



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 2019 to 31 December 2019

November 2020

Background

ORIMA Research was commissioned to design and conduct the 2019 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 2019 ('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](#) (National Statement).

The annual reporting survey for the 2019 reporting period opened in February 2020 and closed in June 2020.

This project was conducted in accordance with the international quality standard ISO 20252, and complies with the Australian Privacy Principles contained in the Privacy Act 1988. ORIMA Research also adheres to the Privacy (Market and Social Research) Code 2014.

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I. Report on the Activity of NHMRC-Registered Human Research Ethics Committees for the Period 1 January 2019 – 31 December 2019

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* (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 2019 to 31 December 2019.

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 2019, 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 advised that they had ceased operation prior to the reporting period.

Of the 201 HRECs who submitted an annual report, 10 indicated that their institution had closed the HREC (i.e. the HREC no longer operates or conducts meetings) in 2019, or in 2020 prior to submitting their annual report. There were 204 HRECs in the previous reporting period (2018), of which 201 submitted an annual report.

Table 1: Reportable HRECs by Jurisdiction

Jurisdiction	Number of HRECs
Victoria	60
New South Wales	51
Queensland	35
South Australia	21
Western Australia	19
Australian Capital Territory	10
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 female layperson (n=5)

- ◆ No lawyer (n=5)
- ◆ No members who perform a pastoral care role in a community (n=5)
- ◆ Less than eight members in total (n=3)
- ◆ No Chairperson (n=2)
- ◆ No members with knowledge of, and current experience in, the professional care, counselling or treatment of people (n=2), and
- ◆ Less than two members with knowledge of, and current experience in, the areas of research regularly considered by the HREC (n=2).

Additional membership

In addition to the minimum membership categories, other members appointed to HRECs during the 2019 reporting period were identified by HRECs as filling the following self-described roles:

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

- Communications and media
- Ethics
- Epidemiology
- Forensic pathology
- Governance
- Haematology
- Information technology and security
- Medical education
- Moral psychology / moral reasoning
- Neurology
- Nursing
- Oncology
- Pathology
- Pharmacy
- Philosophy
- Psychology
- Radiation safety, and
- Statistics.

During the reporting period, almost one-in-three HRECs (30%; n=60) 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. Around one-in-ten HRECs (11%; n=23) 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).

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

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

C. Administration and general operation of the HREC

Terms of reference and procedures

During the reporting period, all but two HRECs (99%; n=199) indicated that their terms of reference met the requirements of National Statement 5.1.27. The remaining HRECs reported that:

- ◆ Their terms of reference had not yet been revised to reflect changes to the National Statement (updated 2018), and were currently undergoing review, and
- ◆ While their terms of reference met the requirements, they were not presently advertised due to ongoing work on the organisation's website.

All but four HRECs (98%; n=197) reported that their standard operating procedures supporting the operations of the HREC met the requirements of National Statement 5.1.37. Two of these were the same HRECs which reported that their terms of reference did not meet the requirements of National Statement 5.1.27, and provided the same reasons as to why their standard operating procedures did not meet the relevant requirements (see above). 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 requirements were met through the HREC's charters, terms of reference, website policies and guidance documentation supporting the processes of ethical review, which 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, 193 (96%) reported that the HREC had considered new³ research proposals during the 2019 reporting period. All but one of these HRECs (99%; n=192) 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. The remaining HREC reported that "National Statement paragraph 5.2.26(m) requirement was not reflected for some records during the reporting period due to staff turnover. Records will be updated by the secretariat to ensure they all meet this requirement, and templates have been reviewed and others developed to assist with documenting the required information."

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.

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 2019 reporting period, around three-in-four HRECs (76%; n=146) reported that they accepted the use of the HREA for some or all submissions, of which:

- ◆ 59 HRECs (40%) required the use of the HREA for **all** submissions
- ◆ 47 HRECs (32%) required the use of the HREA for **some** submissions, and
- ◆ 40 HRECs (27%) **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 193 HRECs that considered new research proposals during the reporting period, over two-in-five (45%; n=86) 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 four HRECs (96%; n=103) 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:

