

**National Health and Medical Research Council**

**Report on the Activity of Human Research  
Ethics Committees and Certified Institutions for  
the period: 1 January 2021 to 31 December  
2021**

October 2022



## Background

---

ORIMA Research was commissioned to design and conduct the 2021 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 2021 ('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 2021 reporting period opened in February 2022 and closed in August 2022.

*This project was conducted in accordance with the international quality standard ISO 20252, the international information security standard ISO 27001, as well as the Australian Privacy Principles contained in the Privacy Act 1988 (Cth). ORIMA Research also adheres to the Privacy (Market and Social Research) Code 2021 administered by the Australian Data and Insights Association (ADIA).*

## Contents

---

<b>I. Report on the Activity of NHMRC-Registered Human Research Ethics Committees for the Period 1 January 2021 – 31 December 2021 .....</b>	<b>5</b>
A. Number of HRECs.....	6
B. HREC membership .....	6
Minimum membership.....	6
Additional membership .....	7
Institutional and non-institutional members .....	8
Gender balance.....	8
C. Administration and general operation of the HREC .....	9
Terms of reference and procedures.....	9
Record keeping and reporting .....	10
Use of the Human Research Ethics Application.....	10
D. HREC meetings .....	10
Number of meetings.....	11
E. Training .....	11
F. Review of research proposals .....	12
Number of research proposals .....	12
Types of research proposals considered by HRECs .....	13
G. Health research involving Aboriginal and Torres Strait Islander Peoples.....	14
H. Research involving low or negligible risk .....	15
I. Monitoring of research .....	15
Problems encountered in monitoring approved research .....	17
J. Complaints handling .....	18
Types of complaints received .....	19
<b>II. Report on the Activity of Certified Institutions’ Human Research Ethics Committees for the Period 1 January 2021 – 31 December 2021 .....</b>	<b>21</b>
A. Number of certified institutions and institutional HRECs.....	22
B. HREC composition.....	23
Membership .....	23
C. Review of multi-centre research proposals.....	24
Number of multi-centre research proposals .....	24
Reduced duplication and timeliness.....	25
Types of multi-centre research proposals .....	26

## Appendices

**Appendix A:** Recording and Monitoring of Decisions – s95 Guidelines

**Appendix B:** Recording and Monitoring of Decisions – s95A Guidelines

## I. Report on the Activity of NHMRC-Registered Human Research Ethics Committees for the Period 1 January 2021 – 31 December 2021

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<sup>1</sup> 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 2021 to 31 December 2021.

Any queries regarding this report can be directed to [HREC.admin@nhmrc.gov.au](mailto:HREC.admin@nhmrc.gov.au).

---

<sup>1</sup> 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 2021, 192 HRECs were registered with NHMRC, and 187 HRECs submitted an annual report on their activities to NHMRC (see **Table 1**). Of the 187 HRECs who submitted an annual report, six indicated that their institution had closed the HREC (i.e. the HREC no longer operates or conducts meetings) in 2021, or in 2022 prior to submitting their annual report.

There were 195 HRECs in the previous reporting period (2020), all of which submitted an annual report.

**Table 1: Reportable HRECs by Jurisdiction (2021)**

Jurisdiction	Number of HRECs
Victoria	51
New South Wales	50
Queensland	30
South Australia	24
Western Australia	18
Australian Capital Territory	9
Northern Territory	3
Tasmania	2
<b>Total</b>	<b>187</b>

## 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’.

Sixteen HRECs (9%) reported that they did not meet the minimum membership requirements during the reporting period. Issues identified were:

- No members who perform a pastoral care role in a community (n=10)
- No female layperson (n=5)
- No male layperson (n=4)
- No lawyer (n=3)
- Less than two members with knowledge of, and current experience in, the areas of research regularly considered by the HREC (n=2)
- No members with knowledge of, and current experience in, the professional care, counselling or treatment of people (n=1), and
- Less than eight members in total (n=1).

### Additional membership

In addition to the minimum membership categories, other members appointed to HRECs during the 2021 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
- Ex-officio members
- Executive representatives (e.g. CEO, Director, General Manager)
- Graduates
- Health service representatives
- Medical professionals
- Members experienced in reflecting on and analysing ethical decision making (National Statement 5.1.32)
- Nominees
- Non-sitting members
- Patient and family representatives
- Pool members
- School representatives
- Student representatives or trainees
- Support staff (e.g. secretary, executive officer)
- Youth representatives, and
- Members with expertise in:
  - Aboriginal and Torres Strait Islander research
  - Clinical psychology
  - Clinical trials
  - Education
  - Ethics

- Family and domestic violence
- Forensic pathology
- Health information
- Information technology and security
- Mental health
- Neurology
- Nursing
- Oncology
- Pharmacy
- Philosophy
- Qualitative research
- Radiation safety
- Science, and
- Statistics.

During the reporting period, around one-in-three HRECs (32%; 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 research.<sup>2</sup> Just over one-in-ten HRECs (13%; n=24) 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. Three HRECs (2%) reported a male: female or female: male ratio of greater than or equal to 80:20.

Five HRECs (3%) reported that they included member(s) not exclusively identifying as male or female.

