



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 2018 to 31 December 2018

July 2019

Background

ORIMA Research was commissioned to design and conduct the 2018 annual reporting survey on behalf of the National Health and Medical Research Council (NHMRC). The information collected provides an annual overview of the activity of Human Research Ethics Committees (HRECs) during calendar year 2018 ('reporting period'). It is also 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).

The annual reporting survey for the 2018 reporting period opened in February 2019 and closed in May 2019. This project was conducted in accordance with the international quality standard ISO 20252.

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I. Report on the Activity of NHMRC-Registered Human Research Ethics Committees for the Period 1 January 2018 – 31 December 2018

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 registered¹ 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, and
- ◆ monitoring of approved research and mechanisms for handling complaints.

The purpose of collecting the information is to gather an annual overview of 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 for the reporting period from 1 January 2018 to 31 December 2018.

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

¹ For an HREC to be 'registered' with NHMRC, the institution(s) that established the HREC notifies NHMRC of the HREC's existence and provides a signed declaration that the HREC will comply with the National Statement.

A. Number of HRECs

During 2018, 204 HRECs were registered with NHMRC, and 201 HRECs submitted an annual report on their activities to NHMRC by the close of the online annual reporting tool (see **Table 1**). The three HRECs which did not submit an annual report later provided the required data directly to NHMRC. This data has not been included in this report.

Of the 201 HRECs who submitted an annual report, four indicated that they had closed in 2018, or in 2019 prior to submitting their annual report. There were 207 HRECs in the previous reporting period (2017), all of which submitted an annual report.

Table 1: Reportable HRECs by Jurisdiction

Jurisdiction	Number of HRECs
Victoria	59
New South Wales	51
Queensland	36
South Australia	20
Western Australia	19
Australian Capital Territory	11
Northern Territory	3
Tasmania	2
Total	201

B. HREC membership

Minimum 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'.

Fifteen HRECs (7%) reported that they did not meet the minimum membership requirements during the reporting period. Issues identified were:

- ◆ No male layperson (n=8)
- ◆ No members who perform a pastoral care role in a community (n=6)
- ◆ No lawyer (n=4)

- ◆ Less than two members with knowledge of, and current experience in, the areas of research regularly considered by the HREC (n=4)
- ◆ No Chairperson (n=3)
- ◆ No female layperson (n=3)
- ◆ No members with knowledge of, and current experience in, the professional care, counselling or treatment of people (n=3), and
- ◆ Less than eight members in total (n=3).

Additional membership

In addition to the minimum membership categories, other members appointed to HRECs during the 2018 reporting period were identified by HRECs as filling the following self-described roles:

- ◆ Aboriginal and Torres Strait Islander representatives
- ◆ Academic representatives
- ◆ Community member
- ◆ Consumer representatives
- ◆ Contemporary veterans
- ◆ Departmental and institutional representatives
- ◆ Deputy Chair
- ◆ Executive representatives (e.g. Board members, CEO, Director)
- ◆ Ex-officio members
- ◆ Graduates
- ◆ Health service representatives
- ◆ Institutional laypersons
- ◆ Medical professionals
- ◆ Members experienced in reflecting on and analysing ethical decision making (National Statement 5.1.32)
- ◆ Members 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)
- ◆ Nominees
- ◆ Non-sitting members
- ◆ Observers
- ◆ Person with a disability
- ◆ Pool members
- ◆ Scientific advisors
- ◆ Student representatives or trainees
- ◆ Sub-committee Chair
- ◆ Support staff (e.g. secretary, executive officer), and
- ◆ Members with expertise in:

- Aboriginal and Torres Strait Islander research
- Accounting
- Clinical trials
- Coaching
- Communications, media and change management
- Data management
- Ethics
- Forensic pathology
- Information technology and security
- Medical education
- Microbiology
- Neurology
- Nursing
- Pathology
- Pharmacy
- Philosophy
- Privacy and governance
- Psychology
- Reproductive health, and
- Statistics.

During the reporting period, one-in-three HRECs (30%; n=61) 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 research². Twenty-one HRECs (10%) 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, or perceptions about decision making, may be affected in situations where there is a significant imbalance in either direction. It is recognised that this may not always be achievable and that, in any event, the National Statement's distinction between 'men' and 'women' members does not give consideration to the full diversity of identities (including trans and intersex members).

² This includes members who have no affiliation, connection or relationship with the institution for which the HREC is reviewing research.

However, NHMRC considered instances in which there was at least an 80:20 gender imbalance as significant and requiring attention. Three HRECs (1%) reported a male: female or female: male ratio of greater than or equal to 80:20.

In addition, two HRECs (1%) reported that they included member(s) not exclusively identifying as male or female, or indeterminate, intersex or unspecified.

C. Administration and general operation of the HREC

Terms of reference and procedures

During the reporting period, all but three HRECs (99%; n=198) indicated that their terms of reference met the requirements of National Statement 5.1.27. The remaining HRECs reported that:

- ◆ The terms of reference are due to be reviewed, and will be updated to include a statement regarding the HREC's relationship to other processes of research review or non-affiliated researchers
- ◆ There is no mention that members do not receive remuneration for their contribution to the HREC, and
- ◆ The HREC has disbanded.

All but three HRECs (99%; n=198) reported that their standard operating procedures supporting the operations of the HREC met the requirements of National Statement 5.1.37. One of these was the same HREC which had disbanded. The remaining two HRECs reported that:

- ◆ The HREC's working procedures for good ethical review were not contained in consolidated standard operating procedures; however the HREC's charters, terms of reference, website policies and guidance documentation supporting the processes of ethical review were available on their website and/or intranet during the reporting period, and
- ◆ Once the HREC's annual reporting template for researchers is approved, researchers will be required to provide an annual report to the HREC regarding the progress of previously approved projects.

Record keeping and reporting

Out of the 201 HRECs which submitted an annual report, 194 (97%) reported that the HREC had considered new³ research proposals during the 2018 reporting period. All of these

³ '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.