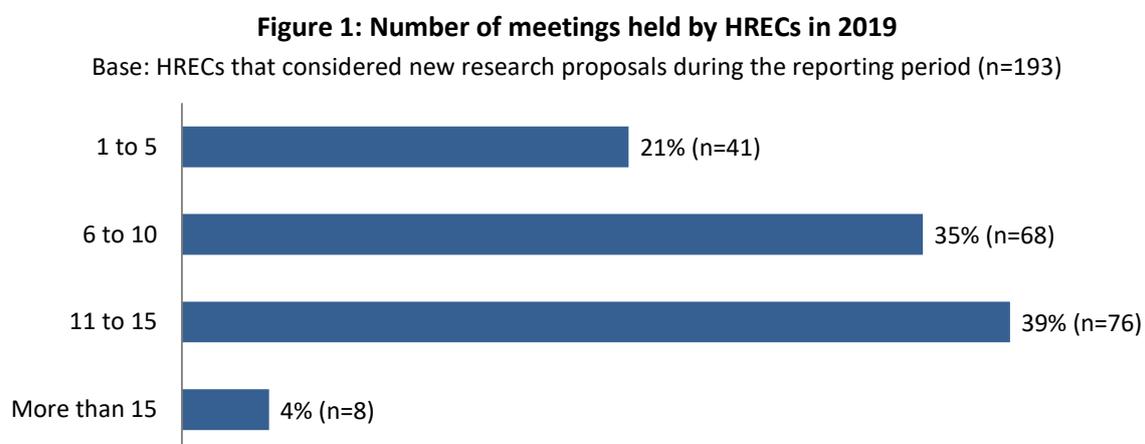
- ◆ There was a vacancy in a minimum membership category, and
- ◆ Low-risk proposals were considered out of session, or were considered by a subset of the committee.

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 (75%; n=144) reported that they held between 6 and 15 meetings during the 2019 reporting period. The maximum number of meetings held by any one HREC during the reporting period was 55 (n=1). This HREC also reported a total of 17 members, with 259 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).

Three-in-four HRECs (75%; n=151) reported that all new members were provided with induction training (as per paragraph 5.1.28(b)(i) of the National Statement). One-in-five HRECs (20%; n=41) 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 15,320 new⁴ research proposals considered⁵ in the 2019 reporting period. Of these new research proposals, 151 (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 2015 to 2019.

Table 2: Research proposals reviewed by HRECs

Details of research proposals	2015	2016	2017	2018	2019
Total number of new research proposals considered	18,768	18,039	16,446	16,314	15,320
Total number of new research proposals approved ⁶	17,056	16,191	14,721 ⁷	14,678	13,736
Percentage of new research proposals approved	91%	90%	90%	90%	90%
Highest number of proposals approved by a single HREC	1,270	880	399	469	442
Number of HRECs that accepted ⁸ the ethics approval of an external HREC	111	113	112	115	121

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 paragraph 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 2019 reporting period.

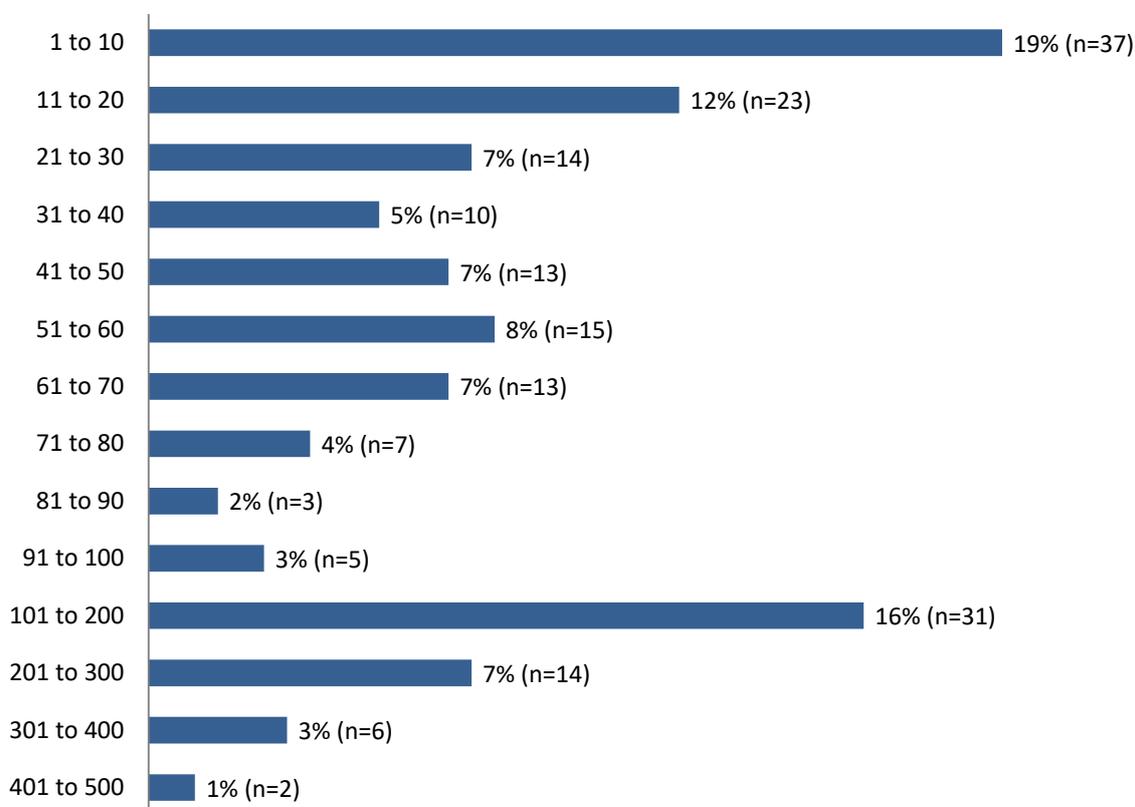
⁷ One HREC incorrectly included proposals that were not new for the 2017 reporting period.

