

National Health and Medical Research Council

Report on the Activity of Human Research
Ethics Committees and Certified Institutions
for the period: 1 January 2023 to 31
December 2023

FINAL REPORT

Background

ORIMA Research was commissioned to design and conduct the 2023 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 2023 ('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).

While the 2007 National Statement was in effect during the reporting period, a revised National Statement was issued on 29 June 2023 which incorporated a revised Chapter 2.1 and Section 5 as well as some minor consequential changes. The NHMRC expected institutions, HRECs and researchers to apply the revised National Statement from the effective date of 1 January 2024. However, as it was acceptable for the Section 5 governance changes to be implemented progressively during the six-month period preceding the formal adoption on 1 January 2024, HRECs were given the opportunity to indicate whether they made any changes to align with the 2023 National Statement ahead of its formal adoption date in the 2023 annual report.

Please note that all references to the National Statement in this report are to the 2007 National Statement.

The annual reporting survey for the 2023 reporting period opened in March 2024 and closed in August 2024.

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

I. Report on the Activity of NHMRC-Registered Human Research Ethics Committees for the Period 1 January 2023 – 31 December 2023	3
A. Number of HRECs	3
B. HREC membership.....	4
Minimum membership.....	4
Additional membership.....	5
Institutional and non-institutional members	6
Gender balance	6
C. Administration and general operation of the HREC.....	6
Terms of reference and procedures.....	6
Record keeping and reporting.....	7
Use of the Human Research Ethics Application	7
D. HREC meetings	7
Number of meetings.....	9
E. Training.....	9
F. Review of research proposals	10
Number of research proposals.....	10
Types of research proposals considered by HRECs	11
G. Health research involving Aboriginal and Torres Strait Islander Peoples	12
H. Research involving low or negligible risk.....	13
I. Monitoring of research	13
Problems encountered in monitoring approved research.....	15
J. Complaints handling	16
Types of complaints received.....	16
II. Report on the Activity of Certified Institutions' Human Research Ethics Committees for the Period 1 January 2023 – 31 December 2023	18
A. Number of certified institutions and institutional HRECs	18
B. HREC composition	19
Membership	19
C. Review of multi-centre research proposals	20
Number of multi-centre research proposals.....	20
Reduced duplication and timeliness	21
Types of multi-centre research proposals.....	22

I. Report on the Activity of NHMRC-Registered Human Research Ethics Committees for the Period 1 January 2023 – 31 December 2023

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 2023 to 31 December 2023.

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

A. Number of HRECs

During 2023, 190 HRECs were registered with NHMRC, and 183 HRECs submitted an annual report on their activities to NHMRC (see **Table 1**). Of the 183 HRECs who submitted an annual report, 2 indicated that their institution had closed the HREC (i.e. the HREC no longer operates or conducts meetings) in 2023, or in 2024 prior to submitting their annual report.

These numbers are consistent with last reporting period (2022), which included 192 HRECs, 185 of which submitted an annual report.

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.

Table 1: Reportable HRECs by jurisdiction (2023)

Jurisdiction	Number of HRECs
Victoria	55
New South Wales	49
Queensland	28
South Australia	23
Western Australia	16
Australian Capital Territory	9
Northern Territory	2
Tasmania	1
Total	183

While the 2007 National Statement was in effect during the reporting period, a revised National Statement was issued on 29 June 2023 which incorporated a revised Chapter 2.1 and Section 5 as well as some minor consequential changes. The NHMRC expected institutions, HRECs and researchers to apply the revised National Statement from the effective date of 1 January 2024. However, it was acceptable for Section 5 governance to be implemented progressively during the six-month period preceding the formal adoption on 1 January 2024. By the end of the reporting period, 48% (n=86) of HRECs had adopted governance changes to align with the requirements in section 5 of the 2023 National Statement.

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'.

Nineteen HRECs (10%) reported that they did not meet the minimum membership requirements during the reporting period based on the above categories. Issues identified were:

- No Chairperson (n=7)
- No male layperson (n=15)
- No female layperson (n=9)
- No members with knowledge of, and current experience in, the professional care, counselling or treatment of people (n=8)
- No members who perform a pastoral care role in a community (n=10)
- No lawyer (n=10), and
- Less than two members with knowledge of, and current experience in, the areas of research regularly considered by the HREC (n=9).

In the 2023 National Statement, the previous requirement to have both a male and female layperson has been replaced with ‘two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution’. Three of the HRECs who did not meet the minimum membership requirements in this area indicated that they had implemented Section 5 changes to the National Statement during the reporting period and thus may be compliant with the 2023 National Statement.

Additional membership

In addition to the minimum membership categories, other members appointed to HRECs during the 2023 reporting period were identified by HRECs as filling the following self-described roles:

- Aboriginal and Torres Strait Islander representatives
- Consumer representatives
- Deputy chair
- Executive representatives (e.g. Director, Manager, Chief Officer)
- Ex-officio members
- Health service representatives
- Hospital representatives
- Medical professionals
- Nominees
- Philosophers
- School representatives
- Student representatives or trainees
- Subcommittee representatives
- Support staff (e.g. secretary)
- Youth representatives
- Members with expertise in:
 - Aboriginal & Torres Strait Islander research
 - Artificial Intelligence
 - Biostatistics
 - Culture
 - Education
 - Ethics
 - Exercise science
 - Forensic pathology
 - Health information management
 - Medical education / science
 - Nursing
 - Oncology
 - Pharmacy

- Radiation safety
- Statistics

During the reporting period, around one-in-three HRECs (32%; n=58) 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.² Just over one-in-ten HRECs (12%; 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. Overall:

- 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.