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

Use of the Human Research Ethics Application

The Human Research Ethics Application (HREA) is an online application form which aims to facilitate efficient and effective ethics review for research involving humans. The application encourages researchers to consider the ethical principles of the National Statement for their research, rather than focus on requirements for approval. Further information can be found on the [HREA website](#).

During the 2018 reporting period, just over three-in-four HRECs (77%; n=150) reported that they accepted the use of the HREA for some or all submissions, of which:

- ◆ 52 HRECs (35%) required the use of the HREA for **all** submissions
- ◆ 52 HRECs (35%) required the use of the HREA for **some** submissions, and
- ◆ 46 HRECs (31%) **did not require** the use of the HREA for submissions.

A HREA can be completed via the NHMRC's own HREA system (<https://hrea.gov.au>), as well as through an increasing number of third-party research management systems, such as Ethical Review Manager (ERM), the Research Ethics and Governance Information System (REGIS) and OnlineForms.

D. HREC meetings

Among the 194 HRECs that considered new research proposals during the reporting period, just over one-in-three HRECs (35%; n=68) 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=121) reported that the chairperson was satisfied that the absent members who belong to the minimum membership had received all papers, had an opportunity to contribute their views, and that these views were recorded and considered before a decision was reached. 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, and
- ◆ Low-risk applications were considered out of session, or were considered by a subset of the committee.

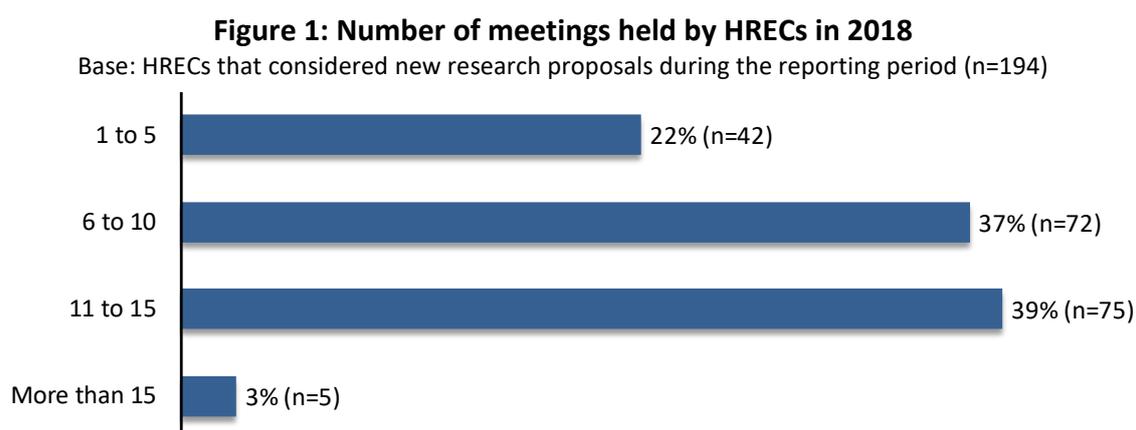
As per paragraph 5.2.32 of the National Statement, the HREC chairperson should be satisfied that the views of those individuals that make up the minimum membership (listed at 5.1.30) have been received and considered before a decision is made on a research project. This is regardless of the number of members that an HREC requires to be in attendance for a meeting to proceed (i.e. quorum). The requirement to ascertain the views

of the minimum membership is also independent of whether the minimum members actually attend the meeting (physically or via teleconference / videoconference).

While the National Statement allows applications assessed as low-risk to be reviewed by a body other than an HREC, the institution must have clear processes for how this assessment and review is conducted (as per paragraphs 5.1.10-5.1.17).

Number of meetings

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



The majority of HRECs (97%; n=189) reported that they had between 1 and 15 meetings during the 2018 reporting period. The maximum number of meetings held by any one HREC during the reporting period was 56 (n=1). This HREC also reported a total of 14 members, with 313 new research proposals considered during the reporting period.

E. Training

Of the HRECs that submitted an annual report, almost four-in-five (78%; n=157) indicated that one or more members participated in training relevant to their work on the HREC (not including induction training).

Just over seven-in-ten HRECs (72%; n=144) reported that all new members were provided with induction training (as per paragraph 5.1.28(b)(i) of the National Statement). Around one-in-four HRECs (24%; n=48) reported that there were no new members appointed during the reporting period.

The requirements for HREC member training are set out in paragraphs 5.1.28(b)(i)(ii) and 5.2.3(c) of the National Statement.

F. Review of research proposals

Number of research proposals

There was a total of 16,314 new⁴ research proposals considered⁵ in the 2018 reporting period. Of these new research proposals, 161 (1%) were denied ethics approval by the HREC and will not be re-considered.

Table 2 shows the number of research proposals considered by HRECs from 2014 to 2018.

Table 2: Research proposals reviewed by HRECs

Details of research proposals	2014	2015	2016	2017	2018
Total number of new research proposals considered	20,892	18,768	18,039	16,446	16,314
Total number of new research proposals approved ⁶	19,134	17,056	16,191	14,721 ⁷	14,678
Percentage of new research proposals approved	92%	91%	90%	90%	90%
Highest number of proposals approved by a single HREC	1,223	1,270	880	399	469
Number of HRECs that accepted ⁸ the ethics approval of an external HREC	126	111	113	112	115

⁴ 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.

⁵ 'Considered' refers to the consideration of research proposals by the full HREC (see 5.1.6 of the National Statement).

⁶ 'Approved' refers to proposals that were either approved upon initial review or after re-consideration in the 2018 reporting period.

⁷ One HREC incorrectly included proposals that were not new for the 2017 reporting period.

