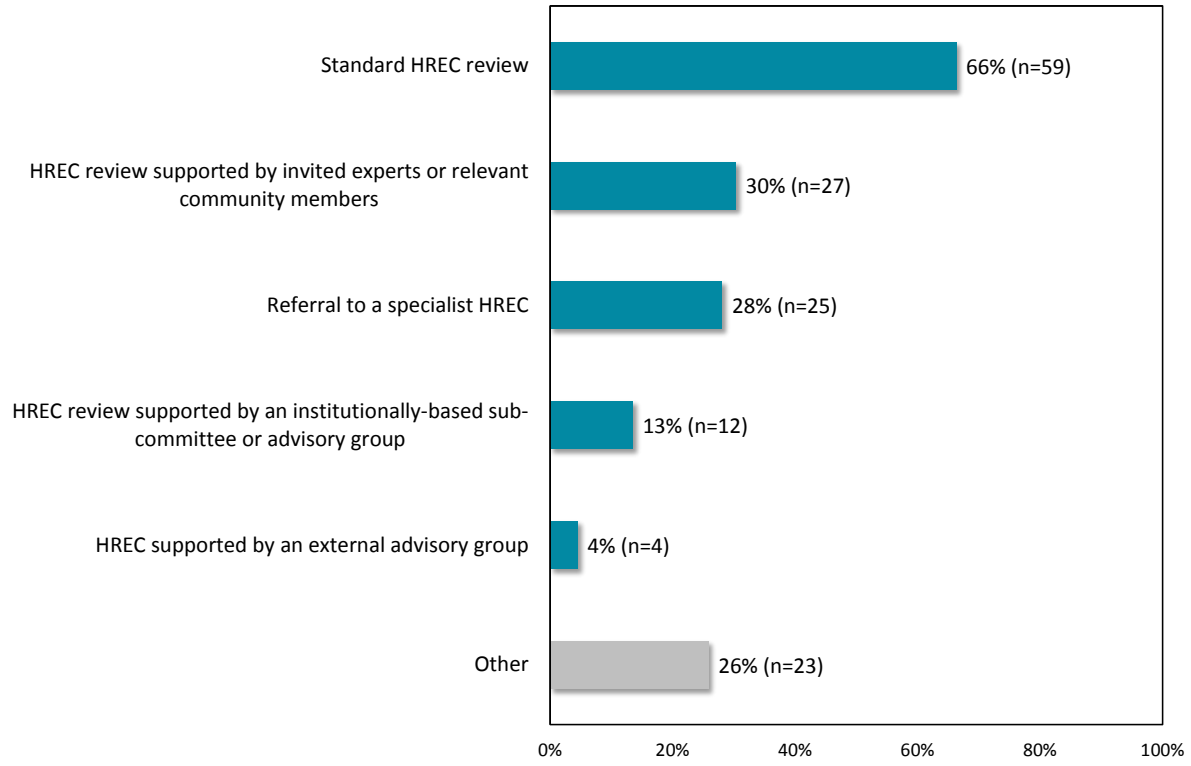
The reasons provided for denying ethical approval for health related research proposals involving Aboriginal and Torres Strait Islander Peoples included:

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

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

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

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



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

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

H. Research involving low or negligible risk

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

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

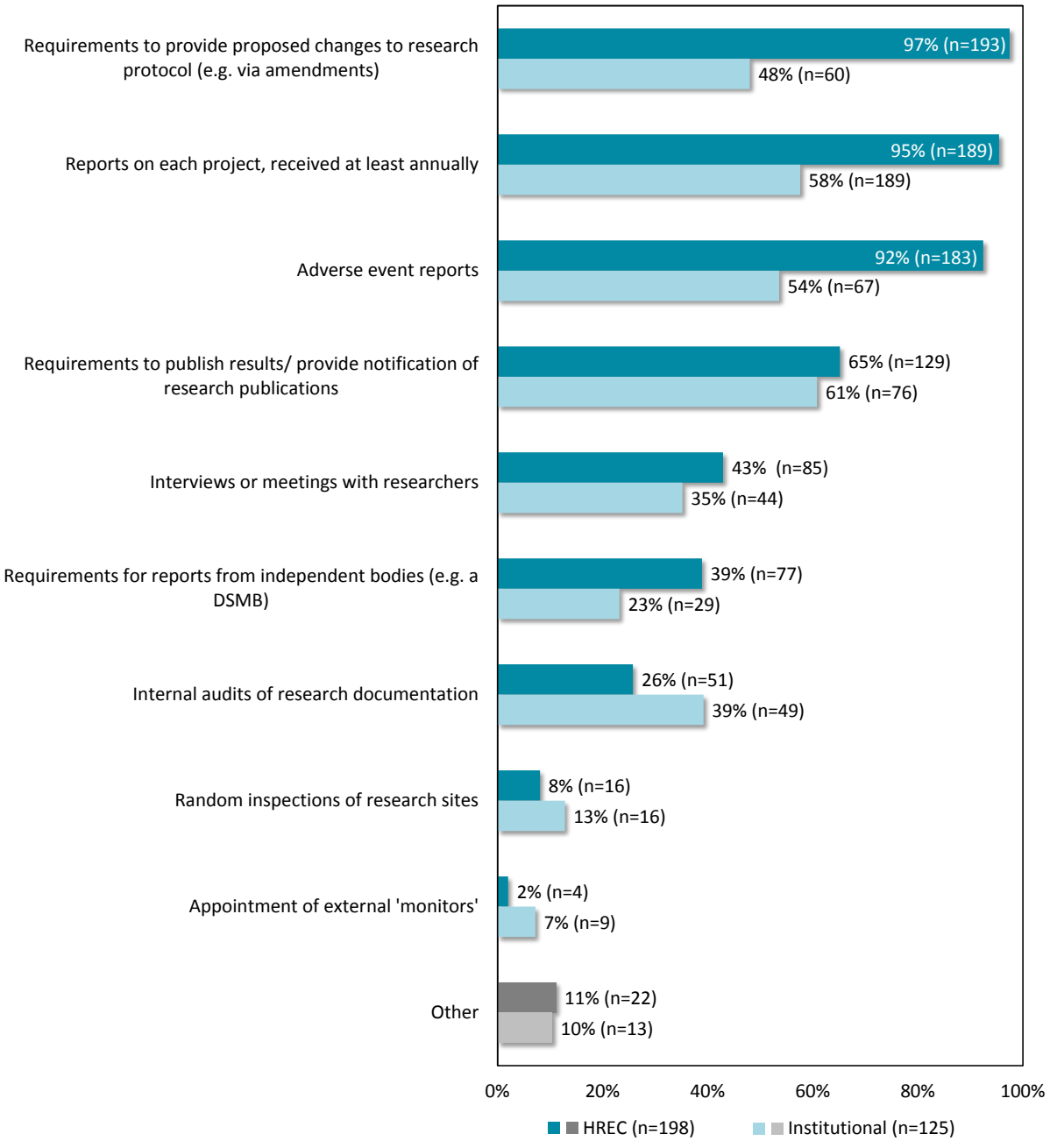
[12] An alternative mechanism could include review by the HREC Chairperson or delegate, review by a sub-committee of the HREC, review by another institutional group or delegated individual etc. (see paragraph 5.1.18-5.1.21 of the National Statement).