C. Administration and general operation of the HREC

Terms of reference and procedures

During the reporting period, almost all HRECs (96%; n=176) indicated that their terms of reference met the requirements of National Statement 5.1.27. The remaining seven HRECs reported that:

- Their terms of reference did not include one or more of the following requirements of National Statement 5.1.27:
 - (c) its relationship to non-affiliated researchers
 - (g) remuneration, if any, for members
- Their terms of reference were under development and/or have since been amended
- The minimum membership requirements were not met, and
- There were changes to the HREC's purpose and membership categories.

All but eight HRECs (96%; n=175) also reported that their standard operating procedures supporting the operations of the HREC met the requirements of National Statement 5.1.37. The remaining HRECs reported that:

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

- The standard operating procedures were in development
- The standard operating procedures were amended and are now compliant in the 2024 reporting period, and
- Their HREC became an advisory committee rather than a reviewing committee.

Record keeping and reporting

174 (95%) HRECs reported that they considered new³ research proposals during the 2023 reporting period. Of these, all (100%; n=174) 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.

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](#).

Around two-thirds of HRECs (68%; n=118) reported that they accepted the use of the HREA for some or all submissions during the 2023 reporting period. Of these:

- 59 HRECs (50%) required the use of the HREA for **all** submissions
- 35 HRECs (30%) required the use of the HREA for **some** submissions, and
- 24 HRECs (20%) **did not require** the use of the HREA for submissions.

A HREA can be completed via the NHMRC's own HREA system ([HREA website](#)), 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 174 HRECs that considered new research proposals during the reporting period, 43% (n=75) reported that at least the minimum membership (as per paragraph 5.1.30 of the National Statement) was present at all meetings where a decision was made on a research proposal.

Of the 99 HRECs who reported that the minimum membership was **not** present at all meetings where a decision was made on a research proposal:

- The average number of meetings that the full membership was not present was 5, and
- The average proportion of all meetings that the full membership was not present was 26%.

Where the minimum membership was **not** present at all meetings (n=99), eight-in-ten of these HRECs (80%; n=79) 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.

³ '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.

Of the 20 HRECs who reported the chairperson was **not** satisfied that prior to a decision being reached the minimum membership received all papers, had an opportunity to contribute their views, and these views were recorded and considered before a decision was made:

- The average number of meetings where the chairperson was not satisfied, as described above, was 5, and
- The average proportion of all meetings where the chairperson was not satisfied, as described above, was 47%.

The main reason reported as to why the absent members did not have an opportunity to contribute their views prior to a decision being reached was a vacancy in a minimum membership category. Other reasons also included:

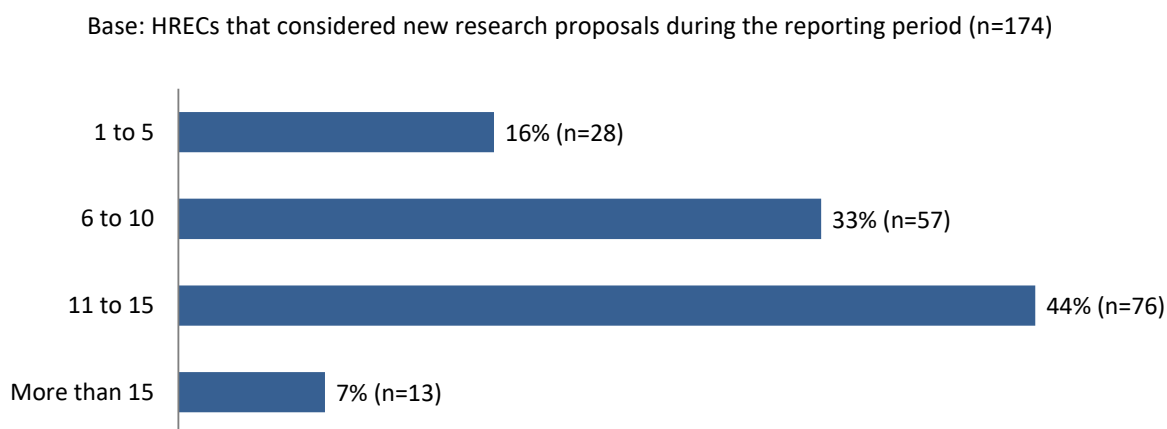
- members did not provide advance notice or comments before meetings, which resulted in no time to consider their views
- lack of procedure for addressing the missing views of absent members
- resignations of members (e.g., pastoral care, layperson, professional care) without immediate replacements
- an inability to attend the meeting due to other commitments (due to holidays or travel, work commitments or illness)
- late apologies from members not reading the meeting papers or attending the meeting as planned, and
- members not responding to follow-up requests for comments.

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

Figure 1: Number of meetings held by HRECs (2023)



Over three-in-four HRECs (76%; n=133) reported that they had held between 6 and 15 meetings during the 2023 reporting period (see **Figure 1**). Across all HRECs, the average number of meetings held was 11. The maximum number of meetings held by any one HREC during the reporting period was 60 (n=2). These HRECs reported that they have a total of 17 and 20 members and considered 219 and 153 new research proposals respectively, during the reporting period.

E. Training

Over four-in-five HRECs (83%; n=151) indicated that one or more members participated in training relevant to their work on the HREC (not including induction training) during the 2023 reporting period.

A slightly lower proportion (80%; n=147) reported that, during the reporting period, all new members were provided with induction training (as per paragraph 5.1.28(b)(i) of the National Statement). Around one-in-five HRECs (18%; n=33) 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

A total of 13,284 new⁴ research proposals were considered⁵ in the 2023 reporting period. Of these new research proposals, 166 (1%) were denied ethics approval by the HREC and will not be reconsidered.

Table 2 shows the number of research proposals considered by HRECs from the last five years (2019 to 2023).