---

<sup>2</sup> 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 seven HRECs (96%; n=180) indicated that their terms of reference met the requirements of National Statement 5.1.27. The remaining HRECs reported that:

- No meetings were held during the reporting period
- No new research proposals or amendments were reviewed during the reporting period
- The minimum membership requirements were not met
- Their terms of reference were under review
- Their terms of reference were not publicised, and
- Their terms of reference did not include one or more of the following requirements of National Statement 5.1.27:
  - (a) the scope of the HREC's responsibilities for ethical review
  - (b) its relationship to other processes of research review
  - (c) its relationship to non-affiliated researchers
  - (d) its institutional accountability, and
  - (e) its mechanisms of reporting.

All but six HRECs (97%; n=181) reported that their standard operating procedures supporting the operations of the HREC met the requirements of National Statement 5.1.37. The remaining HRECs reported that:

- No meetings were held during the reporting period
- No new research proposals or amendments were reviewed during the reporting period
- The frequency of meetings was affected by COVID-19, mandatory lockdowns, and changing support staff
- The institution did not have standard operating procedures available, however these have since been developed and publicised on the institution's website, and
- Their standard operating procedures did not include one or more of the following requirements of National Statement 5.1.37:
  - (h) managing conflicts of interest
  - (i) communicating with researchers, including face to face, by telephone and in writing (including email)
  - (j) reporting on its activities to the institution
  - (m) record keeping
  - (o) reporting and handling of adverse events
  - (q) advising the institution/s of decisions to withdraw ethical approval of a research project
  - (r) attendance, as observers, of people other than members or researchers at meetings, and
  - (t) appropriate confidentiality of the content of applications and the deliberations of review bodies.

## Record keeping and reporting

Of the 187 HRECs who submitted an annual report, 180 (96%) reported that the HREC had considered new<sup>3</sup> research proposals during the 2021 reporting period. All but two of these HRECs (99%; n=178) indicated that the records of all research proposals received and reviewed were kept in accordance with the requirements of National Statement 5.2.25-5.2.29. The remaining HRECs reported that:

- Their standard operating procedures did not outline record keeping, and
- The HREC no longer records the proposed date of completion of the proposal (National Statement 5.2.26(g)).

## 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 2021 reporting period, almost three-in-four HRECs (72%; n=130) reported that they accepted the use of the HREA for some or all submissions, of which:

- 56 HRECs (43%) required the use of the HREA for **all** submissions
- 38 HRECs (29%) required the use of the HREA for **some** submissions, and
- 36 HRECs (28%) **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 third-party research management systems, such as Ethical Review Manager (ERM), the Research Ethics and Governance Information System (REGIS) and the Research Governance and Ethics Management System (Research GEMS).

## D. HREC meetings

---

Among the 180 HRECs that considered new research proposals during the 2021 reporting period, almost half (47%; n=85) 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, around nine-in-ten HRECs (89%; n=85) 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. The primary reason reported as to why the other absent members did not have an opportunity to

---

<sup>3</sup> 'New' research proposals did not include proposals that had already been considered by the HREC during a previous reporting period. They also did not include amendments or annual reports related to approved projects.

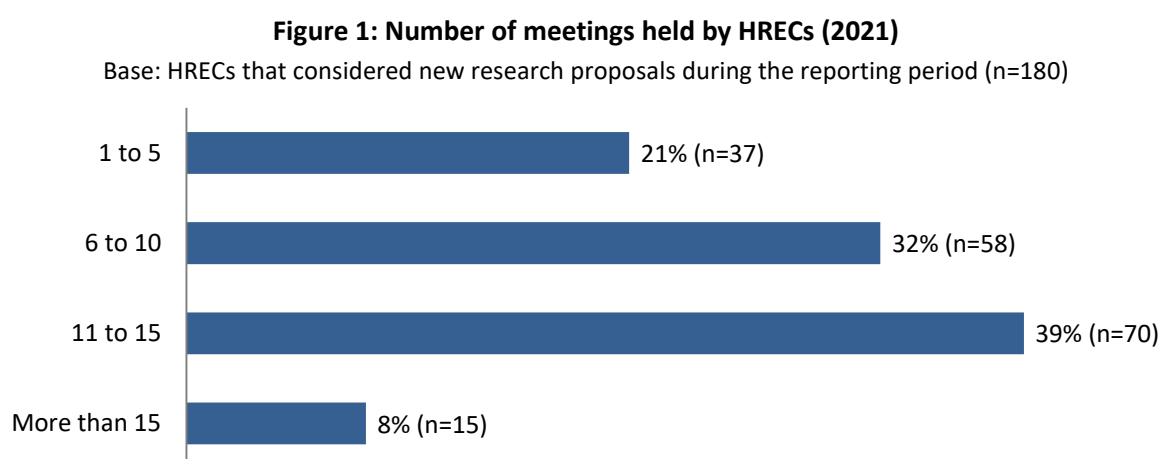
contribute their views prior to a decision being reached was due to a vacancy in a minimum membership category.

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 (71%; n=128) reported that they held between 6 and 15 meetings during the 2021 reporting period. The maximum number of meetings held by any one HREC during the reporting period was 56 (n=2). These two HRECs also reported a total of 16 and 19 members, with 309 and 197 new research proposals considered respectively during the reporting period.

## E. Training

During the 2021 reporting period, around four-in-five HRECs (79%; n=148) indicated that one or more members participated in training relevant to their work on the HREC (not including induction training).

A similar proportion (78%; n=145) reported that all new members were provided with induction training (as per paragraph 5.1.28(b)(i) of the National Statement). Just under one-in-five HRECs (17%; n=32) 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 15,087 new<sup>4</sup> research proposals considered<sup>5</sup> in the 2021 reporting period. Of these new research proposals, 228 (2%) 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 2017 to 2021.