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**.

Figure 2: Number of research proposals considered by HRECs in 2019

Base: HRECs that considered new research proposals during the reporting period (n=193)



The highest number of new research proposals considered by any single HREC during the reporting period was 481 (n=1), and the lowest number was 1 (n=3). The HREC that reported considering 481 proposals met 10 times, and comprised a pool of 34 members.

Types of research proposals considered by HRECs

In the 2019 reporting period, 124 HRECs (64%) considered a total of 2,056 new clinical trial⁹ research proposals. In the previous reporting period (2018), 2,327 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 193 HRECs that considered new research proposals during the reporting period, almost half (46%; n=88) considered health-related research proposals involving Aboriginal and Torres Strait Islander peoples. Of these HRECs, all but four (95%; n=84) reported that they used the [Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018](#) 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:

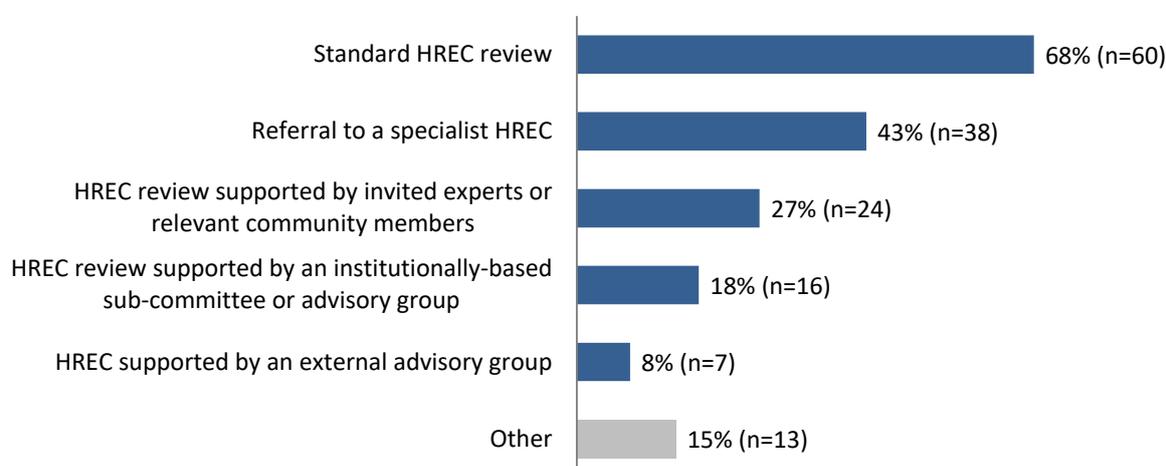
- ◆ The *National Statement on Ethical Conduct in Human Research (2007) – Updated 2018*, and
- ◆ The Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) *Guidelines for Ethical Research in Australian Indigenous Studies (GERAIS)*.

Two 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 2019

Base: HRECs that considered new health research proposals involving Aboriginal and Torres Strait Islander peoples during the reporting period, multiple responses accepted (n=88)



Thirteen HRECs (15%) 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, almost three-in-four HRECs that considered new research proposals (72%; n=138) 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, 69 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 (88%; n=109) 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