Table 2: Research proposals reviewed by HRECs (2019 to 2023)

Details of research proposals	2019	2020	2021	2022	2023
Total number of new research proposals considered	15,320	15,575	15,087	13,066	13,284
Total number of new research proposals approved ⁶	13,736	13,477	13,302	11,744	11,740
Percentage of new research proposals approved	90%	87%	88%	90%	88%
Highest number of proposals approved by a single HREC	442	417	361	418	369
Number of HRECs that accepted ⁷ the ethics approval of an external HREC	121	119	110	113	114

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

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.

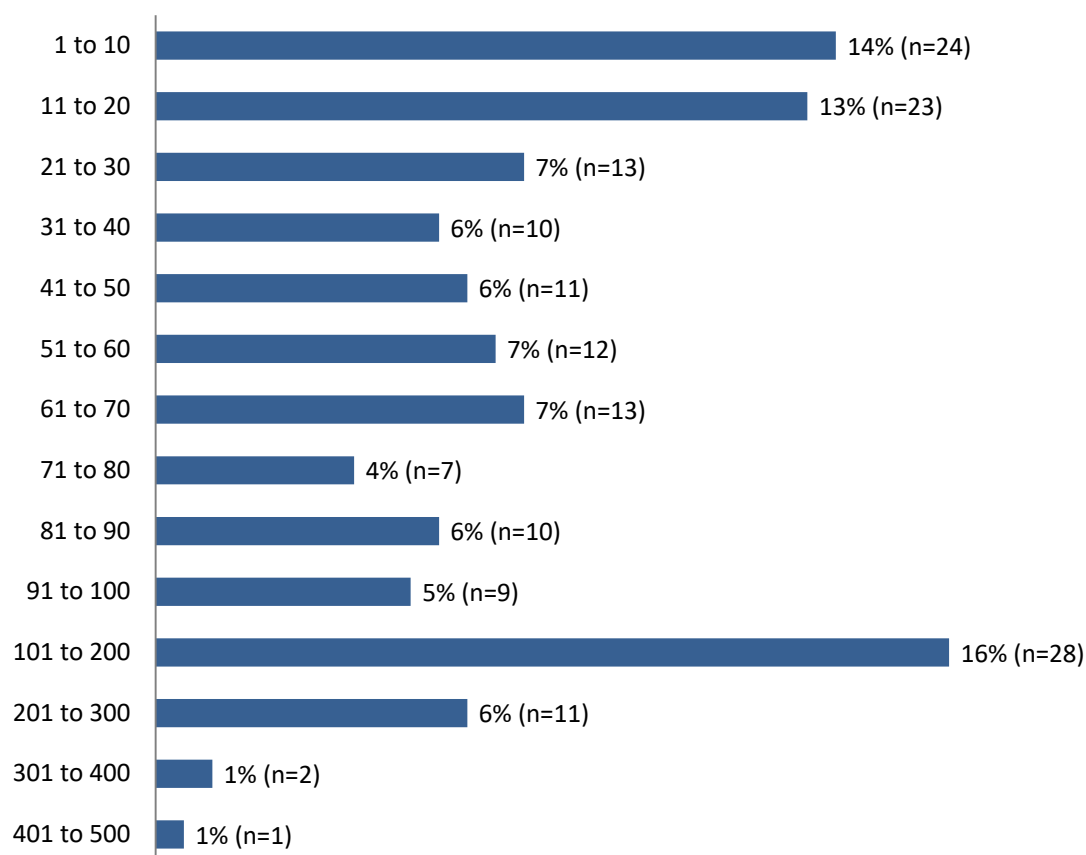
⁵ 'Considered' refers to the consideration of research proposals by the full HREC (see paragraph 5.1.6 of the National Statement).

⁶ 'Approved' refers to proposals that were either approved upon initial review or after re-consideration in the 2023 reporting period.

⁷ 'Accepted' refers to accepting once or on multiple occasions.

Figure 2: Number of new research proposals considered by HRECs (2023)

Base: HRECs that considered new research proposals during the reporting period (n=174)



The highest number of new research proposals considered by any single HREC during the reporting period was 424 (n=1), and the lowest was 1 (n=1). The HREC that reported considering 424 proposals met 11 times and comprised 18 members.

Types of research proposals considered by HRECs

In the 2023 reporting period, 174 HRECs considered a total of 2,204 new clinical trial⁸ research proposals. In the previous reporting period (2022), 1,969 research proposals involving clinical trials were considered.

Seven (4%) HRECs considered proposals involving the use of human gametes (eggs or sperm) or excess Assisted Reproductive Technology (ART) embryos.

⁸ 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 174 HRECs that considered new research proposals during the reporting period, just over half (52%; n=91) considered proposals involving health-related research with Aboriginal and Torres Strait Islander peoples.