**Table 2: Research proposals reviewed by HRECs (2017 to 2021)**

Details of research proposals	2017	2018	2019	2020	2021
Total number of new research proposals <b>considered</b>	16,446	16,314	15,320	15,575	15,087
Total number of new research proposals <b>approved</b> <sup>6</sup>	14,721 <sup>7</sup>	14,678	13,736	13,477	13,302
Percentage of new research proposals <b>approved</b>	90%	90%	90%	87%	88%
Highest number of proposals <b>approved</b> by a single HREC	399	469	442	417	361
Number of HRECs that accepted <sup>8</sup> the ethics approval of an external HREC	112	115	121	119	110

<sup>4</sup> 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.

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

<sup>6</sup> 'Approved' refers to proposals that were either approved upon initial review or after re-consideration in the 2021 reporting period.

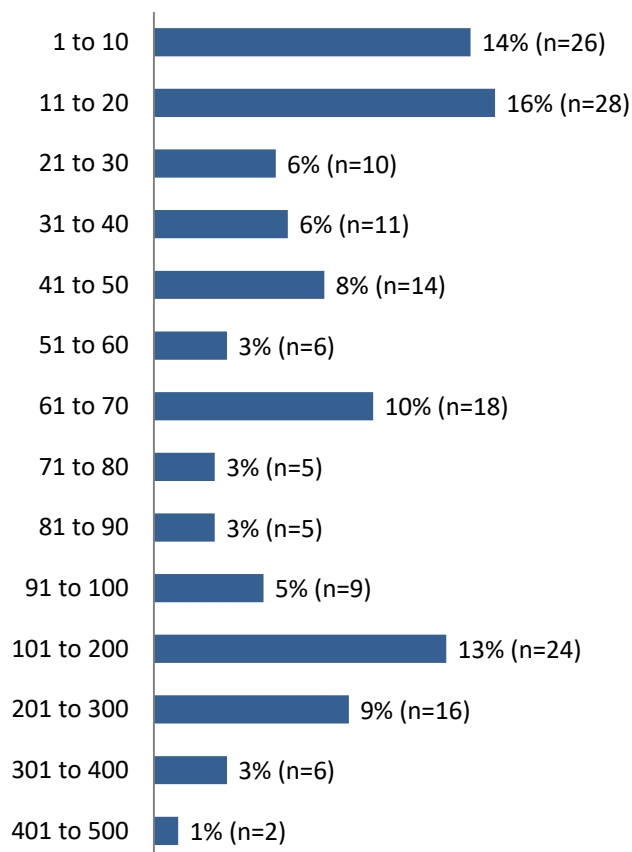
<sup>7</sup> One HREC incorrectly included proposals that were not new for the 2017 reporting period.

<sup>8</sup> '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 new research proposals considered by HRECs (2021)**

Base: HRECs that considered new research proposals during the reporting period (n=180)



The highest number of new research proposals considered by any single HREC during the reporting period was 436 (n=1), and the lowest number was 1 (n=2). The HREC that reported considering 436 proposals met 22 times, and comprised a pool of 41 members.

### Types of research proposals considered by HRECs

In the 2021 reporting period, 118 HRECs (66%) considered a total of 2,226 new clinical trial<sup>9</sup> research proposals. In the previous reporting period (2020), 2,314 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.

<sup>9</sup> 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 180 HRECs that considered new research proposals during the reporting period, half (50%; n=90) considered health-related research proposals involving Aboriginal and Torres Strait Islander peoples. Of these HRECs, all but five (94%; n=85) 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:

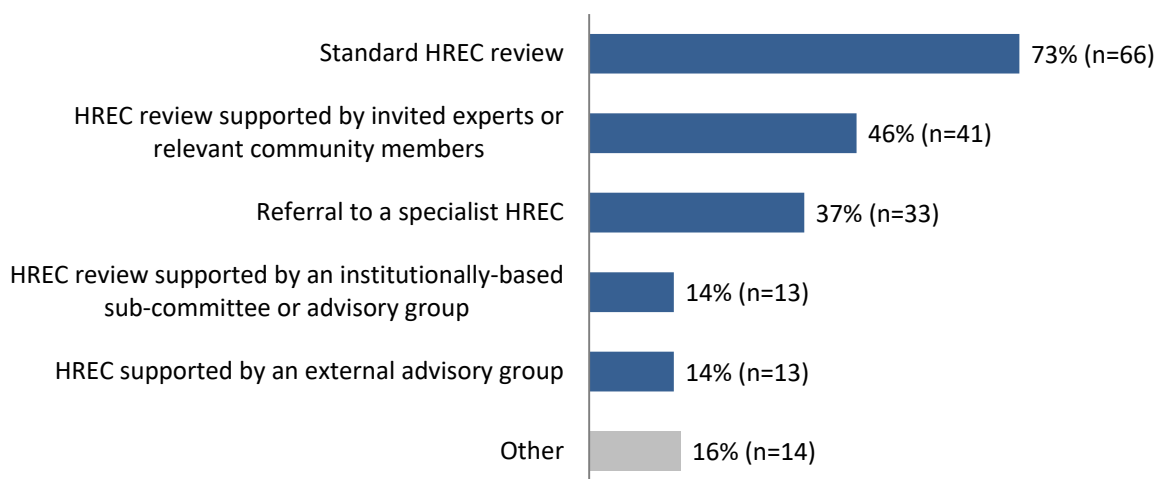
- The *National Statement on Ethical Conduct in Human Research (2007) – Updated 2018*, and
- The Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) *Code of Ethics for Aboriginal and Torres Strait Islander Research*.