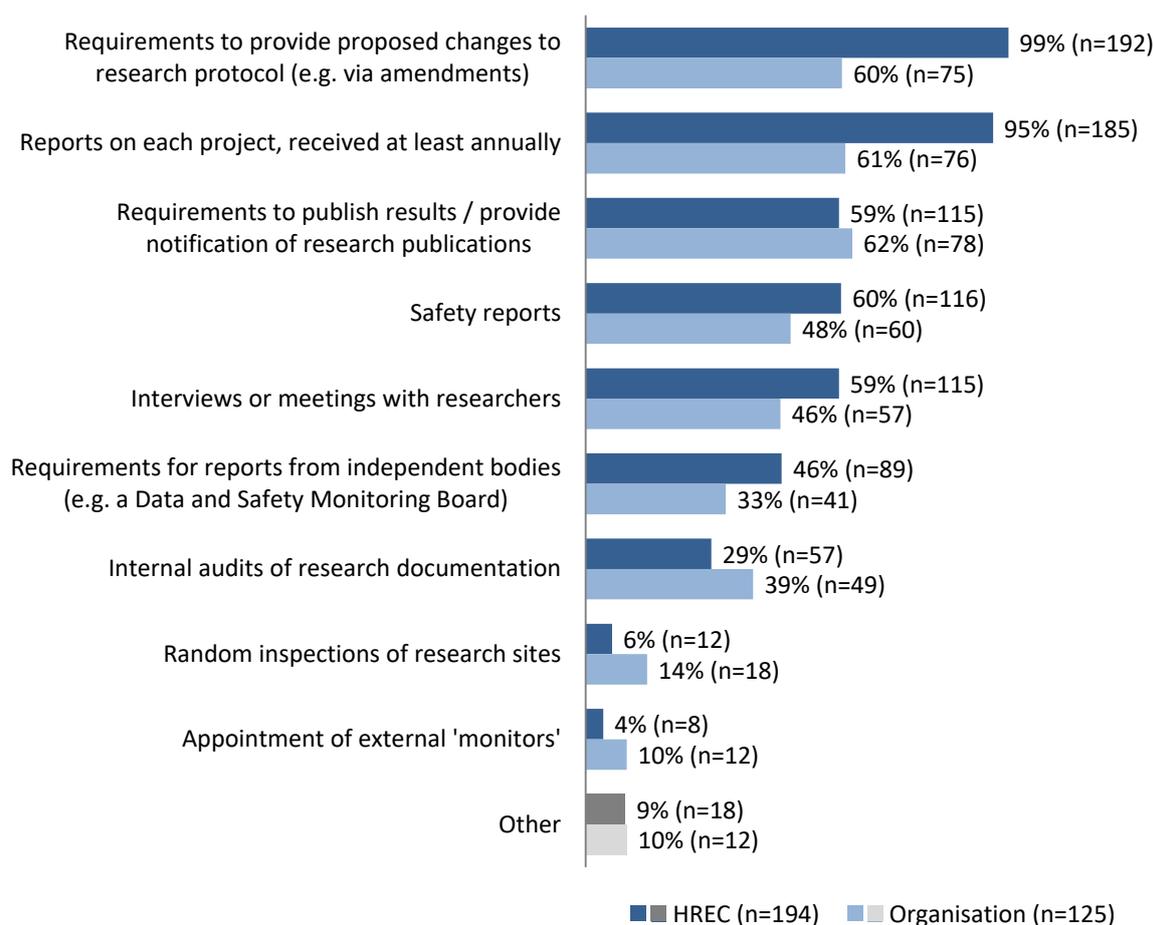
Of the 201 HRECs that submitted an annual report, all but three (99%; n=198) indicated that the organisation and/or the HREC had procedures in place for monitoring approved research. Of these HRECs, all but three (98%; n=195) reported that the organisation and/or the HREC undertook monitoring of approved research. **Figure 4** provides information on the reported monitoring processes in 2019.

The three 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
- ◆ New monitoring procedures were being developed, and
- ◆ There was no ongoing research.

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=195)



Other processes used to monitor research included:

- ◆ A requirement for researchers to provide regular progress updates and reports, including:
 - Adverse event reports
 - Amendment updates for any change in a study (not just protocol changes)
 - Breach reports
 - Investigator change reports
 - Protocol deviation / violation reports, and
 - Safety notifications.
- ◆ Appointing Human Ethics Advisors
- ◆ 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 by Research Integrity staff into cases of research misconduct
- ◆ Inviting researchers to attend committee meetings to discuss and provide updates on their projects
- ◆ Monitoring and review by a sub-committee or steering group
- ◆ Notification of publication outcomes by institutions
- ◆ Providing annual reports and regular updates to the Deputy Vice Chancellor (Research)
- ◆ Review of the organisational Research Strategy, and
- ◆ Self-audits.

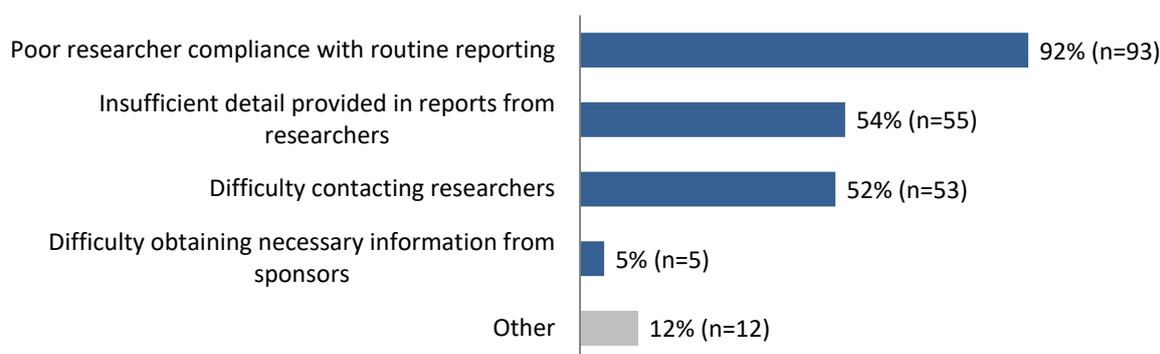
Of the three HRECs that did not undertake monitoring, two reported that there was no approved research to monitor. The remaining HREC reported that the organisation and/or HREC did not undertake monitoring of approved research as the HREC was not operational during the reporting period, and no new studies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