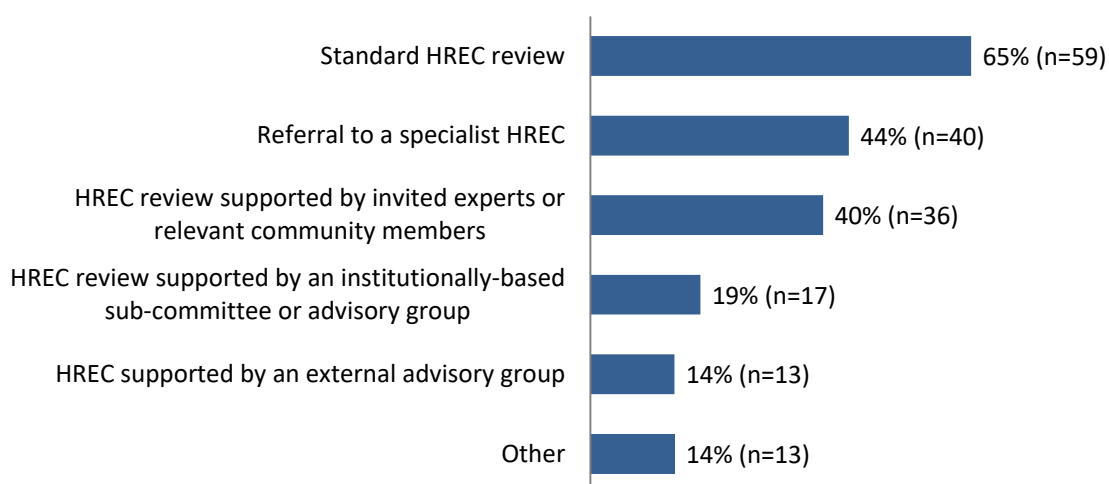
Over nine-in-ten of these HRECs (93%, n=85) reported that they used the [Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018](#) in considering these health research proposals. Other than the above guidelines, the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) *Code of Ethics for Aboriginal and Torres Strait Islander Research* was also reported to have been used in considering health-related research proposals involving Aboriginal and Torres Strait Islander peoples.

Four HRECs indicated that they instead (or also) required a review or approval from a HREC specialising in research with Aboriginal and Torres Strait Islander peoples.

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 (2023)

Base: HRECs that considered new health research proposals involving Aboriginal and Torres Strait Islander peoples during the reporting period, multiple responses accepted (n=91)



Other mechanisms used by these HRECs (14%, n=13) for the review of health research proposals involving Aboriginal and Torres Strait Islander peoples, included:

- advice from or consultation with Aboriginal and Torres Strait Islander committee members and ethics advisors
- advice from local Aboriginal and Torres Strait Islander representatives
- advice from external representatives with subject matter expertise, and
- review or advice 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 2023 reporting period:

- Of the 101 HRECs who indicated that they do review low or negligible risk research, 80% (n=81) indicated that they had actually considered low or negligible risk research proposals during the reporting period.
- 84% (n=146) of HRECs reported that their organisation had established an alternative mechanism⁹ for ethics review (other than by the HREC) for research proposals that involve low or negligible risk.

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

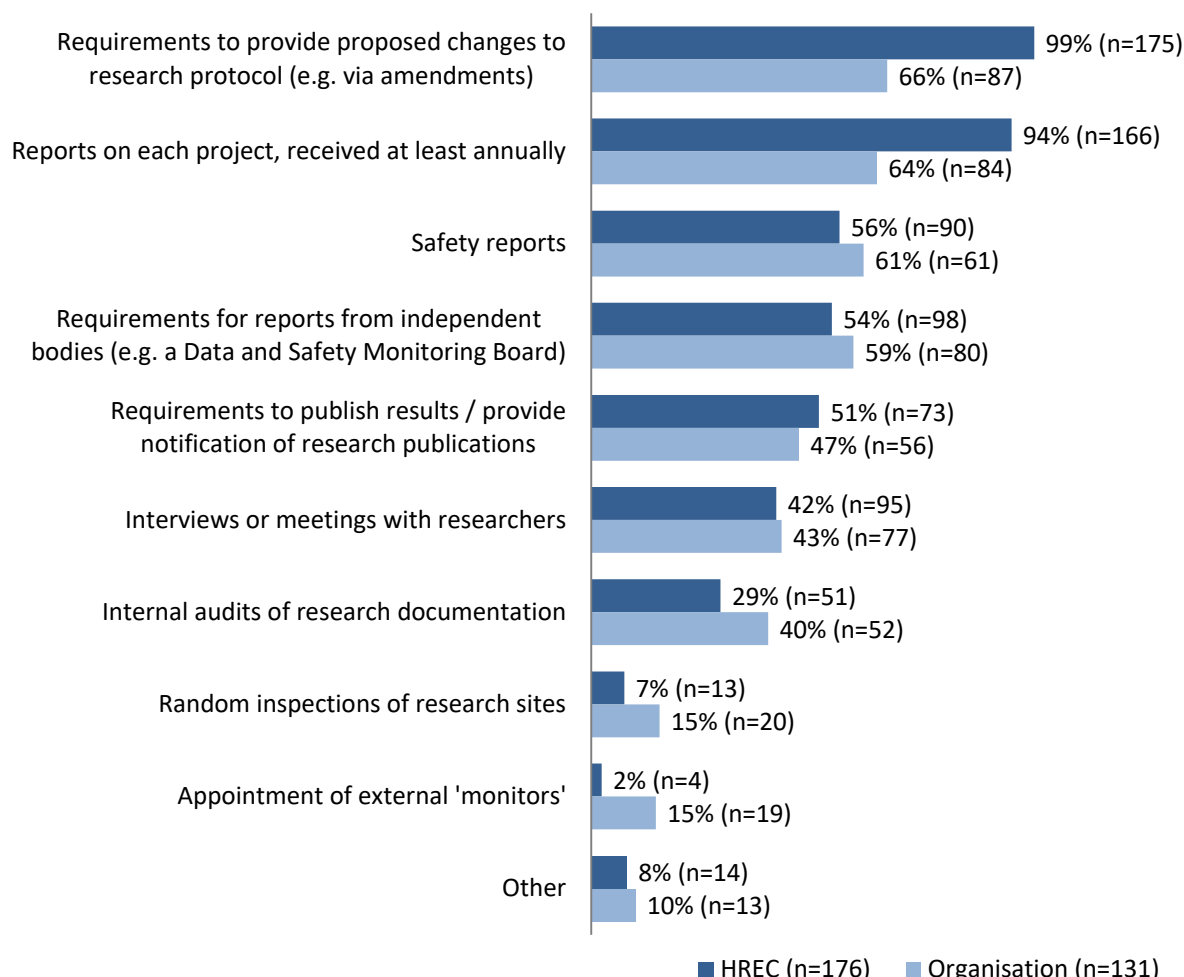
All 183 HRECs (100%) that submitted an annual report indicated that the organisation and/or the HREC had procedures in place for monitoring approved research. Of these, almost all (97%; n=178) indicated that the organisation and/or the HREC had undertaken monitoring of approved research. The monitoring mechanisms used by the HRECs are reported in **Figure 4** (overleaf). Five HRECs indicated that this was not applicable as there was no approved research to monitor.