One HREC also reported that they did not use any guidelines as they ensured that all proposals had been approved, or were pending approval, by 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 (2021)**

Base: HRECs that considered new health research proposals involving Aboriginal and Torres Strait Islander peoples during the reporting period, multiple responses accepted (n=90)



Fourteen HRECs (16%) 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, 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, just over three-in-four HRECs that considered new research proposals (77%; n=139) reported that their organisation had established an alternative mechanism<sup>10</sup> for ethics review (other than by the HREC) for research proposals that involve low or negligible risk. Of these, 79 HRECs indicated that the HREC also reviews some low or negligible risk research.

Of those who reported that the HREC reviews low or negligible risk research, over four-in-five (83%; 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.

## I. Monitoring of research

---

Of the 187 HRECs that submitted an annual report, all but one (99%; n=186) indicated that the organisation and/or the HREC had procedures in place for monitoring approved research. The remaining HREC reported that “while procedures were in place for standard monitoring of projects, there was no research active during the reporting period”.

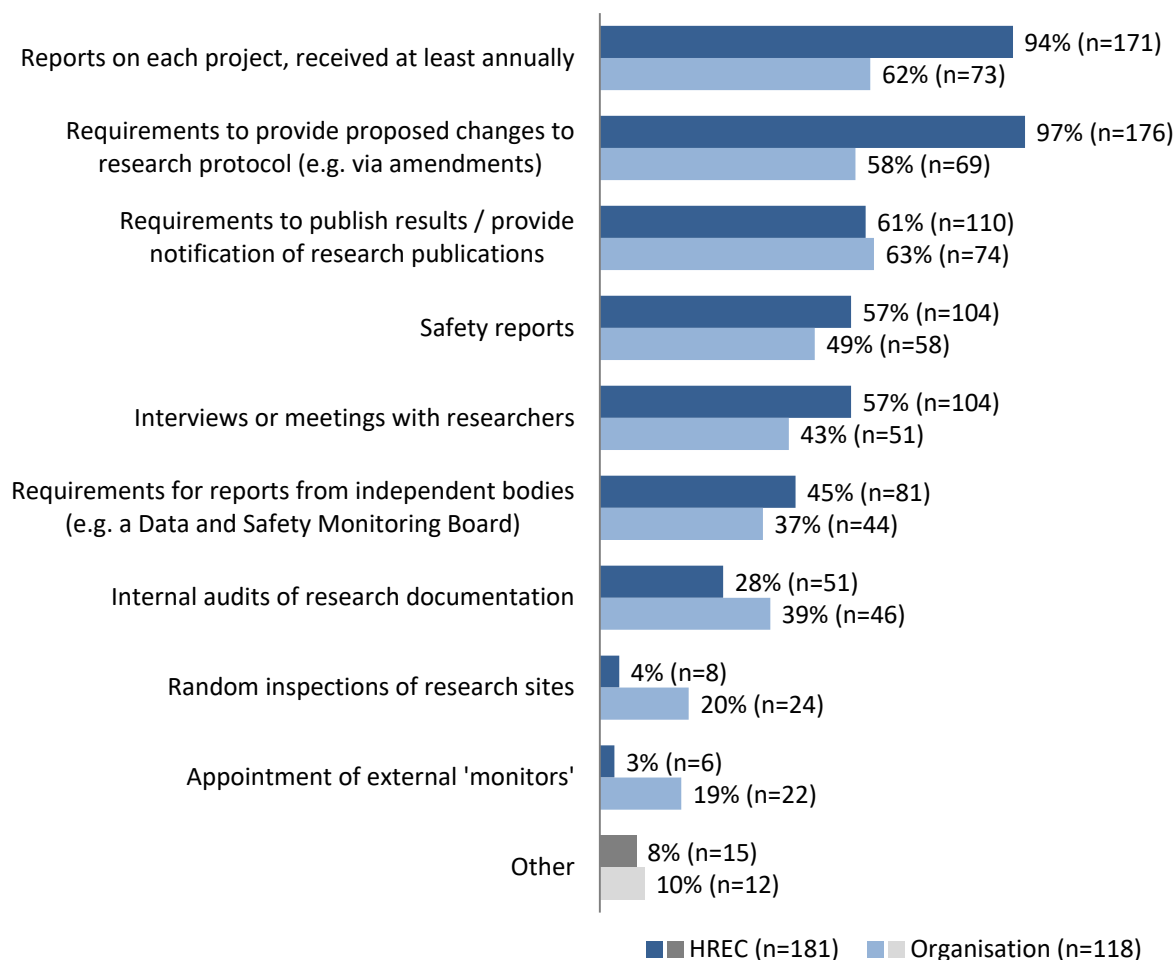
---

<sup>10</sup> 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).

Of the HRECs that had monitoring procedures in place during the reporting period, all but three (98%; n=183) reported that the organisation and/or the HREC undertook monitoring of approved research. **Figure 4** provides information on the reported monitoring processes in 2021.