I. Monitoring of research

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

Figure 6: Monitoring processes

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



Other processes used to monitor research included:

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

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

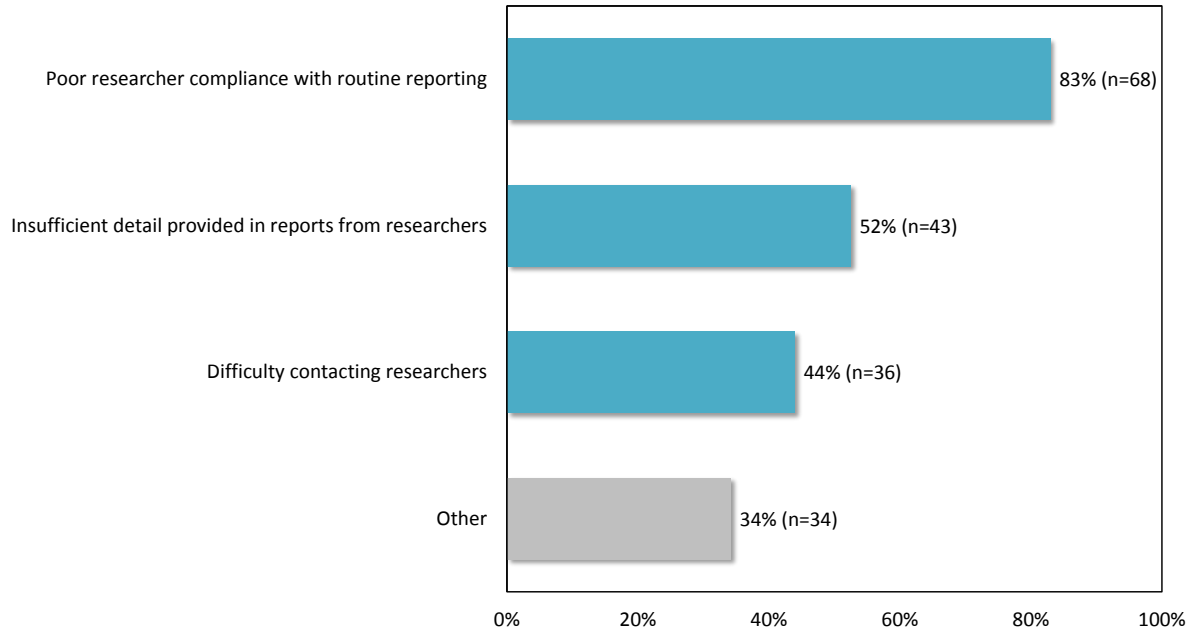
- Lack of resources;
- Approved research projects are low-risk (survey or registry);
- Approved research projects are small-scale (theses) and are supervised by an academic staff member; and
- Work could not be completed as the host institution closed shortly after the inaugural HREC meeting.