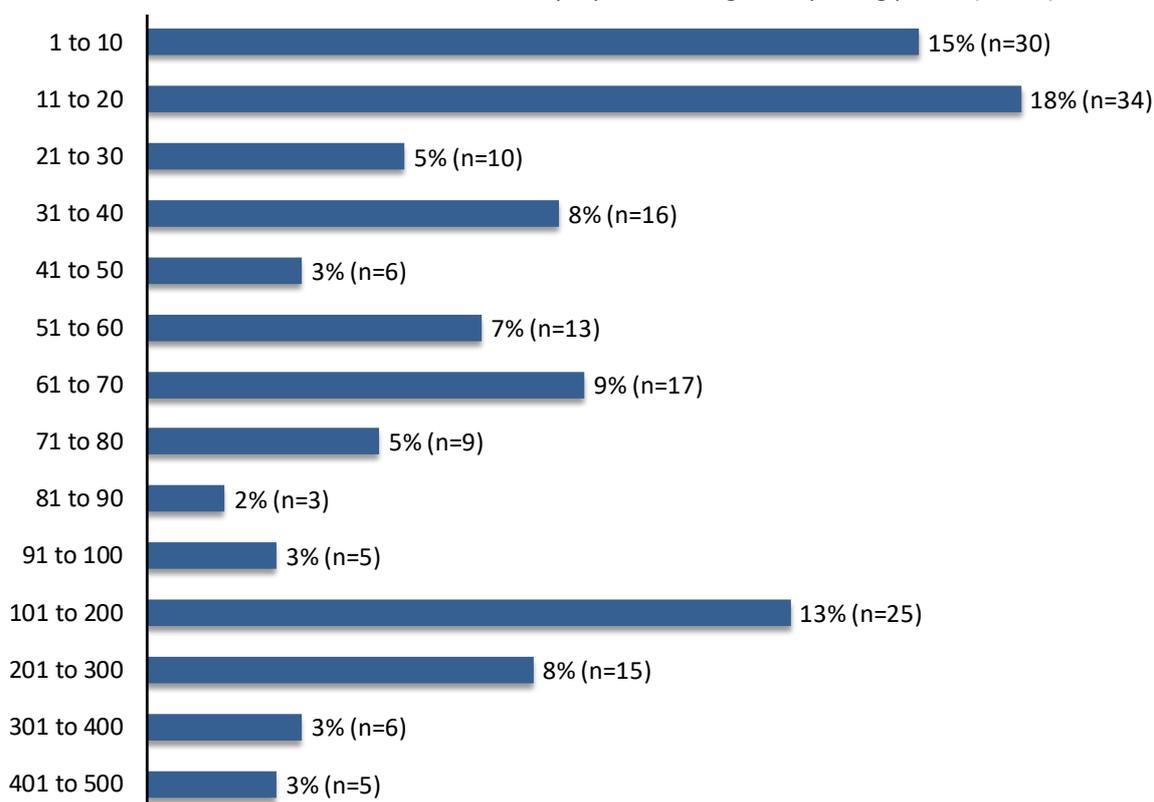
⁸ 'Accepted' refers to accepting once or on multiple occasions.

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 484 (n=1), and the lowest number was 1 (n=4). The HREC that reported considering 484 proposals met 12 times, and comprised a pool of 28 members.

Figure 2: Number of research proposals considered by HRECs in 2018

Base: HRECs that considered new research proposals during the reporting period (n=194)



Types of research proposals considered by HRECs

In the 2018 reporting period, 129 HRECs (66%) considered a total of 2,327 new clinical trial⁹ research proposals. In the previous reporting period (2017), 2,386 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.

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 be 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 194 HRECs that considered new research proposals during the reporting period, over two-in-five HRECs (44%; n=85) considered health related research proposals involving Aboriginal and Torres Strait Islander peoples. Of these HRECs, all but seven (92%; n=78) 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:

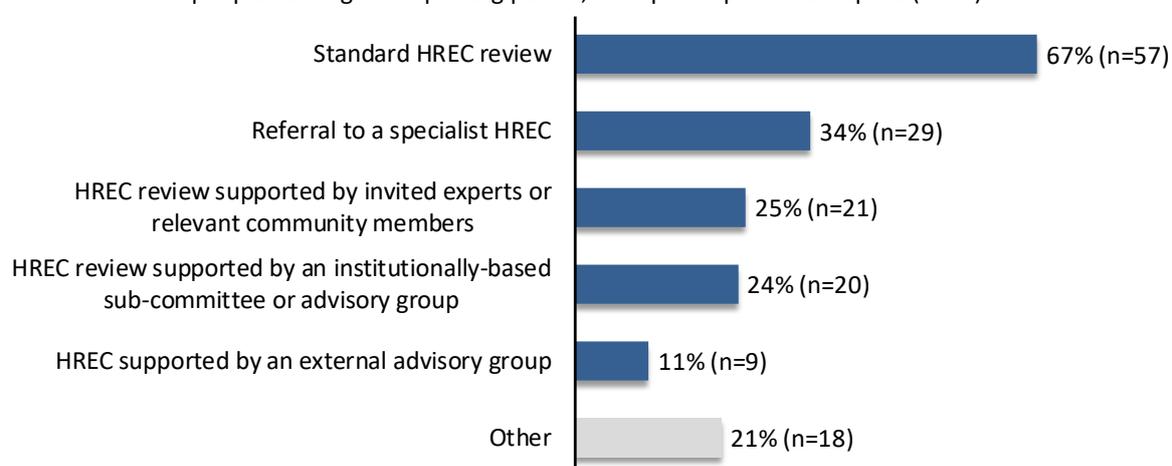
- ◆ The *National Statement on Ethical Conduct in Human Research (2007) – Updated 2018*, and
- ◆ The Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) *Guidelines for Ethical Research in Australian Indigenous Studies (GERAIS)*.

A number of HRECs also reported that they did not use any guidelines as they referred the proposals to a specialist HREC.

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 2018

Base: HRECs that considered new health research proposals involving Aboriginal and Torres Strait Islander peoples during the reporting period, multiple responses accepted (n=85)



Around one-in-five HRECs (21%; n=18) reported using other mechanisms for the review of health research proposals involving Aboriginal and Torres Strait Islander peoples, including:

- ◆ Advice from Aboriginal and Torres Strait Islander committee members and ethics advisors
- ◆ Advice from experts in Aboriginal and Torres Strait Islander health
- ◆ HREC is specialised in Aboriginal and Torres Strait Islander health research
- ◆ Requirement to provide evidence of consideration by external groups, and
- ◆ Review sought from a HREC that specialises in assessing Aboriginal and Torres Strait Islander health research.