The remaining 2 HRECs had subsequently closed, and the reasons provided as to why the organisation and/or HREC did not have monitoring procedures in place both related to their closure.

⁹ 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).

Figure 4: Monitoring processes (2023)

Base: HRECs that reported that the organisation and/or the HREC undertook monitoring of all approved research, multiple responses accepted (n=178)



Other processes used to monitor research included:

- A requirement for researchers to provide regular progress updates and reports, including in relation to
 - Adverse Events
 - Acquittal data
 - Amendments for protocol deviations or other updates to the study
 - Breach reports
 - General safety issues
 - Investigator changes
 - Non-compliance
- A formal project monitoring schedule
- Additional monitoring of approved research for clinical trials where the University is either site or sponsor
- External monitoring, for example by sponsors
- External complaint resolution via an external reviewer
- Institutional handling of notification of publication outcomes

- Inviting researchers to attend committee meetings to discuss and provide updates on their projects
- Providing regular reports and updates to other committees, boards and/or executives
- Random inspections or safety spot checks of labs
- Self-audits, desktop audits and sponsor audits, and
- Site approval monitoring.

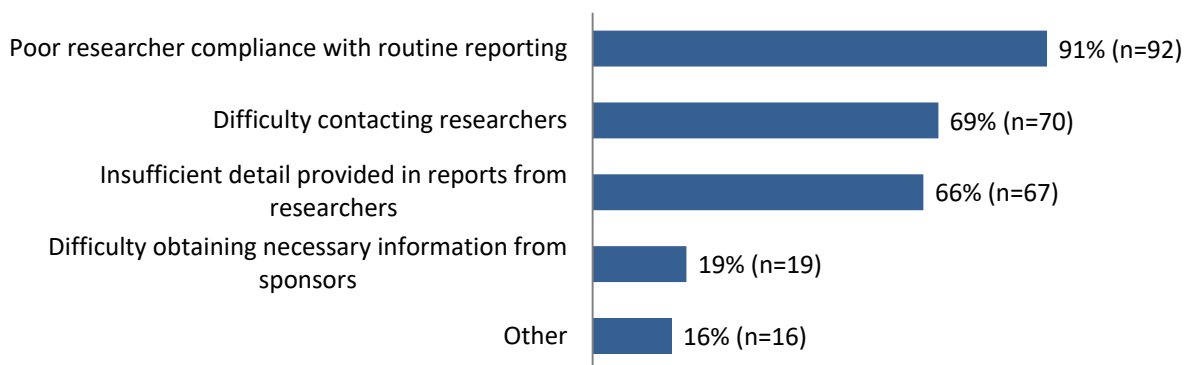
Problems encountered in monitoring approved research

Of the 178 HRECs that undertook monitoring of approved research during the reporting period, over half (57%; n=101) reported that they or their organisation encountered problems in monitoring research.

The types of problems encountered are shown in **Figure 5**.

Figure 5: Problems encountered in monitoring research (2023)

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 encountered in monitoring research predominantly related to resourcing issues, but also included:

- Availability and expertise level of committee members to deal with the volume and scope of research projects
- Limited resources to undertake monitoring
- Missing required documentation
- Researchers not responding to feedback or follow-up requests
- Staff changes / turnover, and
- System limitations.

All but four HRECs (96%; n=97) that reported that they encountered problems in monitoring research 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 183 HRECs that submitted an annual report, most (98%; n=180) 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. Over nine-in-ten HRECs (93%; n=170) 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:¹⁰

- Complaints procedures were in the process of being developed / reviewed / made publicly available
- The HREC was disestablished / there were no active projects during the reporting period
- Complaints procedures were available internally within the organisation, as research projects were internal
- The HREC did not currently have a complaints procedure
- The HREC had not received complaints that warranted the publishing of a publicly available complaints procedure.

Types of complaints received

During the reporting period, over two fifths of HRECs (44%; n=81) received a combined total of 304 complaints **about** researchers or the conduct of an approved research project, and 10% (n=19) of HRECs received a combined total of 35 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 (2023)

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	304	80
Complaints received about researchers or the conduct of an approved research project that involved Aboriginal and Torres Strait Islander peoples	20	4
Complaints received from a researcher about the consideration of their research proposal by the HREC	35	7

¹⁰ 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.