Problems encountered in monitoring approved research

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

Figure 7: Problems encountered in monitoring research

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



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

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

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

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

J. Complaints handling

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

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

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

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

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

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

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

Types of complaints received

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

Table 4: Number of complaints or concerns received by HRECs

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

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

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

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

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

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

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

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

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

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

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

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

A. Number of Certified Institutions and institutional HRECs

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

Table 5: Reportable HRECs by jurisdiction

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

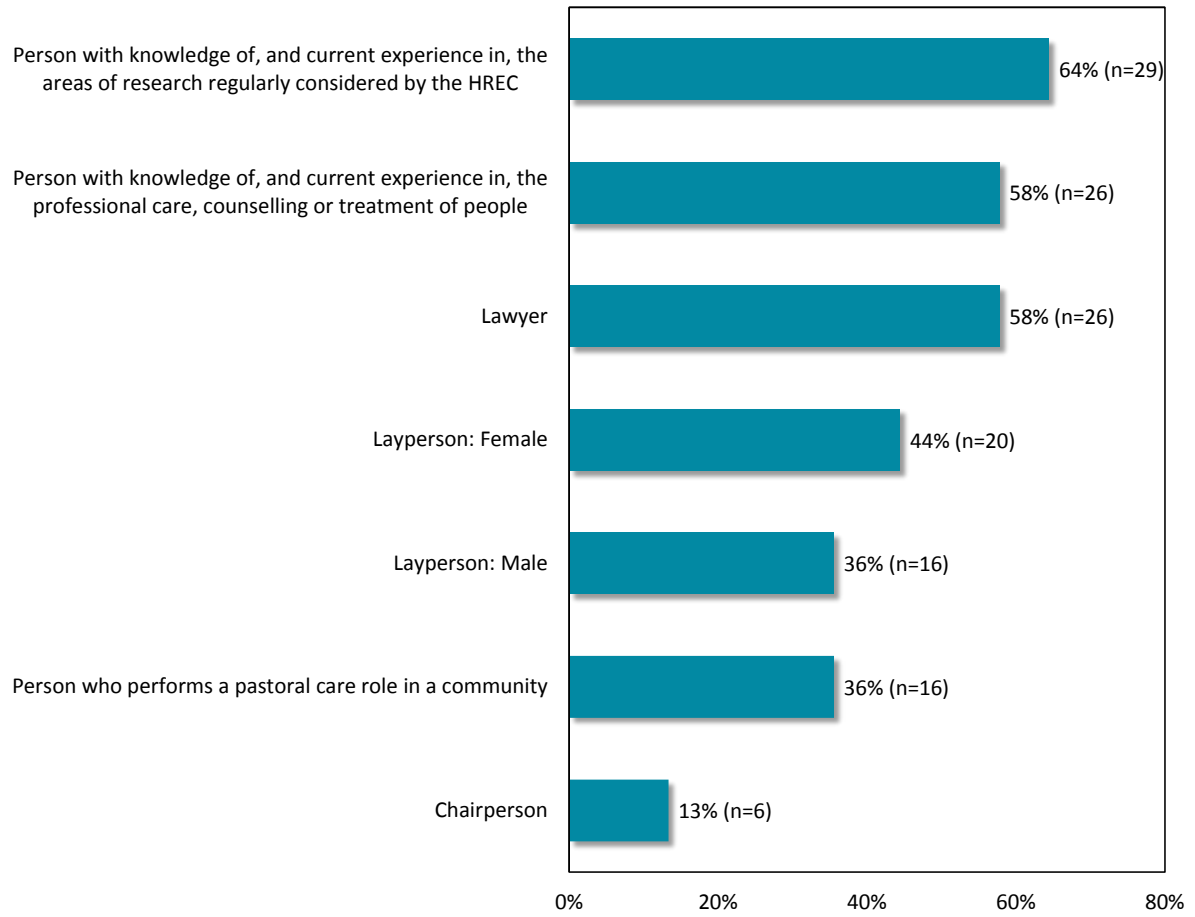
B. HREC composition

Membership

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

Figure 8: Categories of membership in which the change occurred

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



Sub-committee expertise

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

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

C. Review of multi-centre research proposals

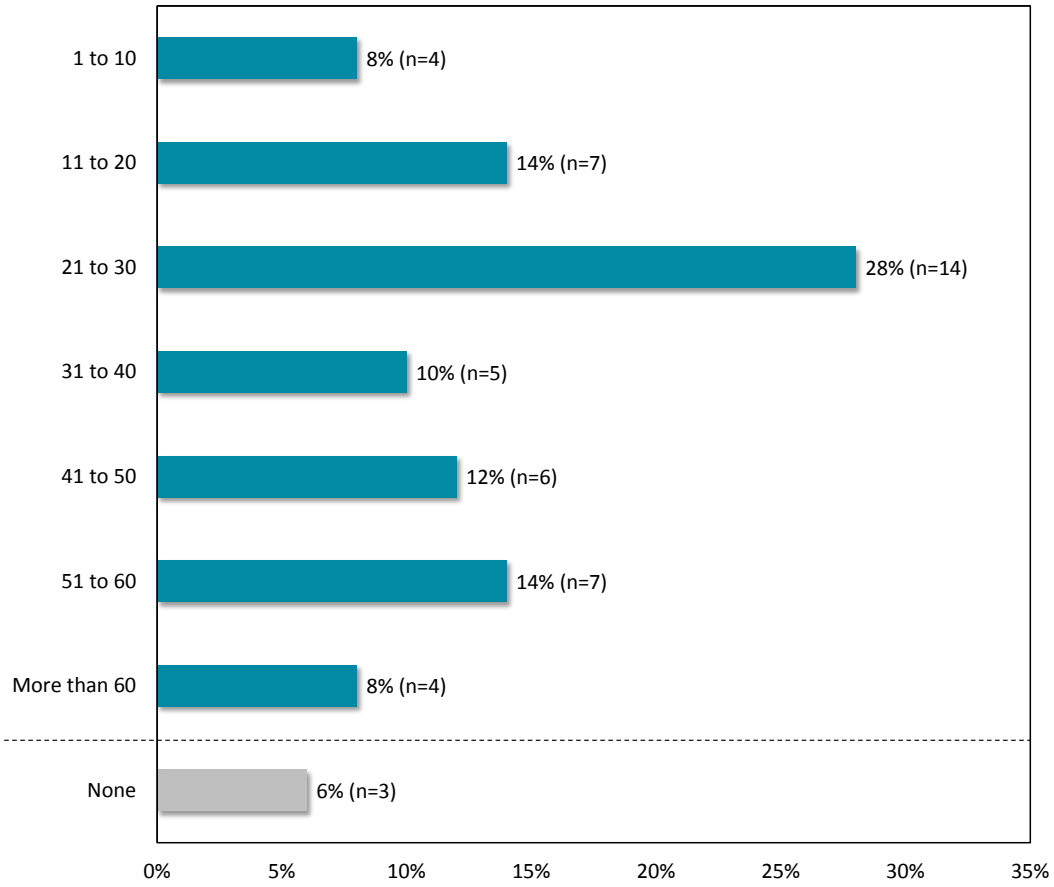
Of the 51 HRECs from certified institutions, there were 50 that considered new research proposals during the reporting period. Of these 50, all but three (94%; n=47) reported that they had considered new **multi-centre**[15] research proposals during 2015.

Number of multi-centre research proposals

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

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

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



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

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

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

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

Research activity – quality, timeliness and reduced duplication

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

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

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

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

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

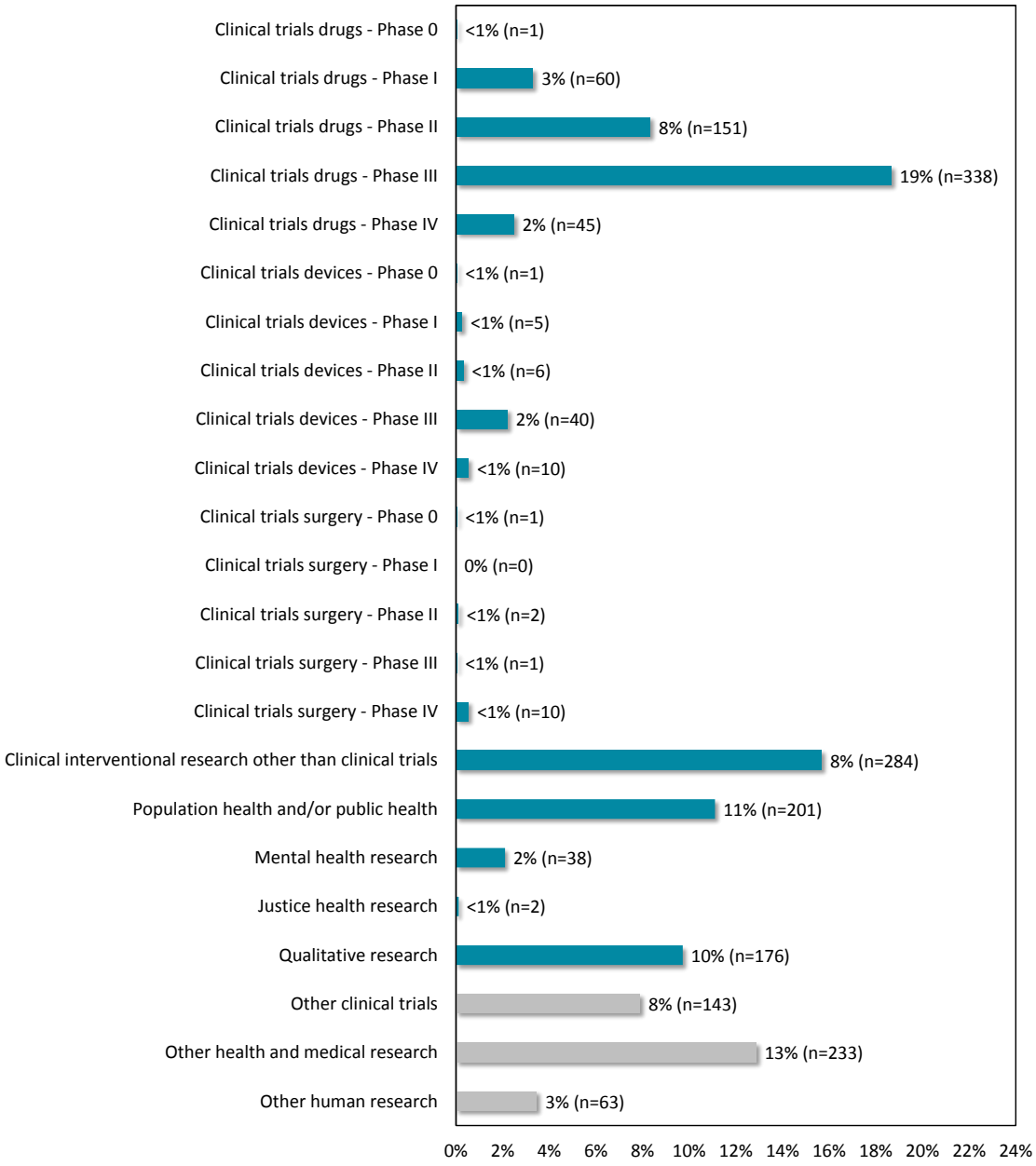
[17] This may be the result of HRECs reviewing multi-centre research outside of formal single ethical review schemes where a lead HREC was not identified or where the project was not eligible for review. This data also reflects that it was not mandatory for HRECs to provide this data.