Further guidance about research with Aboriginal and Torres Strait Islander peoples is provided in Chapter 4.7 of the National Statement.

H. Research involving low or negligible risk

During the reporting period, three-in-four HRECs that considered new research proposals (75%; n=146) reported that their organisation had established an alternative mechanism¹⁰ for ethics review (other than by the HREC) for research proposals that involve low or negligible risk. Of these, 67 HRECs indicated that their organisation had an established alternative mechanism, but the HREC also reviews some low or negligible risk research.

Of those who reported that the HREC reviews low or negligible risk research, almost nine-in-ten (87%; n=100) reported that the HREC had actually considered these research proposals during the reporting period.

Further guidance about research involving low or negligible risk is provided in Chapter 2.1 and paragraphs 5.1.7-5.1.23 of the National Statement.

¹⁰ 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

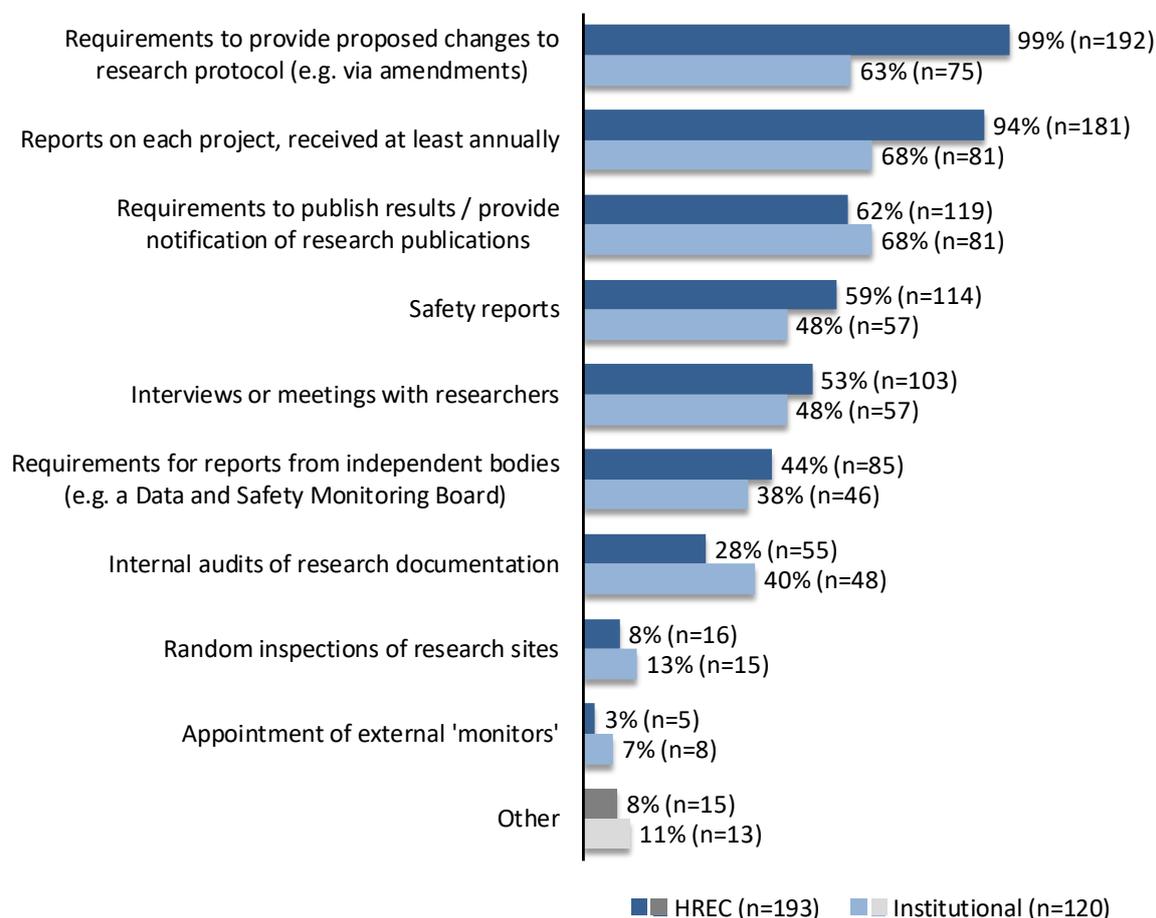
Of the 201 HRECs that submitted an annual report, all but two (99%; n=199) indicated that the organisation and/or the HREC had procedures in place for monitoring approved research. Of these HRECs, all but three (98%; n=196) reported that the organisation and/or the HREC undertook monitoring of approved research. **Figure 4** provides information on the reported monitoring processes in 2018.

The two HRECs that reported that either the HREC or the organisation did not have procedures in place for monitoring approved research, reported that:

- ◆ The HREC only reviewed low risk research proposals, and
- ◆ The HREC has disbanded.

Figure 4: Monitoring processes

Base: HRECs that reported that the organisation and/or the HREC undertook monitoring of all approved research, multiple responses accepted (n=196)



Other processes used to monitor research included:

- ◆ A requirement for researchers to provide regular progress updates and reports, including:
 - Annual reports
 - Adverse event reports

- Breach reports
- Protocol deviation reports, and
- Reports at the completion of each project.
- ◆ Appointing a Clinical Trial Manager to assist clinical trial groups and ensure documentation is in order
- ◆ Establishing monitors and/or Data and Safety Monitoring Boards for clinical trials and projects, where required
- ◆ Holding start-up meetings to ensure that researchers are prepared, with appropriate responses in place, to follow the approved protocol
- ◆ Investigation into cases of research misconduct by Research Integrity staff
- ◆ Inviting researchers to attend committee meetings to discuss and provide updates on their projects
- ◆ Notification of publication outcomes by institutions
- ◆ Requests for researchers to provide copies of feedback sent to participants
- ◆ Self-audits
- ◆ Sub-committee review and monitoring of complaints, breaches, adverse events and Data Safety Monitoring Committee (DSMC) reports
- ◆ Targeted visits to laboratories and research facilities, and
- ◆ Utilising the international quality standard ISO20252.