Problems encountered in monitoring approved research

Of the 195 HRECs that undertook monitoring of approved research during the reporting period, just over half (52%; n=101) 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=101)



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

- ◆ Limited resources to undertake regular and comprehensive monitoring
- ◆ Ongoing changes to submission requirements
- ◆ Problems with implementation of new electronic systems, and
- ◆ Staff changes.

Of the 101 HRECs that reported that they encountered problems in monitoring research, all but two (98%; n=99) 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 (98%; n=197) 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 seven HRECs (97%; n=194) 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)**.

Reported reasons as to why the organisation responsible for the HREC did not have publicly available complaints procedures included¹¹:

- ◆ Complaints procedures were included in Participant Information Sheets, or via the institution's intranet page
- ◆ Complaints procedures were not publicly available due to website upgrades and/or review of the procedures themselves, and
- ◆ No active research was undertaken.

Types of complaints received

During the reporting period, almost two-in-five HRECs (37%; n=74) received a combined total of 231 complaints **about researchers or the conduct of an approved research project**, while under one-in-ten HRECs (6%; n=12) received a combined total of 14 complaints **from researchers about the consideration of their research proposal(s) by the HREC** (see Table 3).

Table 3: Number of complaints or concerns received by HRECs

Nature of concerns or complaints	Total number of complaints	Highest number received by any one HREC
Complaints received about researchers or the conduct of an approved research project	231	20
Complaints received about researchers or the conduct of an approved research project that involved Aboriginal and Torres Strait Islander peoples	15	2
Complaints received from a researcher about the consideration of their research proposal by the HREC	14	2

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

- ◆ Adherence to approved protocol
- ◆ Administrative errors
- ◆ Advertising and promotion of research
- ◆ Appropriateness of research design and methodology
- ◆ Authorship
- ◆ Breaches of ethics approval
- ◆ Conflict of interest
- ◆ Consent and opt-out processes
- ◆ Data security

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.

- ◆ Difficulty contacting researchers
- ◆ Effects caused by research (including distress, physical effects, medical effects)
- ◆ Engagement with Aboriginal and Torres Strait Islander peoples / communities
- ◆ Experience of researchers
- ◆ Inaccurate or inadequate information
- ◆ Participant Information Sheet and Consent Form
- ◆ Payment / reimbursement
- ◆ Privacy and confidentiality concerns
- ◆ Questionnaire design, content and distribution
- ◆ 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
- ◆ Risk management
- ◆ Time commitment
- ◆ Toxicity of study drug
- ◆ Validity and integrity of research, and
- ◆ Waiting times / delays.

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

- ◆ Cost and time associated with obtaining radiation reports
- ◆ Dissatisfaction or disagreement with the HREC's feedback or decision
- ◆ Exemption from ethical review, and
- ◆ Submission procedures and timelines.

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 2019 – 31 December 2019

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. The annual reporting process provides NHMRC with a snapshot of certified institution HREC activities during a calendar year and allows monitoring against the National Statement.

The following overview of the certified institutions' HRECs is drawn from information provided during the reporting period from 1 January 2019 – 31 December 2019.

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

A. Number of certified institutions and institutional HRECs

During 2019, 43 organisations operated as certified institutions under the NHMRC National Certification Scheme. These 43 organisations included 51 HRECs (see **Table 4**). Similarly, there were 43 certified institutions in the 2018 reporting period.

Table 4: HRECs by jurisdiction (2019)

Jurisdiction	Number of Certified Institutions	Number of HRECs
New South Wales	14	15
Victoria	10	10
Queensland	9	9
South Australia	5	12
Western Australia	4	4
Australian Capital Territory	1	1
Total	43	51