D. Research categories considered

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

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

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



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

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

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

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

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

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

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

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

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

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

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

The Privacy Act 1988

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

Guidelines approved under the Privacy Act

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

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

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

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

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

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

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

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

In this report:

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

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

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

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

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

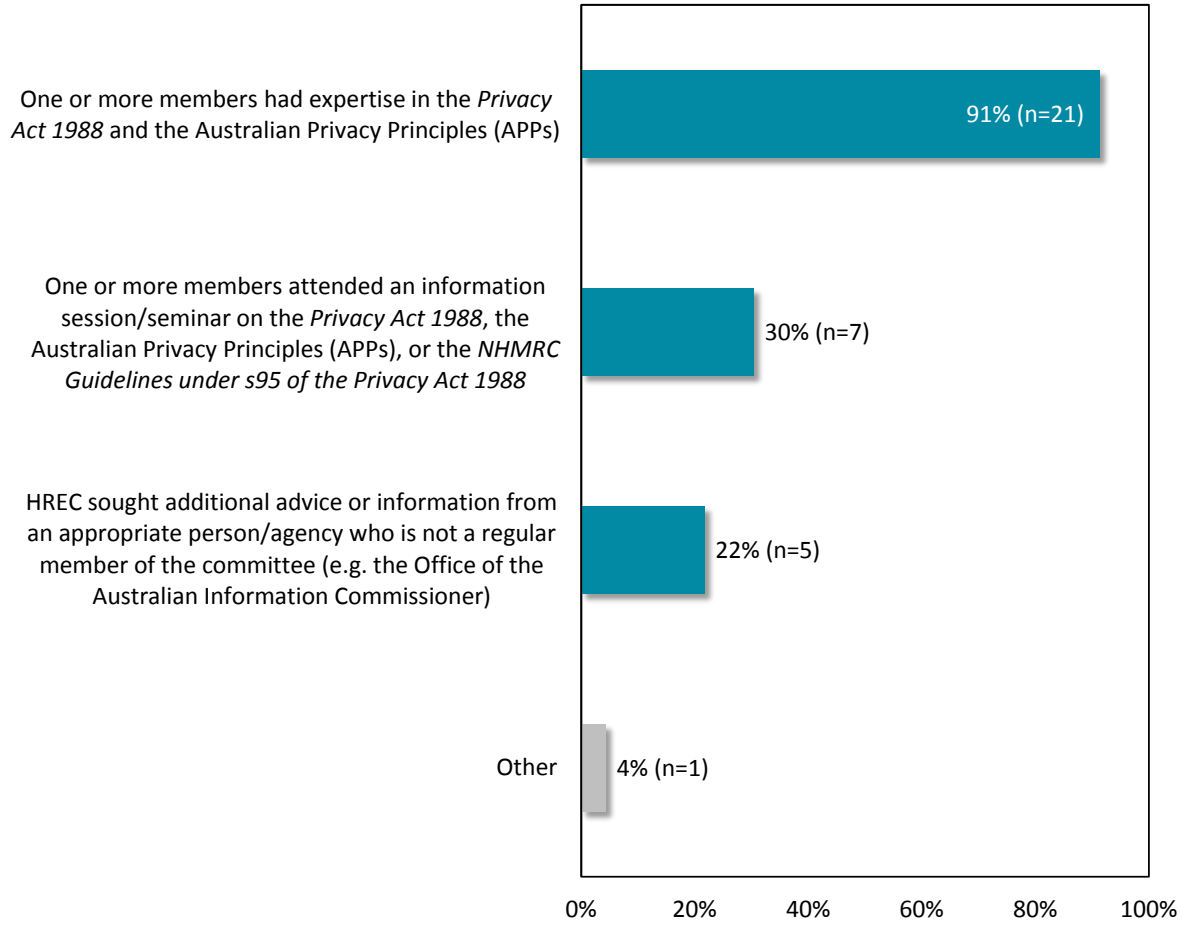
HREC assessment of expertise and understanding of privacy issues (Paragraphs 3.1, 3.2(b) and 3.4)