The general nature of complaints received **about** researchers, or the conduct of approved research projects were as follows:

- Informed consent issues (e.g. opt-out consent, lack of participant information sheet, uninformed consent)
- Privacy and data security concerns (e.g. unauthorised access to contact details, privacy breaches, inappropriate data sharing)
- Communication and administrative oversight (e.g. delayed responses, miscommunication, unresponsive study staff)
- Ethics approval and protocol compliance (e.g. conducting research without approval, deviations from approved protocol, lack of reciprocal ethics approval)
- Participant recruitment methods (e.g. unsolicited emails, inappropriate recruitment strategies, pressure to participate)
- Compensation and reimbursement issues: (e.g. delayed payments, unfair compensation, issues with gift card payments)
- Cultural sensitivity and respect (e.g. inappropriate language in recruitment materials)
- Participant treatment and safety (e.g. beneficence of treatment, injury during clinical trial, concerns about side effects)
- Survey and study design flaws: (e.g. flawed survey design, inappropriate survey questions, exclusionary eligibility criteria)
- Intellectual property and data ownership (e.g. intellectual property theft, data sharing disputes, plagiarism allegations)
- Professionalism and scientific integrity of findings (e.g. misrepresenting results, inappropriate behaviour)
- Misunderstandings and miscommunications: (e.g. misunderstanding of voluntary research aspect, misinterpretation of study purpose)
- Approval processes

The general nature of complaints received **from** researchers about the consideration of their research proposal(s) by the HREC, included:

- Disagreements with HREC decisions, requirements, advice or recommendations
- Disagreements with HREC referral to another HREC for review
- Timelines and process concerns
- Risk assessment disputes
- HREC's lack of relevant expertise or resourcing (including in relation to Aboriginal and Torres Strait Islander Peoples)
- Scope and level of review by the HREC

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 2023 – 31 December 2023

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 way 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 2023 – 31 December 2023. Any queries regarding this report can be directed to HREC.admin@nhmrc.gov.au.

A. Number of certified institutions and institutional HRECs

During 2023, 42 organisations operated as certified institutions under the NHMRC National Certification Scheme. This included 56 HRECs. Of these, 56 HRECs across 42 certified institutions submitted an annual report (see **Table 4**). For comparison, in the 2022 reporting period, there were 43 certified institutions, and 54 HRECs across 42 certified institutions submitted an annual report. A list of certified institutions can be found on the [NHMRC website](#).

Table 4: Reportable HRECs by jurisdiction (2023)

Jurisdiction	Number of Certified Institutions	Number of HRECs
New South Wales	13	15
Queensland	9	9
Victoria	9	10
South Australia	5	16
Western Australia	4	4
Australian Capital Territory	1	1
Northern Territory	1	1
Total	42	56

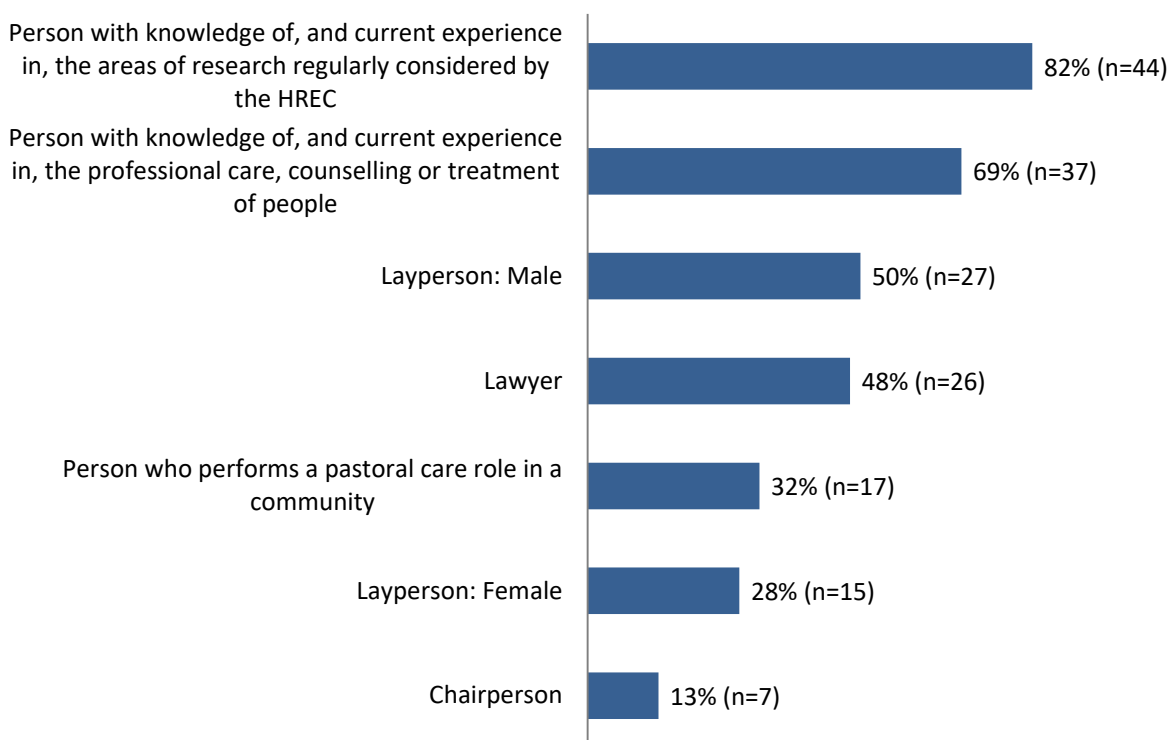
B. HREC composition

Membership

Most certified institutions’ HRECs (96%; n=54) reported a change to Committee membership during 2023. The categories of membership in which changes occurred are shown in **Figure 6**. All HRECs that reported a change to Committee membership in 2023 indicated that they met the minimum membership category requirements¹¹ during the reporting period.

Figure 6: Categories of membership in which the change occurred (2023)

Base: Certified institutions’ HRECs that reported a change to committee membership, multiple responses accepted (n=54)



¹¹ The minimum membership categories are set out in paragraph 5.1.30 of the National Statement.