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

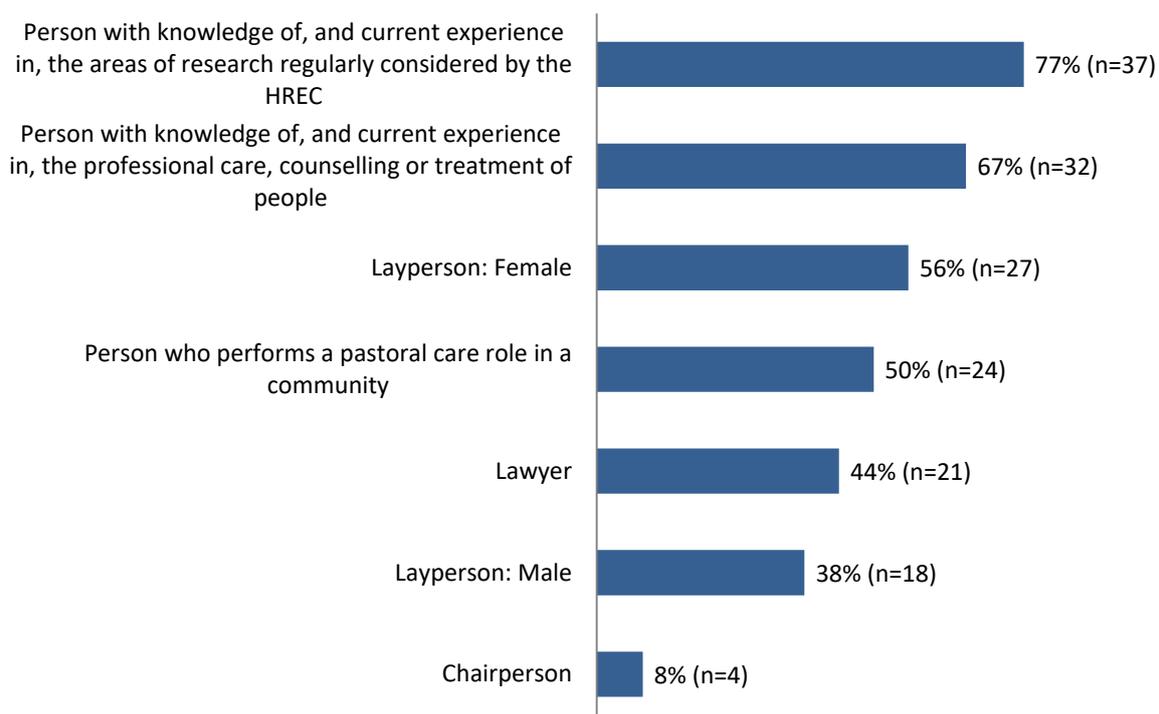
B. HREC composition

Membership

Of the certified HRECs that submitted an annual report, all but three (94%; n=48) reported a change to committee membership during 2019. The categories of membership in which changes occurred are shown in **Figure 6**. All certified HRECs reported that they met the minimum membership category requirements¹² during the reporting period.

Figure 6: Categories of membership in which the change occurred

Base: Certified institutions that reported a change to committee membership, multiple responses accepted (n=48)



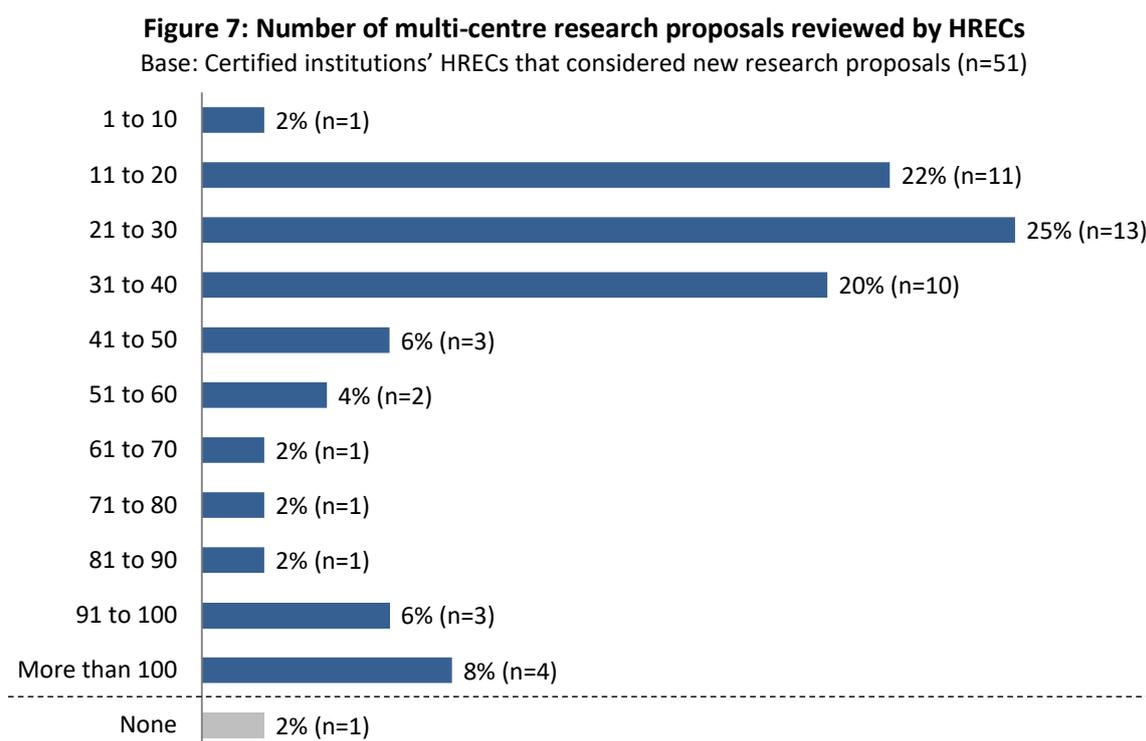
¹² The minimum membership categories are set out in paragraph 5.1.30 of the National Statement.