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

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

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

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



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

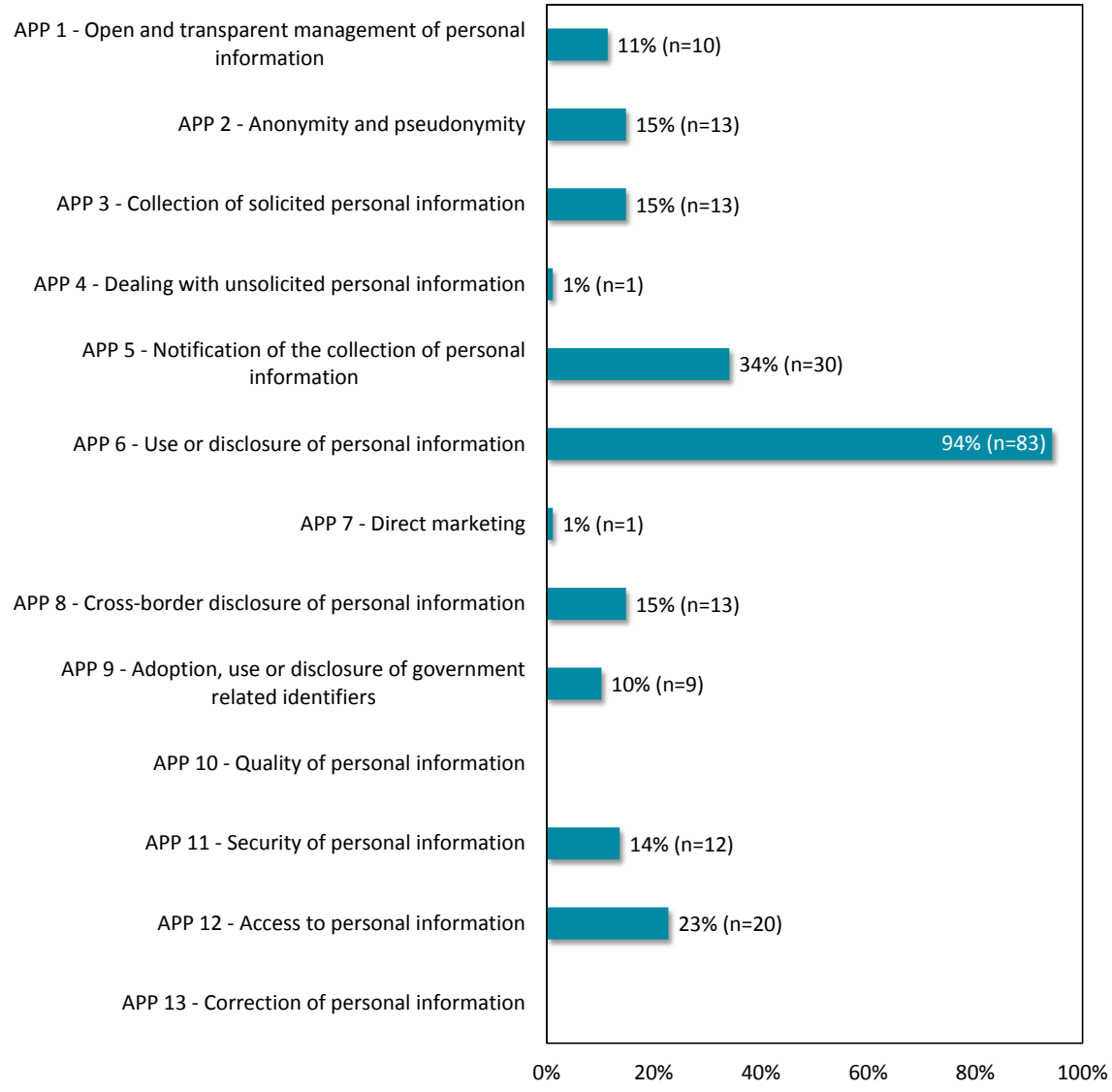
HREC assessment of relevant Australian Privacy Principles (APP) (Paragraphs 3.2(a) and 3.4)

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

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

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

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



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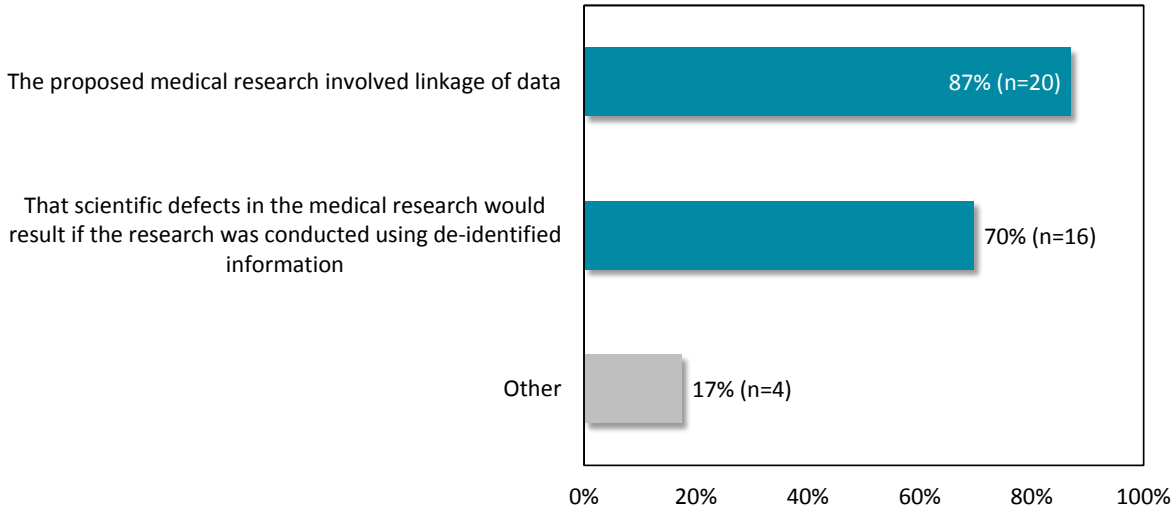
[21] Data was not collected for one HREC (n=7 proposals).

Personal information and consent (Paragraph 3.2(a))

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

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

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



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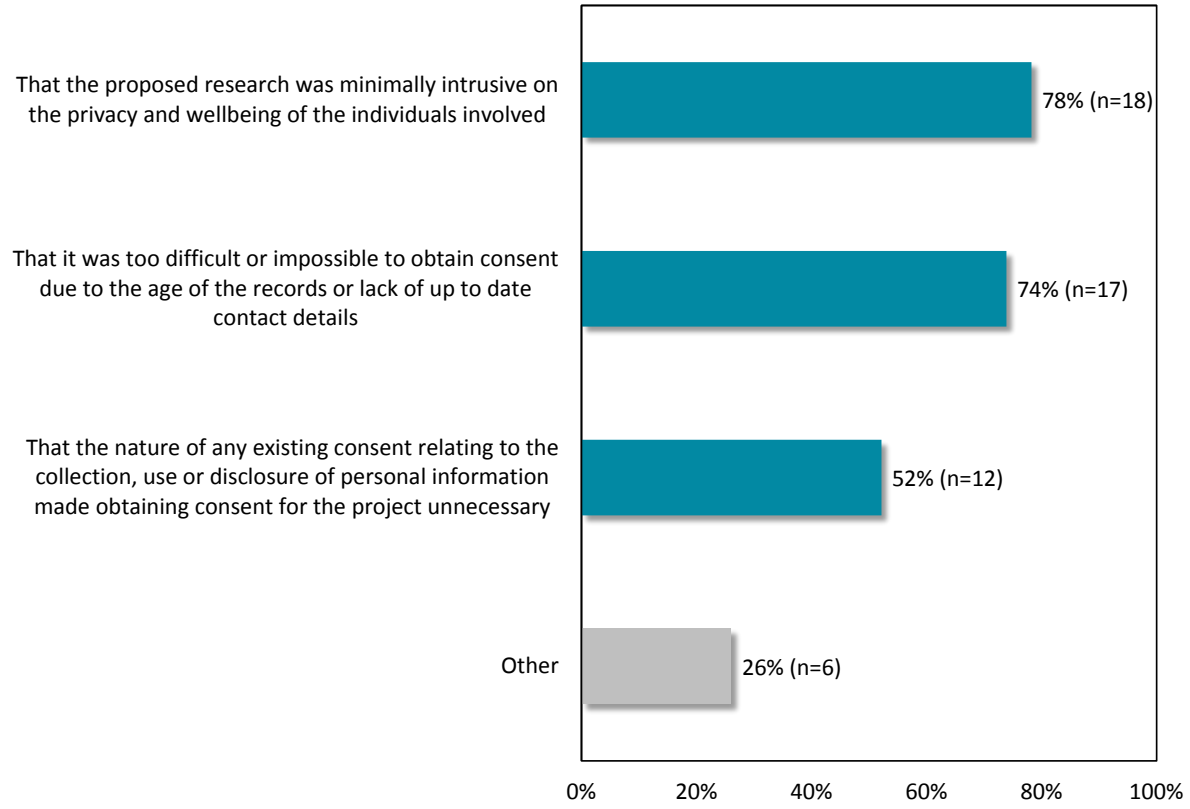
Other considerations with regard to identifiability of data included:

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

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

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

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



Other considerations with regard to consent included:

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

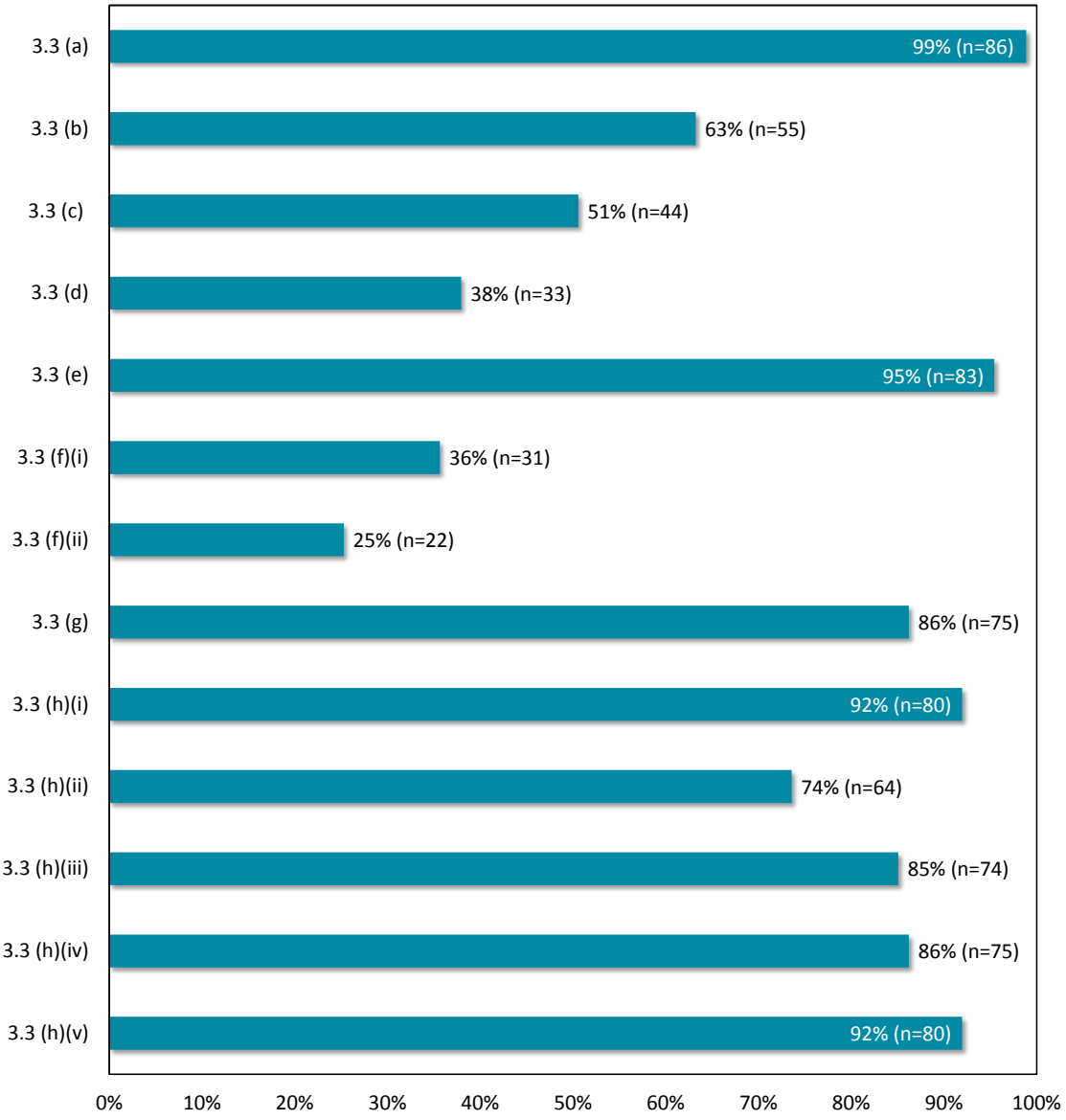
Weighing the public interest (Paragraph 3.3)

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

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

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

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



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

Recording and monitoring of decisions (Paragraphs 3.4 and 3.5)

Recording

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

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

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

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

Monitoring

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

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

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

Complaints

No HREC reported receiving any complaints under the s95 guidelines.

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

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

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

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

The s95A guidelines were reportedly applied to all 123 proposals.