C. Review of multi-centre research proposals

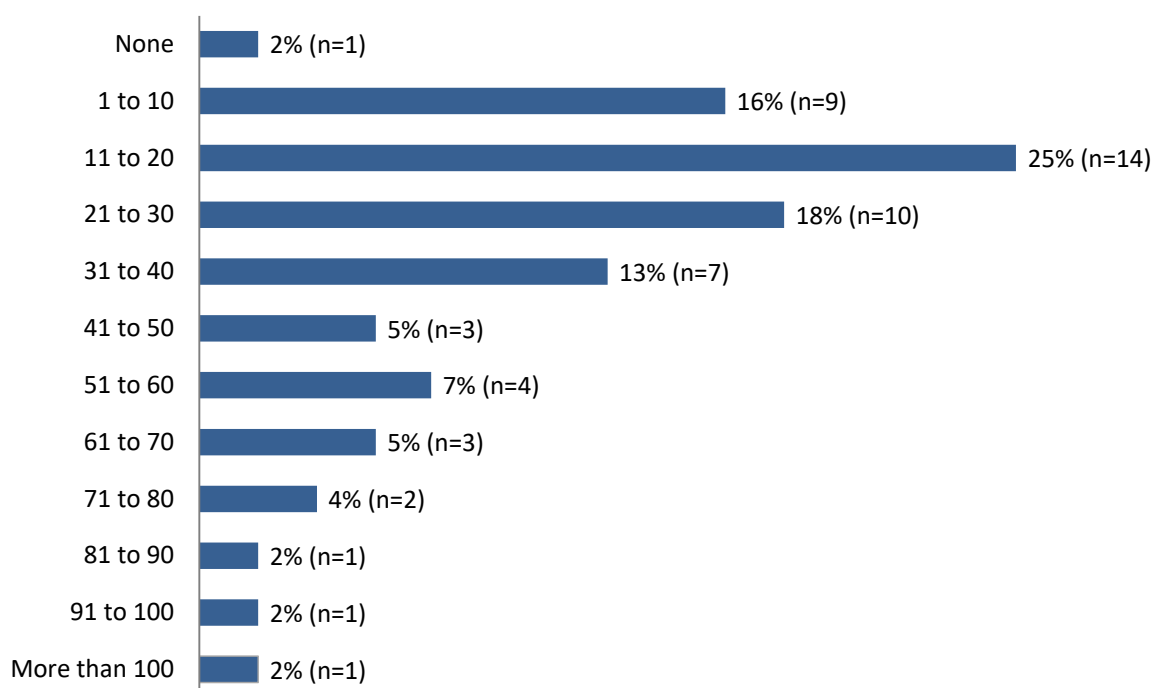
Of the 56 HRECs from certified institutions, all considered new¹² research proposals during the reporting period. Of these HRECs, 98% (n=55) reported that they had reviewed new multi-centre¹³ research proposals during 2023.

Number of multi-centre research proposals

The distribution of the number of new multi-centre research proposals reviewed¹⁴ by HRECs during the reporting period is shown in **Figure 7**.

Figure 7: Number of multi-centre research proposals reviewed by HRECs (2023)

Base: Certified institutions’ HRECs that considered new research proposals (n=56)



A total of 1,785 new multi-centre research proposals were reviewed during the reporting period (1,673 were reviewed in the previous reporting period). The highest number of multi-centre reports reviewed by any one HREC was 115 (n=1), and the lowest was 0 (n=1).

¹² 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.

¹³ 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.

¹⁴ This included all reviews, regardless of whether the HREC was considered the lead.

Reduced duplication and timeliness

Of the 55 HRECs that reviewed new multi-centre research proposals in 2023, all but two (96%; n=53) had reviewed at least one proposal as the lead HREC.¹⁵ Furthermore, just over one third (36%; n=20) of HRECs reviewed at least one new multi-centre research proposal where it was not the lead HREC.

During the reporting period, slightly more than a quarter (27%; n=15) of HRECs that had reviewed new multi-centre research proposals in 2023 reported they were aware of instances where the HREC's approval had not been accepted by another institution. A small number of HRECs (9%; n=5) 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:

- The proposal would trigger a full review by the state government HREC
- The institution is a public health service and declined to accept the review of a private interstate HREC
- Approval would not be accepted from another National Mutual Acceptance (NMA) certified institution if it was reviewed via a Low/Negligible-Risk (LNR) Pathway
- The research related to Aboriginal and/or Torres Strait Islander peoples and required local review to determine if appropriate local consultation occurred, and
- The institution was not a signatory on the National Mutual Acceptance (NMA) scheme.

Of the new multi-centre research proposals reviewed during the reporting period, almost nine-in-ten (88%; n=1,575) were completed within 60 calendar days.¹⁶ Furthermore, around half were:

- intended for conduct within one Australian state or territory only (51%; n=908)
- intended for conduct in two or more Australian states or territories (49%; n=877).

¹⁵ 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.