**Figure 4: Monitoring processes (2021)**

Base: HRECs that reported that the organisation and/or the HREC undertook monitoring of all approved research, multiple responses accepted (n=183)



Other processes used to monitor research included:

- A requirement for researchers to provide regular progress updates and reports, including in relation to:
  - Adverse events
  - Amendment updates for any change in a study (not just protocol changes)
  - Breaches
  - Investigator changes
  - Notifiable events
  - Protocol deviations / violations
  - Safety notifications
- Establishing monitors and/or Data and Safety Monitoring Boards for clinical trials and projects, where required
- External monitoring, for example by sponsors of clinical trials



- Institutional handling of notification of publication outcomes
- Inviting researchers to attend committee meetings to discuss and provide updates on their projects
- Monitoring and review by a sub-committee
- Providing annual reports and regular updates to the Deputy Vice Chancellor (Research)
- Random inspection of labs (safety spot checks)
- Self-audits, and
- Start-up meetings.

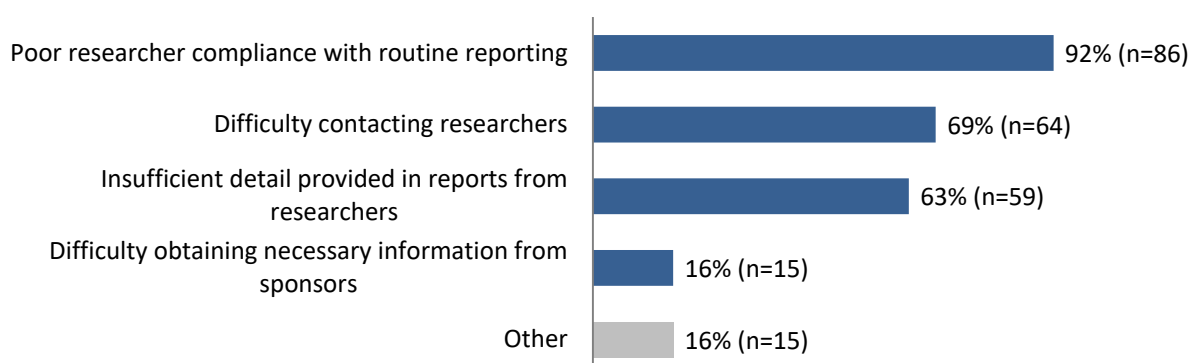
Of the three HRECs that did not undertake monitoring, two reported that there was no approved research to monitor. The remaining HREC reported that “due to the number of applications lodged for review at each meeting, the committee couldn’t undertake monitoring of approved research”.<sup>11</sup>

### Problems encountered in monitoring approved research

Of the 183 HRECs that undertook monitoring of approved research during the reporting period, around half (51%; n=93) 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 (2021)**

Base: HRECs that reported that they or their organisation encountered problems in monitoring research during the reporting period, multiple responses accepted (n=93)



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

- COVID-19 related difficulties and challenges
- Difficulty recruiting committee members
- Limited resources to undertake monitoring
- Staff changes / turnover
- Timely submissions of progress / safety / annual reports, and
- Volume and scope of research projects.

<sup>11</sup> The HREC that did not undertake monitoring was advised that organisations and/or HRECs should undertake monitoring for approved research, as required by Chapters 5.1 and 5.5 of the National Statement.

Of the 93 HRECs that reported that they encountered problems in monitoring research, all but one (99%; n=92) 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 187 HRECs that submitted an annual report, all but three (98%; n=184) 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 six HRECs (97%; n=181) 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 included:<sup>12</sup>

- Complaints procedures were in the process of being developed / reviewed / made publicly available
- Complaints procedures were available internally within the organisation, as research projects were mostly internal
- Complaints procedures were available on request, and
- Website upgrades.

---

<sup>12</sup> 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, around one-in-three HRECs (34%; n=63) received a combined total of 189 complaints **about** researchers or the conduct of an approved research project, while eight HRECs (4%) received a combined total of 20 complaints **from** researchers about the consideration of their proposal(s) by the HREC (see **Table 3**).

**Table 3: Number of complaints or concerns received by HRECs (2021)**

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	189	26
Complaints received about researchers or the conduct of an approved research project that involved Aboriginal and Torres Strait Islander peoples	13	3
Complaints received from a researcher about the consideration of their research proposal by the HREC	20	6

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

- Adverse events
- Conflict of interest
- Consent and opt-out processes
- Consultation / engagement with Aboriginal and Torres Strait Islander peoples / communities
- Data issues (including concerns around data access, storage, use, sovereignty, integrity, validity of data analysis techniques)
- Difficulty contacting researchers
- Effects caused by research (including discomfort, distress, mental health impacts)
- Incorrect / incomplete / unclear / misleading information
- Language issues
- Online survey technical issues
- Participant Information and Consent Form
- Payment / reimbursement
- Perceived bias
- Plagiarism
- Presentation of research results
- Privacy and confidentiality concerns
- Protocol deviations / breaches
- Publication / authorship issues
- Questionnaire design / content

- Recruitment methods and material (including coercion, unsolicited / unapproved recruitment, contacting children, contacting vulnerable persons, contacting deceased persons)
- Research design / methodology
- Research merit / integrity / validity
- Research undertaken, or changes made to research documentation / processes, without ethics approval
- Researcher conduct and communication
- Safety concerns
- Stakeholder consultation / engagement
- Transcripts / recordings, and
- Withdrawal from research.

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

- Dissatisfaction or disagreement with the HREC's feedback or decision, and
- Review processes, requirements, 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 2021 – 31 December 2021

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 2021 – 31 December 2021.

