

National Health and Medical Research Council

Report on the Activity of Human Research
Ethics Committees and Certified Institutions
for the period: 1 January 2022 to 31
December 2022

October 2023

Background

ORIMA Research was commissioned to design and conduct the 2022 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 2022 ('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 2022 reporting period opened in February 2023 and closed in August 2023.

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).

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I. Report on the Activity of NHMRC-Registered Human Research Ethics Committees for the Period 1 January 2022 – 31 December 2022

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
- 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 2022 to 31 December 2022.

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 2022, 192 HRECs were registered with NHMRC, and 185 HRECs submitted an annual report on their activities to NHMRC (see **Table 1**). Of the 185 HRECs who submitted an annual report, 5 indicated that their institution had closed the HREC (i.e. the HREC no longer operates or conducts meetings) in 2022, or in 2023 prior to submitting their annual report.

There were 192 HRECs in the previous reporting period (2021), 187 of which submitted an annual report.

Table 1: Reportable HRECs by jurisdiction (2022)

Jurisdiction	Number of HRECs
Victoria	54
New South Wales	48
Queensland	30
South Australia	24
Western Australia	16
Australian Capital Territory	10
Northern Territory	2
Tasmania	1
Total	185

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’.

Fourteen HRECs (8%) reported that they did not meet the minimum membership requirements during the reporting period based on the above categories. Issues identified were:

- No male layperson (n=8)
- No members who perform a pastoral care role in a community (n=6)
- No female layperson (n=6)
- No lawyer (n=5)
- Less than two members with knowledge of, and current experience in, the areas of research regularly considered by the HREC (n=5)
- No members with knowledge of, and current experience in, the professional care, counselling or treatment of people (n=4).

Additional membership

In addition to the minimum membership categories, other members appointed to HRECs during the 2022 reporting period were identified by HRECs as filling the following self-described roles:

- Aboriginal and Torres Strait Islander representatives
- Academic representatives
- Affiliate or board member representatives
- Community representatives
- Consumer representatives
- Deputy chair
- Ex-officio members
- Executive representatives (e.g. CEO, Director, General Manager)
- Graduates
- Health service representatives
- Medical professionals
- Mental health representatives
- Nominees
- Representative for athletes
- Patient and family representatives
- Pool members
- School representatives
- Student representatives or trainees
- Support staff (e.g. secretary)
- Youth representatives
- Members with expertise in:
 - Aboriginal and Torres Strait Islander research (including Indigenous advancement)
 - Biostatistics
 - Business / operations
 - Clinical trials
 - Data collection and management
 - Ethics
 - Forensic pathology
 - Health (including public health)
 - Information security
 - Oncology
 - Pharmacy
 - Philosophy
 - Neurology
 - Radiation Safety
 - Research
 - Statistics.

During the reporting period, around one-in-three HRECs (34%; n=63) 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 (11%; n=21) 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

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

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. Overall:

- Two HRECs (1%) 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 (99%; n=183) indicated that their terms of reference met the requirements of National Statement 5.1.27. The remaining two HRECs reported that:

- The minimum membership requirements were not met, and
- Their terms of reference were under review.

All but two HRECs (99%; n=183) 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:

- Their standard operating procedures will be reviewed, and
- That they were currently working to ensure the following items are included in the standard operating procedures (and that any other remaining items are clearly identifiable whilst revising for the new National Statement 2023) to address the requirements of National Statement 5.1.37:
 - (a) frequency of meetings
 - (b) attendance at meetings
 - (d) preparation of agendas and minutes
 - (e) timely distribution of papers before meetings
 - (h) managing conflicts of interest
 - (k) methods of decision making
 - (o) reporting and handling of adverse events
 - (p) receiving and handling of complaints
 - (s) fees, if any, to be charged
 - (t) appropriate confidentiality of the content of applications and the deliberations of review bodies.

Record keeping and reporting

Of the 185 HRECs, 178 (96%) reported that they considered new³ research proposals during the 2022 reporting period. Of these, all but one HREC (99%; n=177) indicated that the records of all

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.

research proposals received and reviewed were kept in accordance with the requirements of National Statement 5.2.25-5.2.29. The remaining HREC reported that “records of minutes for some meetings were not taken, kept, or filed due to resourcing issues and an acting HREC Chair covering an unexpected period of absence”.

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](#).