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 2019.

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 2,066 (2,370 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 134 (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, regardless of whether the HREC was considered the lead.

Reduced duplication and timeliness

Of the 50 HRECs that reviewed new multi-centre research proposals in 2019, all but two (96%; n=48) had reviewed at least one proposal as the lead HREC¹⁶. Around one-in-four HRECs (26%; n=13) 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. Eight HRECs (16%) 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:

- ◆ A paediatric study had been reviewed / approved by a HREC which was not certified to review paediatric research
- ◆ Additional ethical issues and/or suggested amendments were raised during an expedited review process
- ◆ Differences in requirements could not be settled
- ◆ Localised review was required for research targeting Aboriginal and Torres Strait Islander peoples
- ◆ The institution was not part of the National Mutual Acceptance (NMA) scheme
- ◆ The state (South Australia) does not accept approvals for Phase 0 / 1 clinical trial research, and
- ◆ The state (Western Australia) has different consent legislation to other states.

Of the new multi-centre research proposals reviewed during the reporting period, around nine-in-ten reviews (91%; n=1,876) were completed within 60 calendar days¹⁷. Furthermore:

- ◆ Over half (54%; n=1,106) were intended for conduct within one Australian state or territory only, and
- ◆ Over two-in-five (46%; n=960) 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.

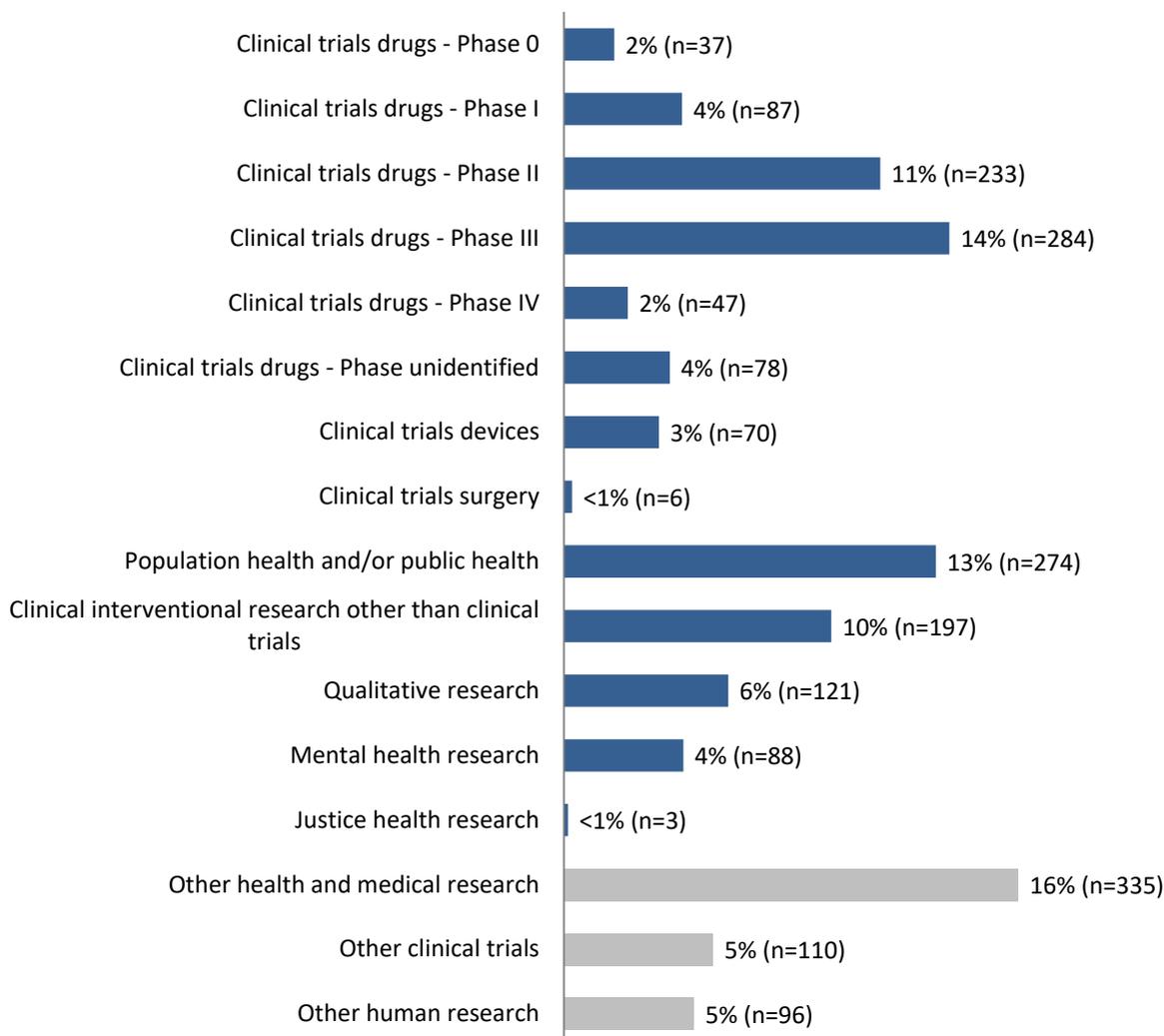
¹⁷ Further information on the 60 calendar day timeframe is provided in the [National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research Certification Handbook, November 2012](#).