Any queries regarding this report can be directed to [HREC.admin@nhmrc.gov.au](mailto:HREC.admin@nhmrc.gov.au).

## A. Number of certified institutions and institutional HRECs

During 2021, 43 organisations operated as certified institutions under the NHMRC National Certification Scheme. These 43 organisations included 55 HRECs. Of these, 54 HRECs across 42 certified institutions submitted an annual report (see **Table 4**).

In the 2020 reporting period, there were 42 certified institutions, all of which submitted an annual report.

**Table 4: Reportable HRECs by Jurisdiction (2021)**

Jurisdiction	Number of Certified Institutions	Number of HRECs
New South Wales	14	15
Queensland	9	9
Victoria	8	8
South Australia	5	16
Western Australia	4	4
Australian Capital Territory	1	1
Northern Territory	1	1
<b>Total</b>	<b>42</b>	<b>54</b>

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

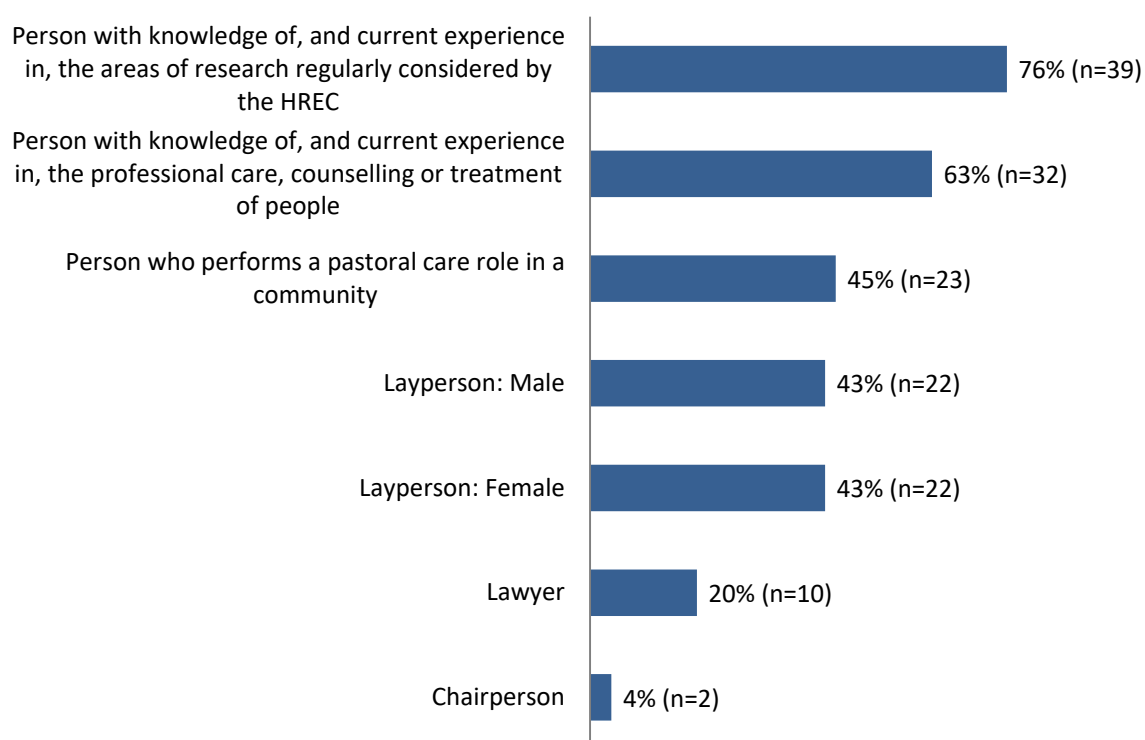
## B. HREC composition

### Membership

All but three certified HRECs (94%; n=51) reported a change to committee membership during 2021. The categories of membership in which changes occurred are shown in **Figure 6**. All certified HRECs reported that they met the minimum membership category requirements<sup>13</sup> during the reporting period.

**Figure 6: Categories of membership in which the change occurred (2021)**

Base: Certified institutions' HRECs that reported a change to committee membership, multiple responses accepted (n=51)



<sup>13</sup> The minimum membership categories are set out in paragraph 5.1.30 of the National Statement.