Almost three-in-four HRECs (72%; n=129) reported that they accepted the use of the HREA for some or all submissions during the 2022 reporting period. Of these:

- 61 HRECs (47%) required the use of the HREA for **all** submissions
- 31 HRECs (24%) required the use of the HREA for **some** submissions
- 37 HRECs (29%) **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 178 HRECs that considered new research proposals during the 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.

Of the 93 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 4, and
- The average proportion of all meetings that the full membership was not present was 39%.

Where the minimum membership was **not** present at all meetings (n=93), over nine-in-ten of these HRECs (92%; n=86) 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.

Of the 7 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 that the chairperson was not satisfied, as described above, was 4, and
- The average proportion of all meetings that the chairperson was not satisfied, as described above, was 40%.

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:

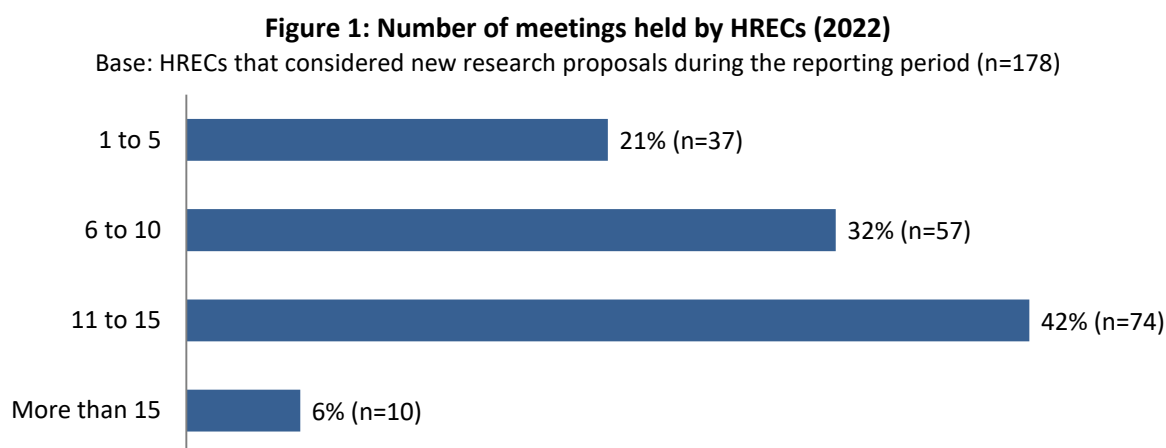
- an inability to attend the meeting due to other commitments (due to holidays or travel, work commitments or illness)
- late apologies from members not reading the meeting papers or attending the meeting as planned.

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**.



Almost three-in-four HRECs (74%; n=131) reported that they had held between 6 and 15 meetings during the 2022 reporting period. Across all HRECs, the average number of meetings held was 10. The maximum number of meetings held by any one HREC during the reporting period was 57 (n=1). This HREC reported that they have a total of 20 members and considered 156 new research proposals during the reporting period.

E. Training

Over four-in-five HRECs (85%; n=157) indicated that one or more members participated in training relevant to their work on the HREC (not including induction training) during the 2022 reporting period.

A slightly lower proportion (77%; n=142) 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 (21%; n=39) 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 13,066 new⁴ research proposals were considered⁵ in the 2022 reporting period. Of these new research proposals, 134 (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 2018 to 2022.

Table 2: Research proposals reviewed by HRECs (2018 to 2022)

Details of research proposals	2018	2019	2020	2021	2022
Total number of new research proposals considered	16,314	15,320	15,575	15,087	13,066
Total number of new research proposals approved ⁶	14,678	13,736	13,477	13,302	11,744
Percentage of new research proposals approved	90%	90%	87%	88%	90%
Highest number of proposals approved by a single HREC	469	442	417	361	418
Number of HRECs that accepted ⁷ the ethics approval of an external HREC	115	121	119	110	113

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).