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=2,066)



Other **health and medical research¹⁹** considered during the reporting period related to:

- ◆ Action research
- ◆ Allied health
- ◆ Ambulatory services
- ◆ Artificial Intelligence (AI)
- ◆ Audits / quality assurance
- ◆ Best practice techniques

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.

- ◆ Biobanks
- ◆ Biospecimen studies
- ◆ Burns and trauma
- ◆ Cancer / oncology
- ◆ Child development
- ◆ Clinical medical and science research
- ◆ Cohort studies
- ◆ Data linkage / access / outcomes
- ◆ Delirium
- ◆ Dementia
- ◆ Dentistry / oral health
- ◆ Descriptive studies
- ◆ Diagnostic validity studies
- ◆ Drugs and alcohol
- ◆ Education
- ◆ Emergency
- ◆ Epidemiology
- ◆ Gastroenterology
- ◆ Genetics
- ◆ Gynaecology
- ◆ Health services
- ◆ Human movement
- ◆ Hyperbaric medicine
- ◆ Intensive care unit (ICU)
- ◆ Laboratory studies
- ◆ Machine learning
- ◆ Maternal health
- ◆ Medical imaging
- ◆ Microbiology
- ◆ Microbiome
- ◆ Neonatology
- ◆ Neurology
- ◆ Nursing
- ◆ Nutrition and dietetics
- ◆ Observational studies
- ◆ Orthopaedics
- ◆ Patient-reported outcome measures (PROMs)
- ◆ Pharmacy
- ◆ Physiotherapy
- ◆ Psychology
- ◆ Registries
- ◆ Retrospective review / data collection
- ◆ Review of medical records
- ◆ Review of treatment / service

- ◆ Social science
- ◆ Speech pathology
- ◆ Surgery
- ◆ Surveys
- ◆ Telehealth / telemedicine, and
- ◆ Thoracic medicine.

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

- ◆ Laboratory studies
- ◆ Observational studies, and
- ◆ Trials related to:
 - Aboriginal and Torres Strait Islander health
 - Acupuncture
 - Anaesthetics
 - Application development
 - Blood transfusion
 - Cancer
 - Chinese medicine
 - Delivery of trauma therapy
 - Dementia
 - Echo detected cardiac dysfunction
 - Emergency medicine
 - Exercise
 - Genetics
 - Genomics
 - Interventions
 - Medical imaging
 - Models of care
 - Music therapy
 - Nutrition and dietetics
 - Online cognitive behavioural therapy (CBT) treatment
 - Palliative care
 - Physiotherapy
 - Point prevalence
 - Radiotherapy
 - Registries
 - Rehabilitation
 - Respiratory tests
 - Screening protocol
 - Sexual health
 - Speech pathology
 - Telehealth, and

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

- Washed versus unwashed blood cells.

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

- ◆ Aboriginal and Torres Strait Islander peoples
- ◆ Bacteriology
- ◆ Biobanks
- ◆ Biospecimens
- ◆ Blinding assessment
- ◆ Clinical science / research
- ◆ Data banks
- ◆ Education
- ◆ Evaluations
- ◆ Mathematical modelling of patient flow
- ◆ Mixed methods research
- ◆ Non-clinical trials
- ◆ Observational studies
- ◆ Quantitative studies
- ◆ Social policy
- ◆ Social science, and
- ◆ Workplace practices.

During the reporting period, just over two-in-three HRECs (68%; n=34) reviewed multi-centre research proposals involving children and young people / paediatrics.

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