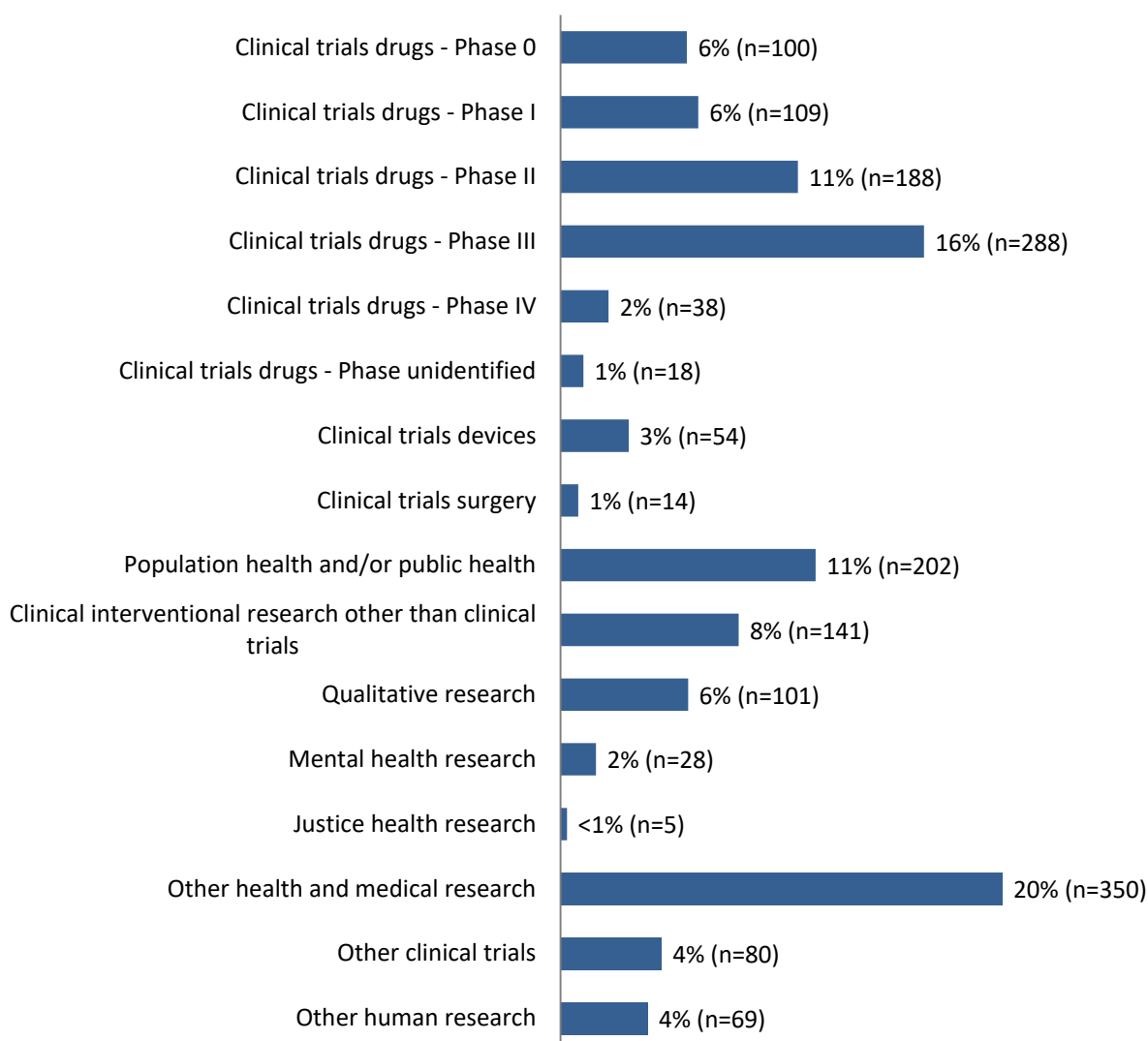
¹⁶ Further information on the 60 calendar day timeframe is provided in the [National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research Certification Handbook, November 2012](#).

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 considered¹⁷ (2023)

Base: Total number of multi-centre research proposals considered by certified institutions' HRECs (n=1,785)



¹⁷ Definitions for the categories of multi-centre research proposals that are included in Figure 8 can be found in the [National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research Certification Handbook, November 2012](#).

Other **clinical trials**¹⁸ considered during the 2023 reporting period included trials involving or related to:

- Alternative medicine / interventions
- Biology
- Cancer (incl. diagnosis and treatment)
- Comparison trials
- Education
- Exercise
- Gastroenterology
- Health interventions
- Infectious disease
- Management plans
- Maternal health
- Nutrition and dietetics
- Observation
- Orthodontology
- Psychology / Mental health
- Public Health / Health services
- Pulmonology
- Randomised control trials
- Screening
- Sleep and sleep disorders
- Surgery / Hospitals / Intensive care, and
- Technology (including algorithm development and virtual reality-based care).

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

- Aboriginal and Torres Strait Islander Health
- Adolescent / Child health
- Anaesthesia
- Ambulance services and paramedicine
- Artificial Intelligence algorithm training / machine learning
- Biobanking
- Biomarker identification
- Biospecimen analysis
- Cancer (including Oncology)
- Cardiorespiratory medicine
- Cardiology / cardiovascular research
- Case control studies
- Clinical research
- Cohort studies
- Complementary and alternative medicine
- Correlational research
- Data banking and data linkage
- Dentistry
- Descriptive studies
- Diabetes research
- Emergency medicine
- Feasibility studies
- Haematology
- Immunology
- Infectious diseases
- Intensive care
- Laboratory-based research
- Maternal and reproductive health
- Mental health
- Mitochondrial donation
- Neonatal health
- Neurology / Neuroscience
- Nursing
- Nutrition and dietetics
- Observational research
- Ophthalmology
- Paediatrics
- Pain and pain management
- Palliative care
- Paediatrics
- Pharmacology
- Physiotherapy
- Pilot studies
- Program evaluation
- Public and health services research
- Quantitative research
- Qualitative research
- Quality improvement studies
- Registry studies
- Respiratory medicine
- Retrospective research

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

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

- Rural and remote health issues
- Social science
- Speech pathology
- Validation research, and
- Women's health.

Other human research considered during the reporting period related to:

- Aboriginal and Torres Strait Islander health
- Biospecimen analysis
- Child research
- Clinical research
- Data linkage
- Ecology
- Education, students and teaching
- Evaluation research
- Feasibility studies
- Gender studies
- Health research
- Observational research
- Patient experience
- Prevalence
- Clinical research
- Education, students and teaching
- Qualitative research (interviews / focus groups)
- Retrospective research, and
- Social science.

During the 2023 reporting period, slightly fewer than half of HRECs (48%; n=27) reviewed multi-centre research proposals involving children and young people / paediatrics