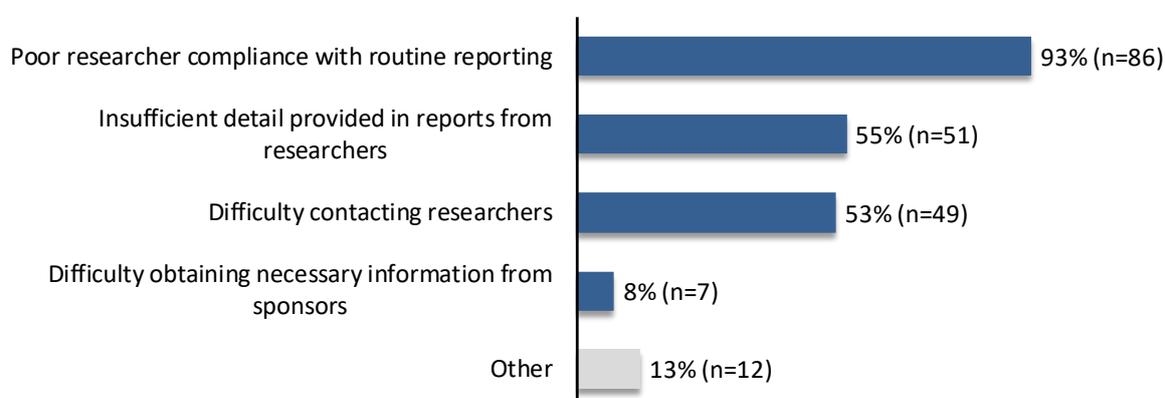
Of the three HRECs that did not undertake monitoring, two reported that there was no approved research to monitor. The remaining HREC reported that the organisation and/or HREC did not undertake monitoring of approved research as there were no active studies.

Problems encountered in monitoring approved research

Of the 196 HRECs that undertook monitoring of approved research during the reporting period, just under half (47%; n=92) reported that the HREC or organisation 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 or their organisation encountered problems in monitoring research during the reporting period, multiple responses accepted (n=92)



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

- ◆ Limited resources to undertake regular and comprehensive monitoring beyond annual reports
- ◆ Necessity to repeatedly remind researchers, and to confirm updated contact details, to provide annual or final reports, and
- ◆ Staff changes.

Of the 92 HRECs that reported that they encountered problems in monitoring research, all but two (98%; n=90) indicated that these problems had been communicated to an appropriate level of management within the organisation.

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

J. Complaints handling

Of the 201 HRECs that submitted an annual report, almost all (97%; n=195) indicated that the organisation responsible for the HREC had a publicly available procedure(s) for receiving and handling complaints or concerns **about researchers or the conduct of approved research** projects. All but nine HRECs (96%; n=192) reported that the organisation responsible for the HREC had a publicly available procedure(s) for receiving and handling complaints or concerns **from researchers about the conduct of the HREC in consideration of their research proposal(s)**¹¹.

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

- ◆ Complaints procedures and HREC contact details were included in Participant Information Sheets and Consent Forms, or the HREC terms of reference
- ◆ Complaints procedures were not publicly available due to website upgrades and/or development or revision of the procedures themselves
- ◆ Complaints procedures had not been required to date
- ◆ Oversight, which will be rectified
- ◆ The HREC reviews applications for organisational projects only and, as such, no publicly available procedures are required as all researchers are fully aware of the HREC processes and attend meetings assessing their projects
- ◆ The HREC does not manage the way in which this information is publicly disseminated, and
- ◆ The HREC has disbanded.

¹¹ The HRECs that did not have publicly available procedures for receiving and handling complaints or concerns **about researchers or the conduct of approved research projects** or **from researchers about the conduct of the HREC in consideration of their research proposal(s)** were advised of the requirements at Chapter 5.6 of the National Statement.

Types of complaints received

During the reporting period, two-in-five HRECs (40%; n=80) received a combined total of 224 complaints **about researchers or the conduct of an approved research project**, while around one-in-ten HRECs (9%; n=18) received a combined total of 22 complaints **from researchers about the consideration of their research proposal(s) by the HREC** (see **Table 3**). Many HRECs (60%, n=121) did not receive any complaints or concerns.

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	224	18
Complaints received about researchers or the conduct of an approved research project that involved Aboriginal and Torres Strait Islander peoples	13	4
Complaints received from a researcher about the consideration of their research proposal by the HREC	22	2

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

- ◆ Adherence to protocol
- ◆ Administrative errors
- ◆ Adverse events
- ◆ Advertising and promotion of research
- ◆ Appropriateness of research design and methodology
- ◆ Authorship
- ◆ Breaches of ethics approval
- ◆ Changes implemented without approval
- ◆ Conflict of interest
- ◆ Consent and opt-out processes
- ◆ Data security
- ◆ Difficulty contacting researchers
- ◆ Duplication
- ◆ Effects caused by research (including distress, physical effects, medical effects)
- ◆ Ethical acceptability of research
- ◆ Inaccurate or inadequate information
- ◆ Legal protocols governing the collection and handling of Aboriginal objects
- ◆ Nature of sample

- ◆ Participant Information Sheet and Consent Form
- ◆ Payment / reimbursement
- ◆ Personnel changes
- ◆ Plagiarism
- ◆ Privacy and confidentiality concerns
- ◆ Qualifications and responsibilities of researchers
- ◆ Questionnaire design and content
- ◆ Recruitment methods and material (including coercion, inclusion / exclusion criteria, unsolicited / unapproved recruitment, contacting deceased persons)
- ◆ Research findings
- ◆ Research undertaken without ethics approval
- ◆ Researcher behaviour and communication
- ◆ Researcher not listed on a project
- ◆ Timing of information sessions
- ◆ Validity and integrity of research, and
- ◆ Waiting times.