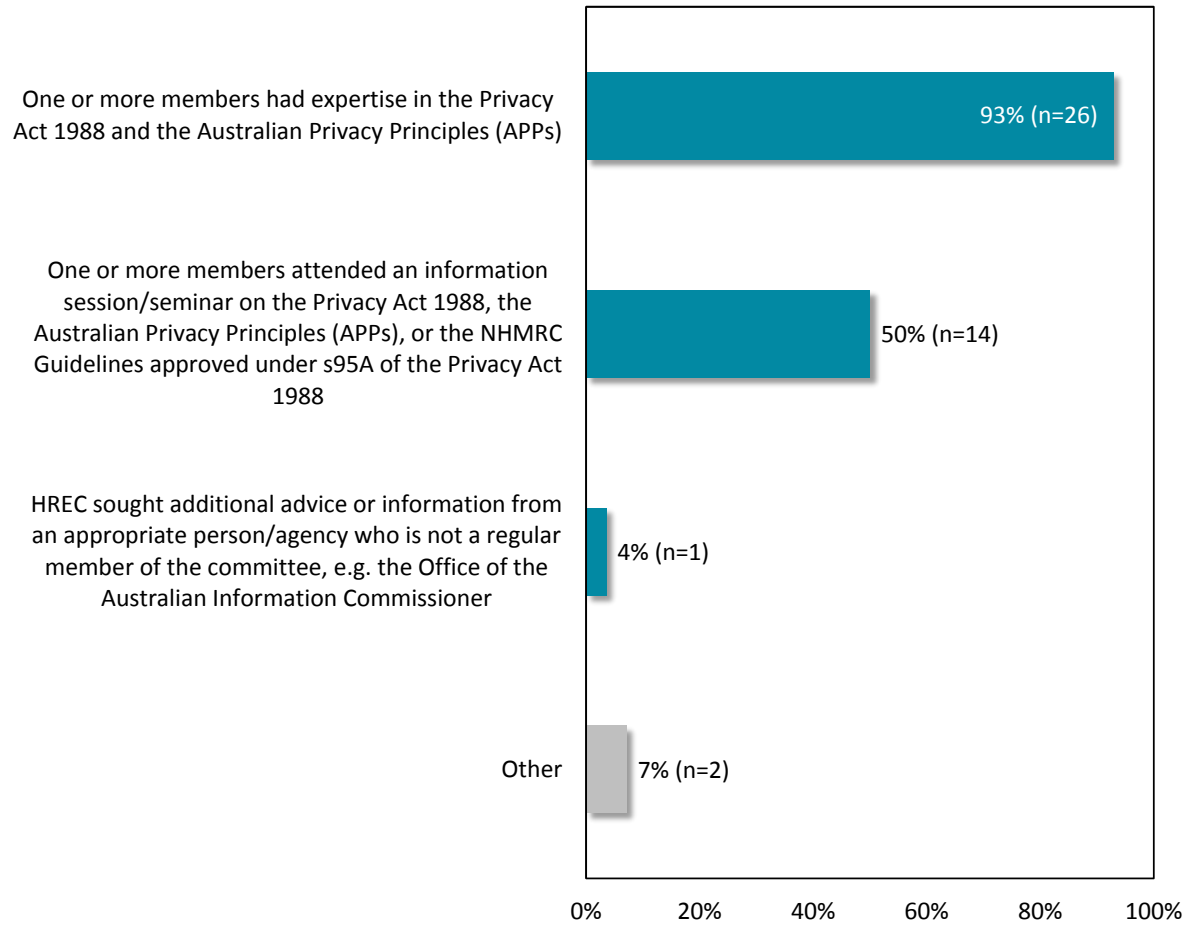
HREC assessment of expertise and understanding of privacy issues (Paragraphs D.1, D.3 and D.6(e))

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

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

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

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



Other expertise included:

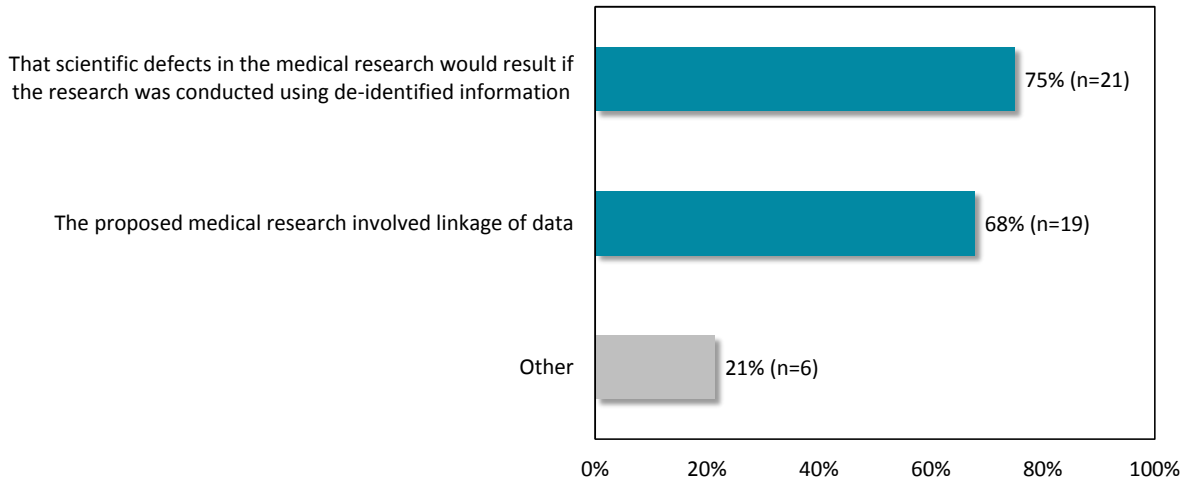
- Lawyer members had knowledge of privacy issues; and
- Members accessed written guidance about privacy issues.

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

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

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

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



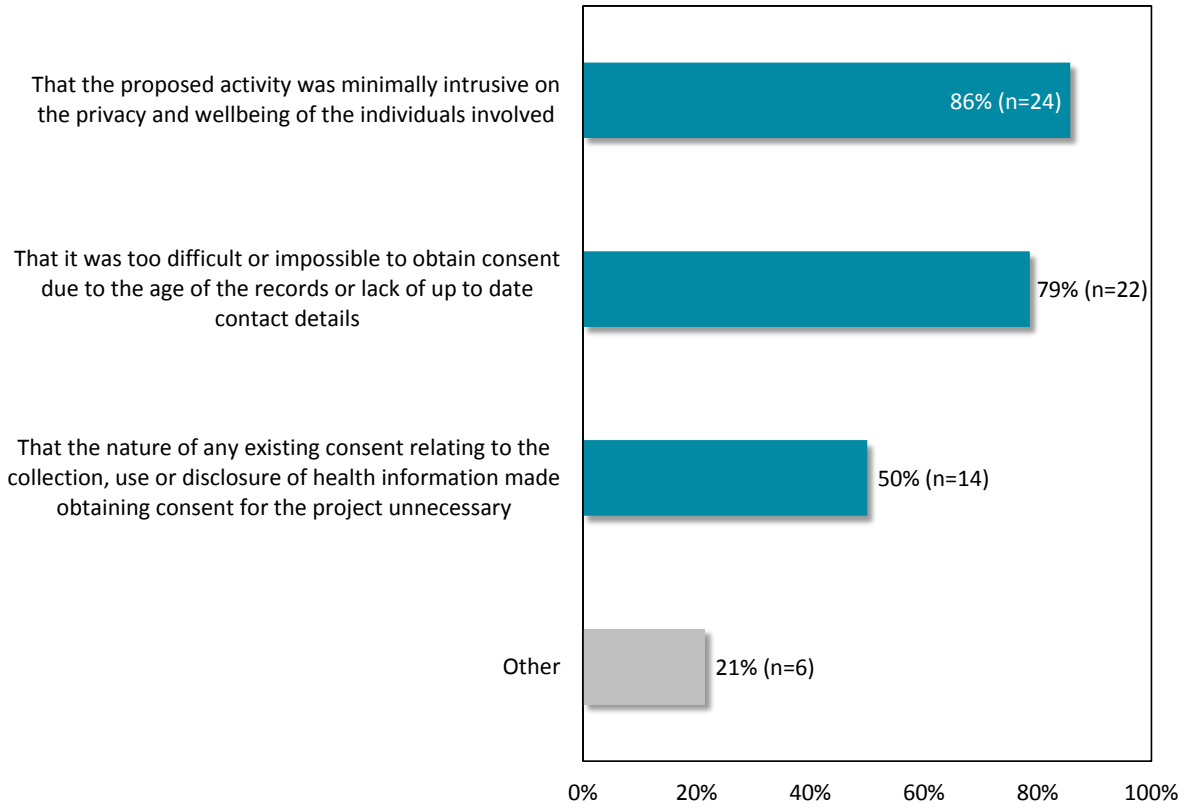
Other considerations with regard to the use of de-identified data included:

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

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

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

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



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

Other considerations with regard to consent included:

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

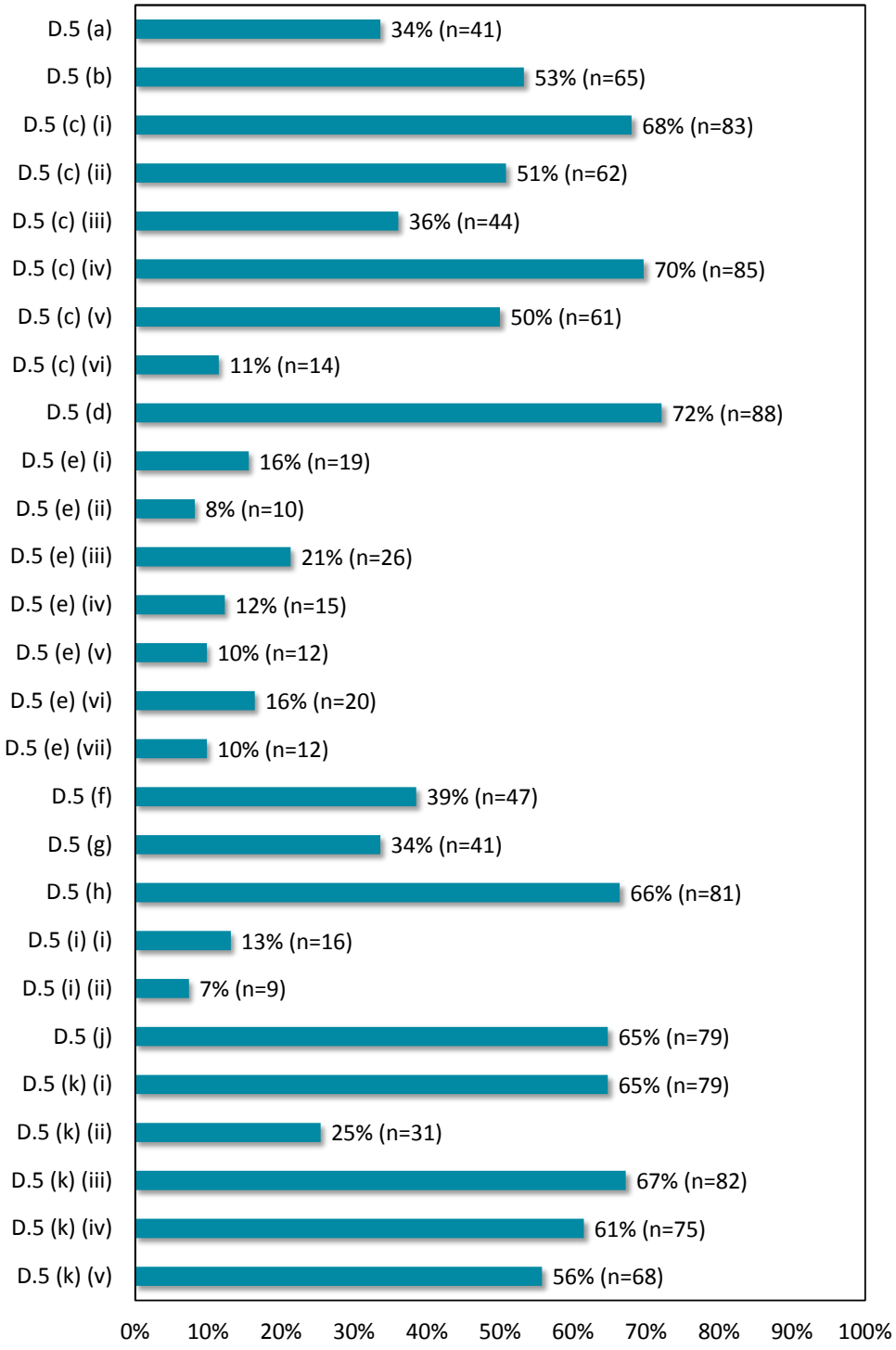
Weighing the public interest (Paragraphs D.4 and D.5)

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

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

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

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



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

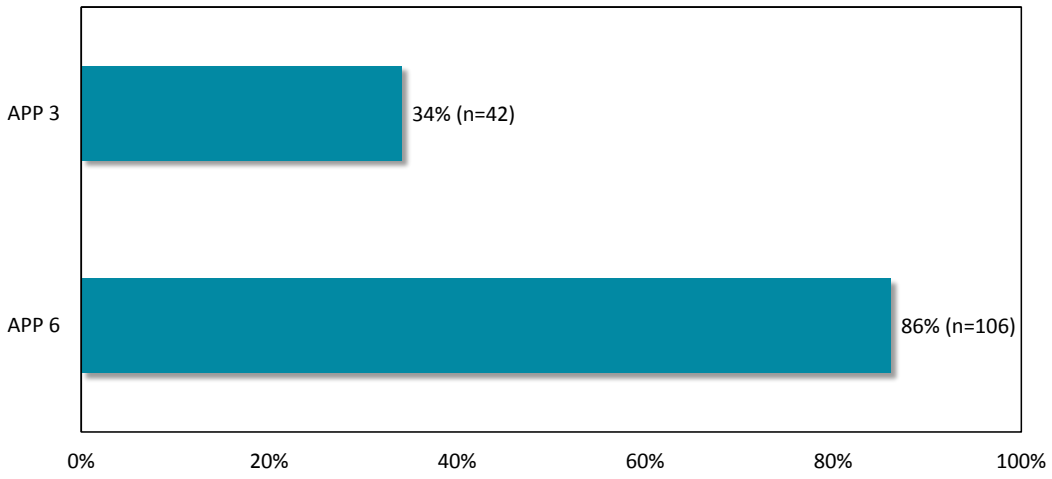
HREC assessment of relevant Australian Privacy Principles (APP) (Paragraph D.6(d))

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

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

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

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



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

Recording

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

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

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

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

Monitoring

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

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

Complaints (Paragraph G.1(b))

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

C. Discussion

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

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

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

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

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

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