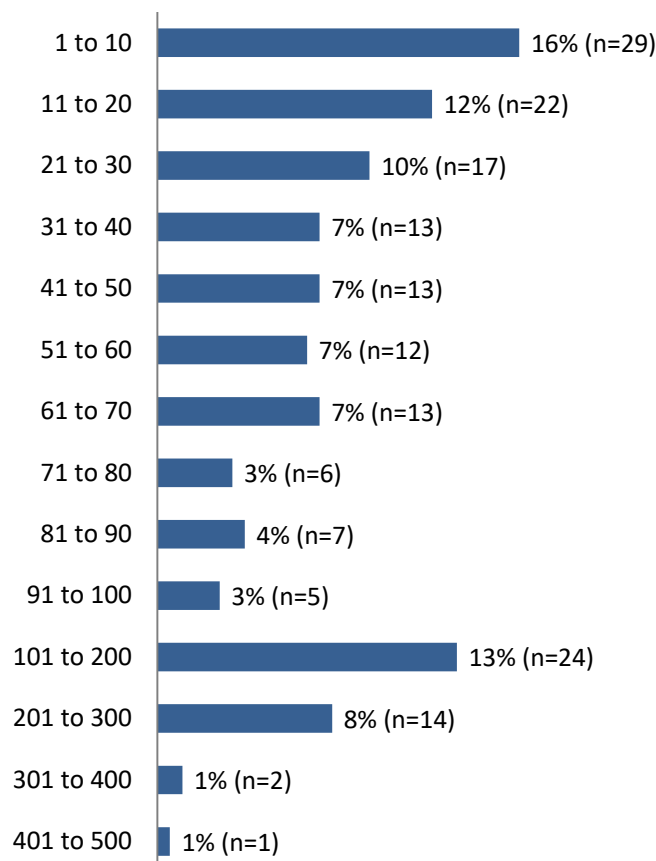
⁶ 'Approved' refers to proposals that were either approved upon initial review or after re-consideration in the 2022 reporting period.

⁷ '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 (2022)

Base: HRECs that considered new research proposals during the reporting period (n=178)



The highest number of new research proposals considered by any single HREC during the reporting period was 418 (n=1), and the lowest was 1 (n=3). The HREC that reported considering 418 proposals met 11 times and comprised 16 members.

Types of research proposals considered by HRECs

In the 2022 reporting period, 120 HRECs considered a total of 1,969 new clinical trial⁸ research proposals. In the previous reporting period (2021), 2,226 research proposals involving clinical trials were considered.

Eight (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 178 HRECs that considered new research proposals during the reporting period, almost half (48%; n=85) considered proposals involving health-related research with Aboriginal and Torres Strait Islander peoples.

Almost nine-in-ten of these HRECs (88%, n=75) 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:

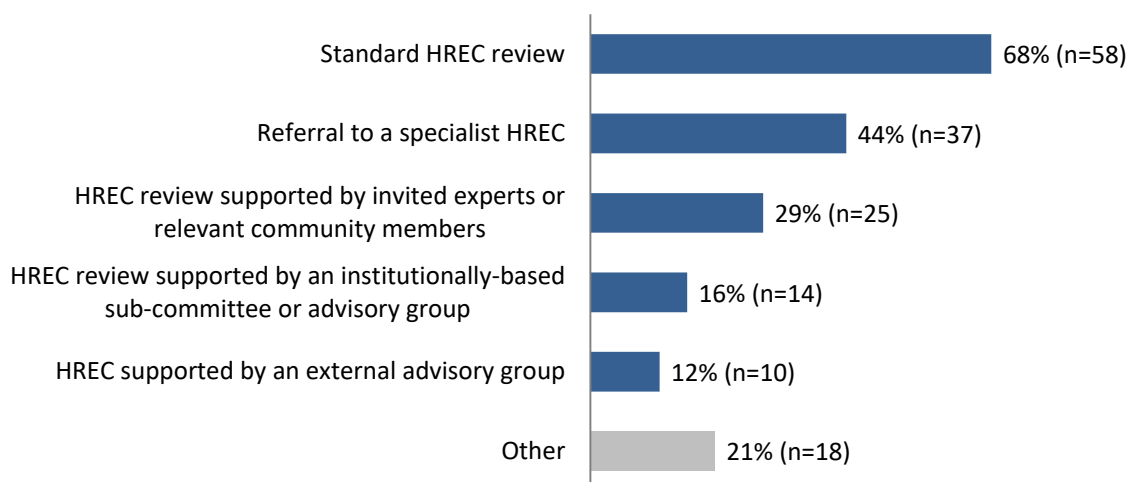
- The Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) *Code of Ethics for Aboriginal and Torres Strait Islander Research*, and *Guide to applying the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander research*.
- The Lowitja Institute *Supporting Indigenous Researchers: A practical guide for supervisors* and *The CRC for Aboriginal Health - Researching Indigenous Health: A practical guide for researchers*
- The Indigenous Knowledge Institute *Indigenous Knowledges Research Guide*
- The National Health and Medical Research Council *Ethical guidelines for research with Aboriginal and Torres Strait Islander Peoples*.
- Council developed guidelines: *Keeping research on track II*.