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

- ◆ Composition of the HREC (perceived lack of expertise)
- ◆ Dissatisfaction or disagreement with the HREC's feedback or decision
- ◆ Inadequate opportunity to justify and explain research
- ◆ Multiple rounds of HREC feedback
- ◆ Review fee
- ◆ Submission procedures and timelines, and
- ◆ Time delays.

Further guidance on handling complaints is provided in Chapter 5.6 of the National Statement.

II. Report on the Activity of Certified Institutions' Human Research Ethics Committees for the Period 1 January 2018 – 31 December 2018

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 an institution's 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 2018 – 31 December 2018.

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

A. Number of certified institutions and institutional HRECs

During 2018, 43 organisations operated as certified institutions under the NHMRC National Certification Scheme. These 43 organisations had 51 HRECs (see **Table 4**). Comparably, there were 44 certified institutions in the 2017 reporting period.

Table 4: HRECs by jurisdiction (2018)

Jurisdiction	Number of Certified Institutions	Number of HRECs
New South Wales	14	15
Victoria	10	10
Queensland	9	10
South Australia	5	11
Western Australia	4	4
Australian Capital Territory	1	1
Total	43	51

A list of certified institutions can be found on the [NHMRC website](#).

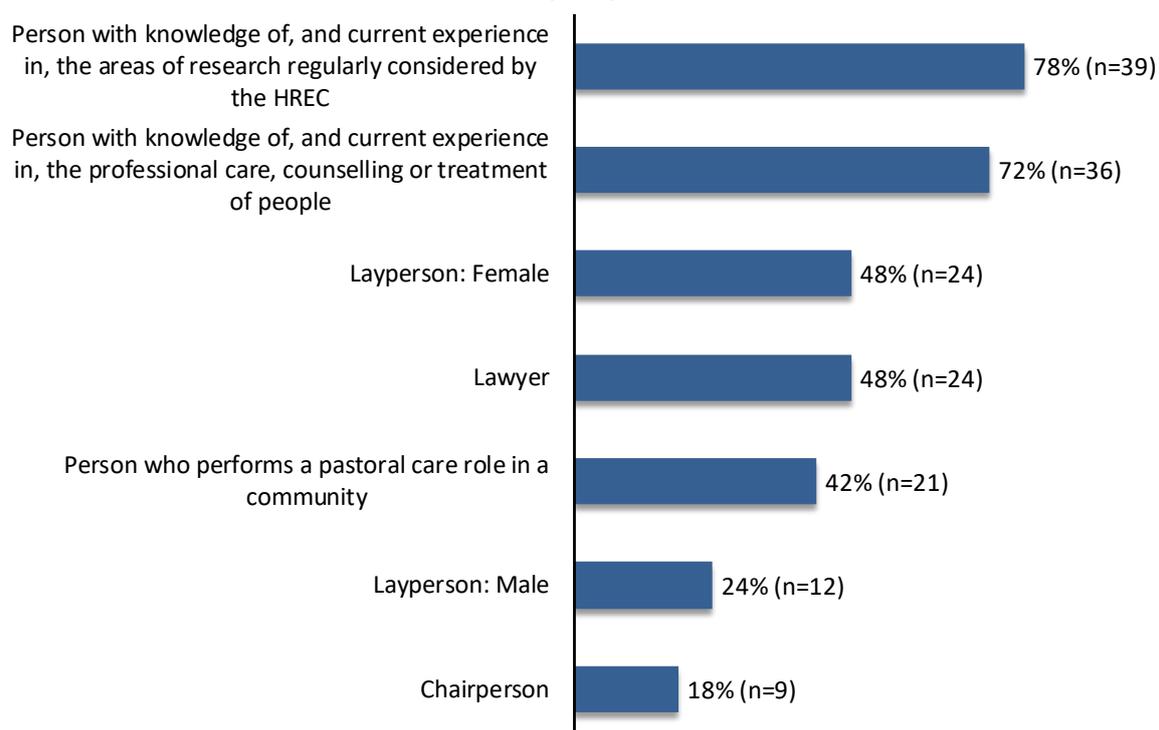
B. HREC composition

Membership

Of the certified HRECs that submitted an annual report, all but one (98%; n=50) reported a change to committee membership during 2018. The categories of membership in which changes occurred are shown in **Figure 6**. All but one HREC (98%; n=50) also reported that they met the minimum membership category requirements during the reporting period¹².

Figure 6: Categories of membership in which the change occurred

Base: Certified institutions that reported a change to committee membership, multiple responses accepted (n=50)