## C. Review of multi-centre research proposals

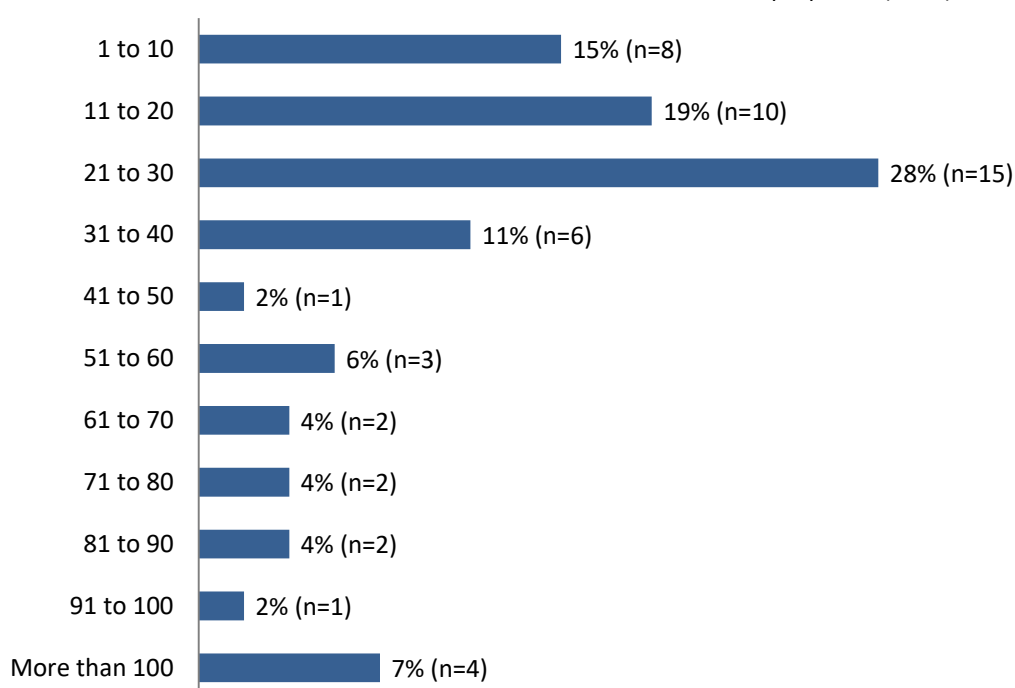
All 54 HRECs from certified institutions reported that they had considered new<sup>14</sup> research proposals during the reporting period. All of these HRECs also reported that they had reviewed new multi-centre<sup>15</sup> research proposals during 2021.

### Number of multi-centre research proposals

The distribution of the number of new multi-centre research proposals reviewed<sup>16</sup> by HRECs during the reporting period is shown in **Figure 7**.

**Figure 7: Number of multi-centre research proposals reviewed by HRECs (2021)**

Base: Certified institutions' HRECs that considered new research proposals (n=54)



<sup>14</sup> 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.

<sup>15</sup> 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.

<sup>16</sup> This included all reviews, regardless of whether the HREC was considered the lead.



The total number of new multi-centre research proposals reviewed during the reporting period was 2,123 (2,254 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 221 (n=1), and the lowest was 4 (n=1).

### Reduced duplication and timeliness

Of the 54 HRECs that reviewed new multi-centre research proposals in 2021, all but two (96%; n=52) had reviewed at least one proposal as the lead HREC.<sup>17</sup> Around one-in-four HRECs (26%; n=14) reviewed at least one new multi-centre research proposal where it was not the lead HREC.

During the reporting period, almost one-in-three HRECs (31%; n=17) reported that they were aware of instances where the HREC's approval had not been accepted by another institution. Seven HRECs (13%) 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:

- Additional scientific and ethical issues were raised during an expedited review process
- The institution was private / not part of the National Mutual Acceptance (NMA) scheme, and
- The research targeted Aboriginal and Torres Strait Islander peoples or communities.

Of the new multi-centre research proposals reviewed during the reporting period, over nine-in-ten reviews (94%; n=1,993) were completed within 60 calendar days.<sup>18</sup> Furthermore:

- Over half (54%; n=1,142) were intended for conduct within one Australian state or territory only, and
- Almost half (46%; n=981) were intended for conduct in two or more Australian states or territories.

---

<sup>17</sup> 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.

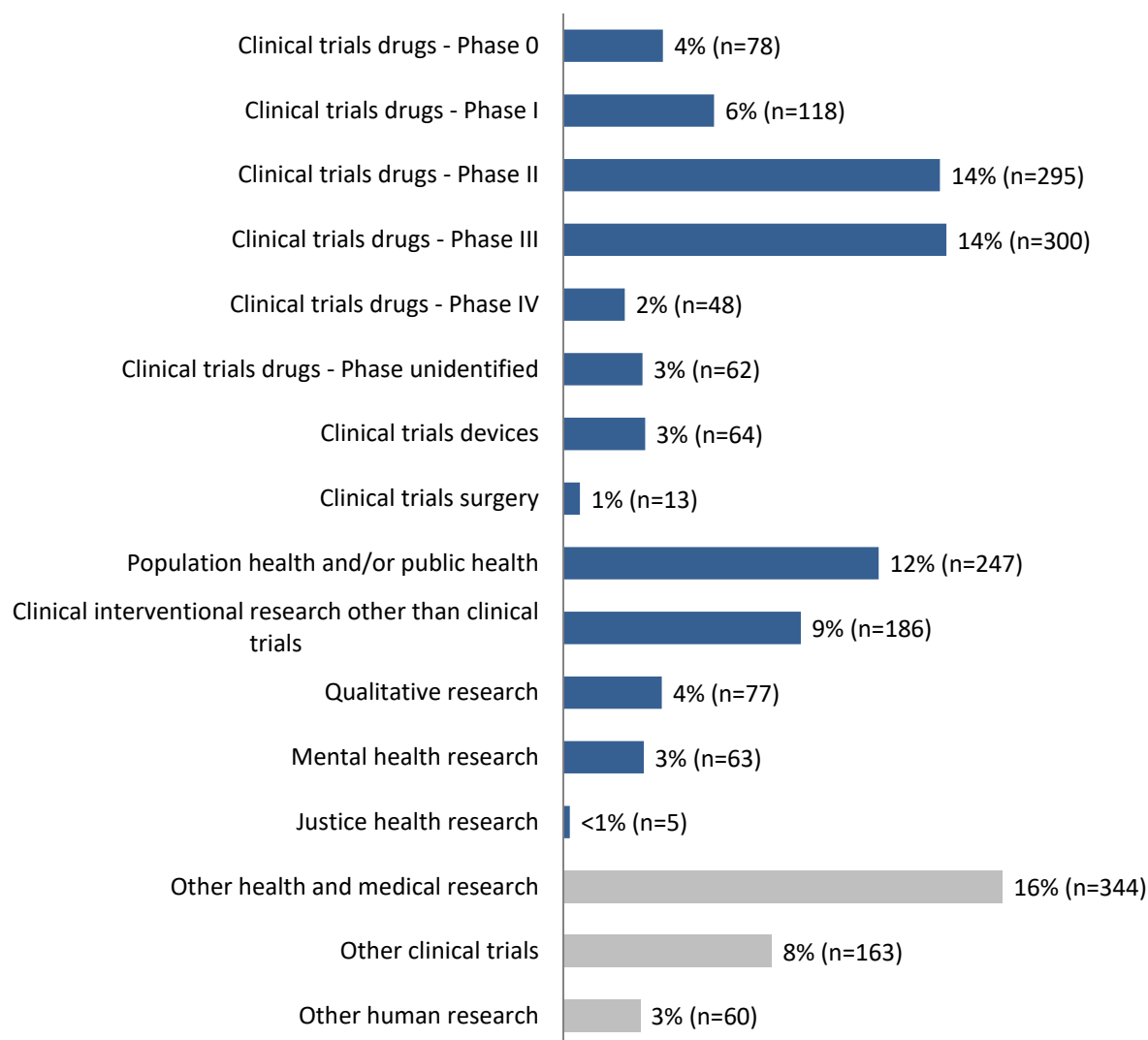
<sup>18</sup> Further information on the 60 calendar day timeframe is provided in the [National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research Certification Handbook, November 2012](#).