Six 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 (2022)

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



Other mechanisms used by these HRECs (21%, n=18) 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
- review or advice sought from a HREC that specialises in assessing Aboriginal and Torres Strait Islander health research, and
- requirements to demonstrate community consultation and support.

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 2022 reporting period:

- 83% (n=147) 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
- Of the 103 HRECs who indicated that they do review low or negligible risk research, a similar proportion (82%; n=84) indicated that they had actually considered low or negligible risk 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

All 185 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=179) indicated that the organisation and/or the HREC had undertaken monitoring of approved research. Four HRECs indicated that this was not applicable as there was no approved research to monitor.

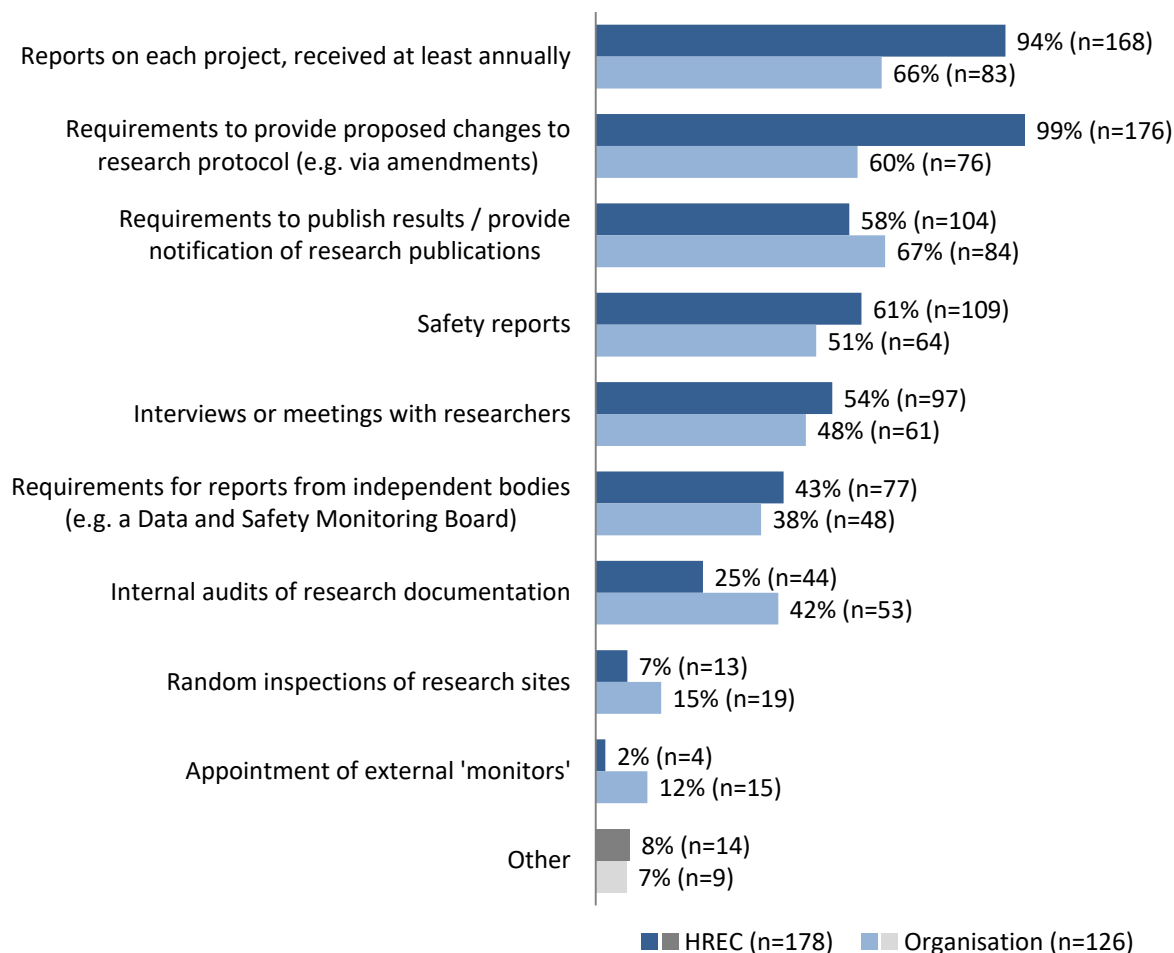
The remaining 2 HRECs had subsequently closed, and the reasons provided as to why the organisation and/or HREC did not have monitoring procedures in place both related to their closure.