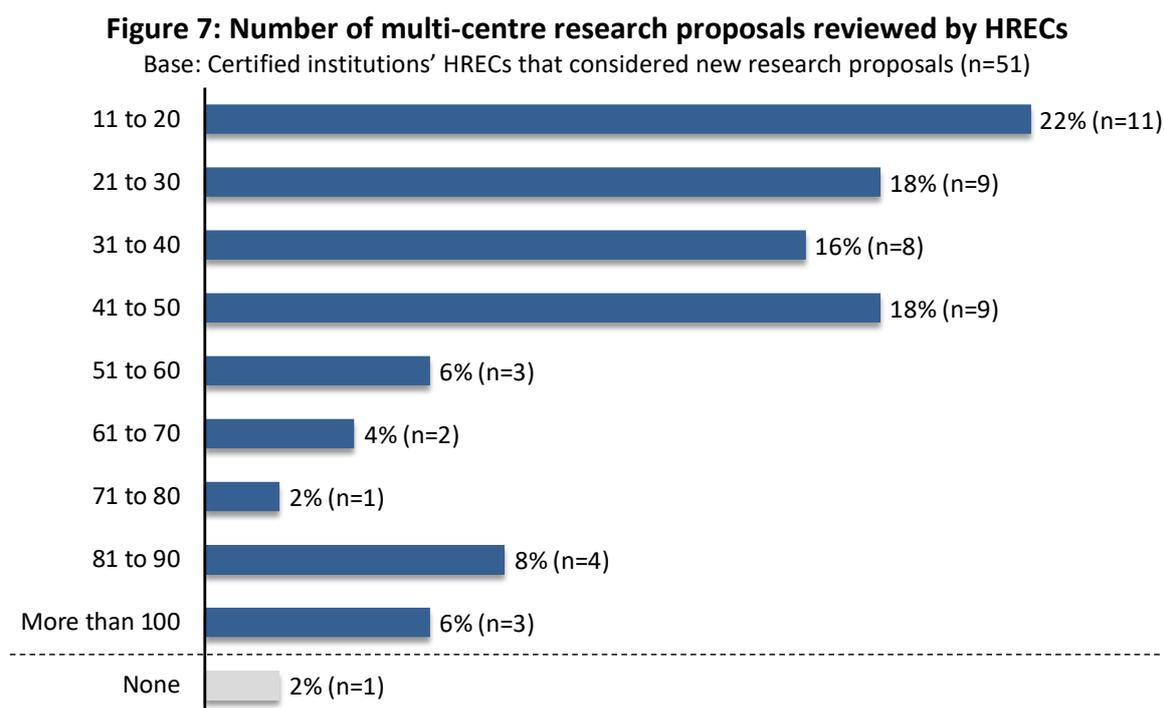
¹² The minimum membership categories are set out in paragraph 5.1.30 of the National Statement. The HREC reported that, during the reporting period, it did not have a member in the category of 'person with knowledge of, and current experience in, the areas of research regularly considered by the HREC' (at least 2 members are required). NHMRC is working with this certified institution and HREC to resolve this issue.

C. Review of multi-centre research proposals

All 51 HRECs from certified institutions reported that they had considered new¹³ research proposals during the reporting period. Of these HRECs, all but one (98%; n=50) reported that they had reviewed new multi-centre¹⁴ research proposals during 2018.

Number of multi-centre research proposals

The distribution of the number of new multi-centre research proposals reviewed¹⁵ by HRECs during the reporting period is shown in **Figure 7**.



The total number of new multi-centre research proposals reviewed during the reporting period was 2,370 (1,882 were reviewed in the previous reporting period). The highest number of multi-centre research proposals reviewed by any one HREC during the reporting period was 250 (n=1), and the lowest was 0 (n=1).

¹³ 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.

¹⁴ Multi-centre research included 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 did 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 a formal single ethical review scheme such as the National Mutual Acceptance scheme.

¹⁵ This included all reviews, whether or not the HREC was considered the lead.

Reduced duplication and timeliness

Of the 50 HRECs that reviewed new multi-centre research proposals in 2018, all but two (96%; n=48) had reviewed at least one proposal as the lead HREC¹⁶. One-in-five HRECs (20%; n=10) reviewed at least one new multi-centre research proposal where it was not the lead HREC.

During the reporting period, around one-quarter of HRECs (26%; n=13) reported that they were aware of instances where the HREC's approval had not been accepted by another institution. Ten HRECs (20%) 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:

- ◆ Ambiguity regarding the legality of waivers of consent
- ◆ Approvals did not align with the organisational research strategy
- ◆ Approvals were not part of the National Mutual Acceptance (NMA) scheme
- ◆ Differences in requirements could not be settled
- ◆ Inadequacy and inappropriateness of wording in the Participant Information and Consent Form
- ◆ The institution did not accept approvals from private HRECs
- ◆ The institution was not involved in conducting the research, and
- ◆ The proposal was not reviewed in compliance with the agreed NMA guidelines.

Of the new multi-centre research proposals reviewed during the reporting period, over nine-in-ten reviews (93%; n=2,202) were completed within 60 calendar days¹⁷. Furthermore:

- ◆ Three-in-five (60%; n=1,425) were intended for conduct within one Australian state or territory only, and
- ◆ Two-in-five (40%; n=943) were intended for conduct in two or more Australian 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.

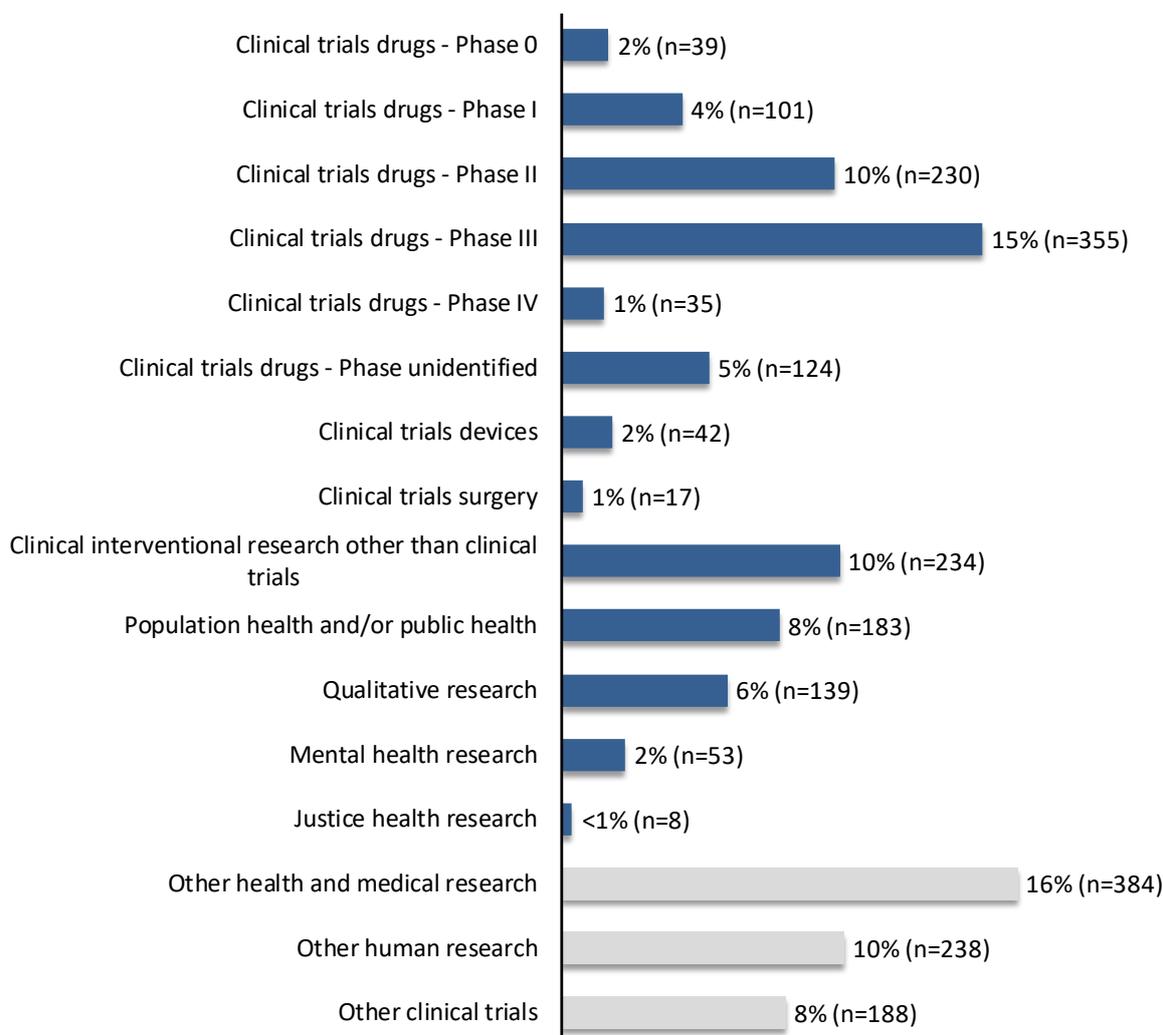
¹⁷ Further information on the 60 calendar day timeframe is provided in the [National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research Certification Handbook, November 2012](#).