## 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 considered<sup>19</sup> (2021)**

Base: Total number of multi-centre research proposals considered by certified institutions' HRECs (n=2,123)



Other **health and medical research**<sup>20</sup> considered during the reporting period related to:

- Aboriginal and Torres Strait Islander health
- Allied health
- Ambulance
- Aphasia

<sup>19</sup> 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](#).

<sup>20</sup> The topics listed have been self-reported by HRECs.

- Artificial intelligence (AI)
- Biobanks
- Biospecimen analysis
- Cancer
- Cardiorespiratory / cardiovascular health and medicine
- Case-control studies
- Clinical research not otherwise specified
- Correlation research
- COVID-19
- Data linkage
- Databanks
- Dental and oral health
- Descriptive research
- Driving behaviour
- Emergency and trauma
- Ethnographic research
- Evaluations
- Genetics
- Haematology
- Health and social science
- Health services and staff
- Human movement and sports science
- Immunology
- Infectious diseases
- Injury
- Insulin therapy
- Integrated care program of research
- Laboratory research
- Maternal health
- Mental health
- Nanopore sequencing
- Neonatal research
- Nephrology
- Neurosciences
- Nursing
- Nutrition and dietetics
- Obesity
- Observational research
- Obstetrics
- Occupational therapy
- Ophthalmology and optometry
- Orthopaedics
- Paediatrics

- Palliative care
- Pathology
- Pathway analysis
- Patient satisfaction
- Pharmacy
- Physiotherapy
- Prediction research
- Prevalence research
- Prospective research
- Pulse oximetry using smart watch technology
- Qualitative research (including interviews)
- Quantitative research (including surveys, questionnaires)
- Radiology
- Registries
- Rehabilitation
- Reproductive medicine
- Retrospective research / review
- Safety research
- Social research
- Stroke
- Surgery
- Thoracic medicine
- Trend research
- Urology
- Vaccines
- Validation research, and
- Violence in hospital emergency departments.

Other **clinical trials**<sup>21</sup> considered during the reporting period included trials involving / related to:

- Anaesthesia
- Atrial fibrillation management strategies
- Bacteriophage
- Cancer
- Child health
- Clinical sciences
- Community health navigator
- COVID-19
- Critical / intensive care
- Dentistry
- Exercise
- Facial taping for facial palsy

---

<sup>21</sup> The topics listed have been self-reported by HRECs.

- Fluid restriction during the induction of labour
- Gameplay devices
- Genetics
- Holistic management
- Imaging
- Ingestion of a ginger derivative
- Ingestion of various purple foods
- Interventions
- Light therapy treatment
- Long-term follow-up studies
- Mental health
- Monitoring
- Neurology
- Nursing
- Observation
- Peer support for / by breastfeeding Aboriginal women
- Physiotherapy
- Post-Phase IV trials
- Radiotherapy
- Registries
- Screening and referral processes
- Sleep apnoea
- Standards of care
- Standard treatments
- Targeted net ultrafiltration rate during renal replacement therapy
- Thoracic medicine
- Topical coconut oil
- Upper limb and language impairment training
- Virtual reality technology for surgery, and
- Withdrawal of treatment.

Other **human research**<sup>22</sup> considered during the reporting period related to:

- Allied health studies
- Audits
- Basic science
- Biospecimens
- Clinical research
- Cohort studies
- Data linkage
- Education effectiveness
- Ethnography

---

<sup>22</sup> The topics listed have been self-reported by HRECs.

- Gender and sexuality
- International registry
- Laboratory-based research / analysis
- Race horse retraining
- Retrospective data collection
- Review of medical records
- Social policy
- Social science, and
- Surveys.

During the reporting period, around seven-in-ten HRECs (69%; n=37) reviewed multi-centre research proposals involving children and young people / paediatrics.