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 provides information on the reported monitoring processes in 2022.

Figure 4: Monitoring processes (2022)

Base: HRECs that reported that the organisation and/or the HREC undertook monitoring of all approved research, multiple responses accepted (n=185)



Other processes used to monitor research included:

- A requirement for researchers to provide regular progress updates and reports, including in relation to
 - Adverse events
 - Amendments for protocol deviations or other updates to the study
 - Breach reports
 - Investigator changes
 - Notifiable events
 - Safety notifications / general safety issues
- Additional monitoring of approved research for clinical trials where the University is either the site or sponsor
- 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

- Providing annual reports and regular updates to the Deputy Vice Chancellor (Research)
- Requirement to disseminate results to participants
- Random inspections of labs (safety spot checks)
- Self-audits.

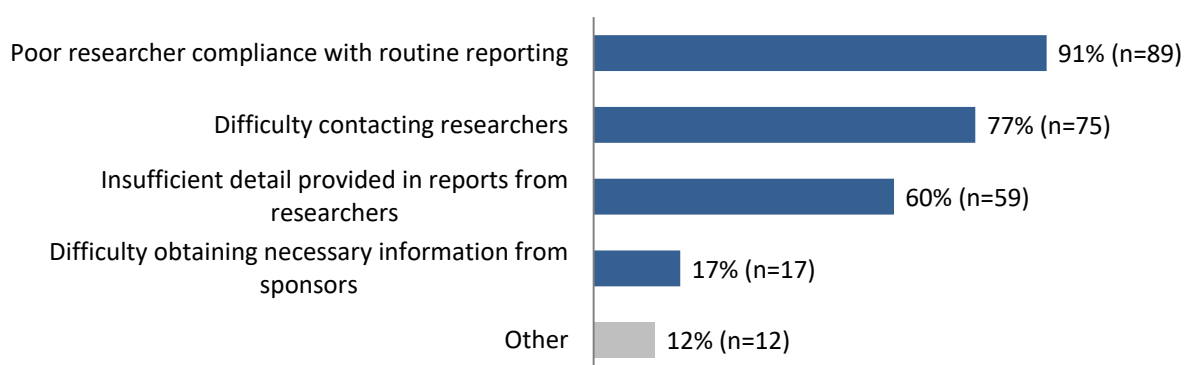
Problems encountered in monitoring approved research

Of the 179 HRECs that undertook monitoring of approved research during the reporting period, over half (55%; n=98) 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 (2022)

Base: HRECs that reported that they or their organisation encountered problems in monitoring research during the reporting period, multiple responses accepted (n=98)



Other problems encountered in monitoring research predominantly related to resourcing issues, though included:

- Availability and expertise level of committee members to deal with the volume and scope of research projects
- COVID-19 related difficulties and challenges
- Difficulty recruiting committee members
- Limited resources to undertake monitoring
- Staff changes / turnover
- Technical issues resulting in a backlog of work.

All HRECs (100%; n=98) 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 185 HRECs that submitted an annual report, most (98%; n=181) 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. A similar proportion of HRECs (97%; n=179) 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, and
- Complaints procedures were available internally within the organisation, as research projects were internal.

Types of complaints received

During the reporting period, over one third of HRECs (37%; n=69) received a combined total of 224 complaints **about** researchers or the conduct of an approved research project, and 13% (n=24) of HRECs received a combined total of 44 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 (2022)

Nature of concerns or complaints	Total number of complaints	Highest number received by any one HREC
Complaints received about researchers or the conduct of an approved research project	224	26
Complaints received about researchers or the conduct of an approved research project that involved Aboriginal and Torres Strait Islander peoples	13	4
Complaints received from a researcher about the consideration of their research proposal by the HREC	44	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:

- Adverse events
- Conflict of interest
- Consent and opt-out processes
- Data security / access / integrity / use (including concerns regarding data breaches and unauthorised use of data)
- Difficulty contacting researchers or lodging a complaint
- Effects caused by research (including distress, injury)
- Incorrect or inadequate information
- Participant Information Sheet and Consent Form
- Participant support / care / safety
- Payment / reimbursement
- Personnel qualifications
- Privacy and confidentiality concerns
- Protocol deviations / breaches
- Protocols for child participants
- Publication / authorship issues
- Questionnaire design / content
- Recruitment methods and material (including advertising of research, eligibility criteria, unsolicited / unapproved recruitment, contacting deceased persons)
- Research design / methodology
- Research merit / integrity / validity / quality / values
- Research undertaken, or changes made to research documentation, without ethics approval
- Researcher conduct and communication
- Risk assessment
- Time commitment
- Funding.