Types of multi-centre research proposals

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 considered¹⁸

Base: Total number of multi-centre research proposals considered by certified institutions' HRECs (n=2,370)



Other **health and medical research**¹⁹ considered during the reporting period related to:

- ◆ Aboriginal and Torres Strait Islander health
- ◆ Action research
- ◆ Allied health studies
- ◆ Ambulatory services
- ◆ Audits / quality assurance

¹⁸ 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](#).

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

- ◆ Best practice identification
- ◆ Biobanks
- ◆ Biomarker expression
- ◆ Biomedical testing procedures
- ◆ Biospecimen analysis
- ◆ Cancer
- ◆ Cardiology
- ◆ Care of vulnerable patients
- ◆ Cerebral palsy
- ◆ Clinical decision making
- ◆ Clinical non-interventional research
- ◆ Cohort studies
- ◆ Data linkage
- ◆ Dermatology
- ◆ Development of smartphone app
- ◆ Development of survey / interview / data collection tool
- ◆ Diagnostic methods
- ◆ Disease modelling using human tissue
- ◆ Emergency medicine
- ◆ Endocrinology
- ◆ Ethnography
- ◆ Evaluations
- ◆ Genetics
- ◆ Gynaecology
- ◆ Health service administration
- ◆ Health / social science
- ◆ Identification of credentialing scope
- ◆ Infectious diseases
- ◆ Intensive care unit
- ◆ Laboratory research
- ◆ Neurology
- ◆ Nursing
- ◆ Nutrition and dietetics
- ◆ Observational studies
- ◆ Obstetrics and midwifery
- ◆ Occupational therapy
- ◆ Orthopaedics
- ◆ Paediatrics
- ◆ Pathology
- ◆ Patient medication compliance

- ◆ Pharmacology
- ◆ Pharmacy
- ◆ Physiotherapy
- ◆ Pregnancy
- ◆ Psychology
- ◆ Quantitative research
- ◆ Radiology
- ◆ Registries
- ◆ Renal
- ◆ Research culture
- ◆ Retrospective data collection
- ◆ Review of medical records
- ◆ Rheumatology
- ◆ Sexual health
- ◆ Social determinants
- ◆ Social policy
- ◆ Special care nursery
- ◆ Stroke
- ◆ Surgery
- ◆ Urogynecology
- ◆ Vaginal microbiome, and
- ◆ Workforce.

Other **clinical trials**²⁰ considered during the reporting period included:

- ◆ Feasibility studies
- ◆ Follow-up studies
- ◆ Laboratory research
- ◆ Pilot studies
- ◆ Qualitative research, and
- ◆ Trials related to:
 - Alternate standards of care
 - Anaesthesia
 - Biobanks
 - Biological products
 - Broccoli sprout extract
 - Dental
 - Diagnostic tests
 - Diet supplements
 - Drug administration procedures

²⁰ The topics listed have been self-reported by HRECs.

- Drugs and devices
- Education and technology
- Emergency medicine
- Exercise
- Histopathology
- Human behaviour
- Interval training
- Interventions
- Local brain stimulation
- Medical imaging
- Microbiome study
- Neurology
- Nursing
- Nutrition
- Protocol change
- Psychology
- Registries
- Rehabilitation
- Risk guided strategy
- Smartphone apps
- Software
- Sterile water injections
- Stroke, and
- Telehealth.

Other **human research**²¹ considered during the reporting period related to:

- ◆ Biospecimen for personalised medicine
- ◆ Child and family research
- ◆ Contact precautions
- ◆ Epidemiology
- ◆ Gender inequality
- ◆ Health / social science
- ◆ Immune cell
- ◆ Laboratory research
- ◆ Non-clinical trials
- ◆ Nutrition
- ◆ Observational research
- ◆ Oncology
- ◆ Orthopaedics

²¹ The topics listed have been self-reported by HRECS.

- ◆ Registries
- ◆ Social policy
- ◆ Stroke management
- ◆ Tissue banks, and
- ◆ Various non health disciplines.

During the reporting period, three-in-five HRECs (60%; n=30) reviewed multi-centre research proposals involving children and young people / paediatrics.