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

- Collection of certain demographic information
- Dissatisfaction or disagreement with the HREC's feedback or decision
- HREC's lack of relevant expertise or resourcing (including in relation to Aboriginal and Torres Strait Islander Peoples)
- Requests for clarification / additional information
- 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 2022 – 31 December 2022

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 2022 – 31 December 2022.

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

A. Number of certified institutions and institutional HRECs

During 2022, 43 organisations operated as certified institutions under the NHMRC National Certification Scheme. These 43 organisations included 54 HRECs. Of these, 54 HRECs across 42 certified institutions submitted an annual report (see **Table 4**). In the 2021 reporting period, there were also 43 certified institutions, and 54 HRECs across 42 certified institutions who submitted an annual report.

Table 4: Reportable HRECs by jurisdiction (2022)

Jurisdiction	Number of Certified Institutions	Number of HRECs
New South Wales	13	14
Queensland	9	9
Victoria	9	9
South Australia	5	16
Western Australia	4	4
Australian Capital Territory	1	1
Northern Territory	1	1
Total	42	54

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

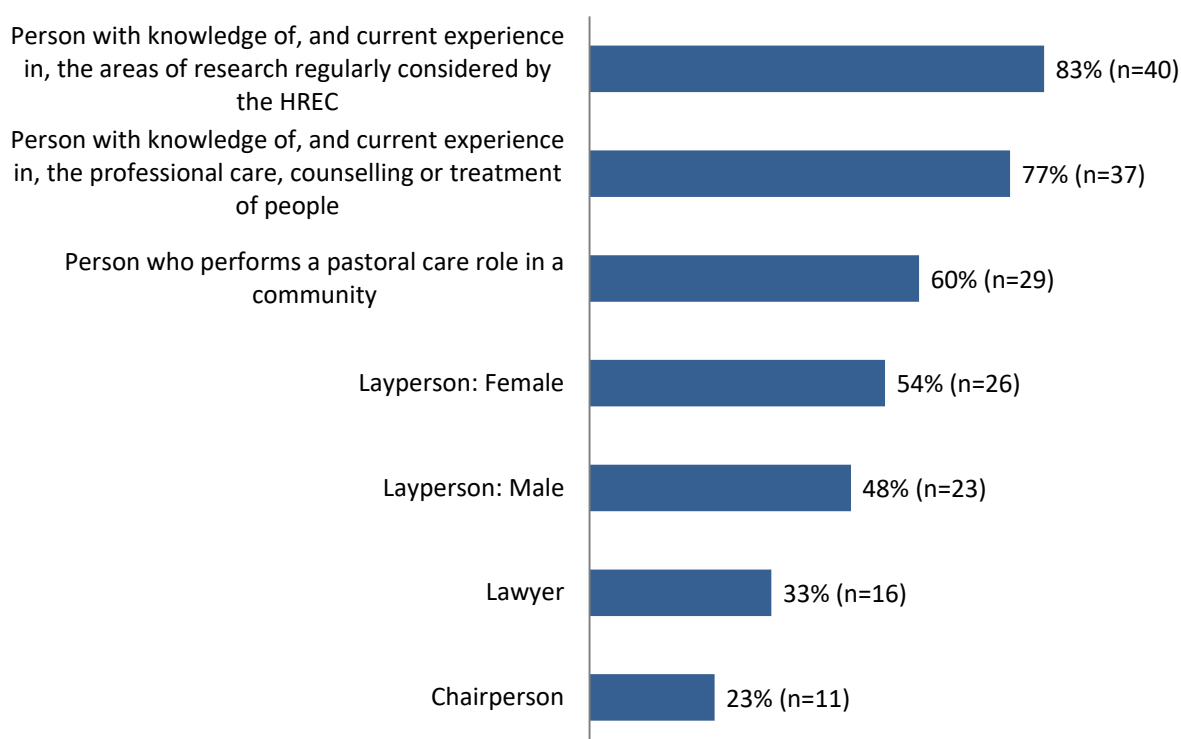
B. HREC composition

Membership

Many certified institutions' HRECs (89%; n=48) reported a change to committee membership during 2022. The categories of membership in which changes occurred are shown in **Figure 6**. All certified HRECs reported that they met the minimum membership category requirements¹¹ during the 2022 reporting period.

Figure 6: Categories of membership in which the change occurred (2022)

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



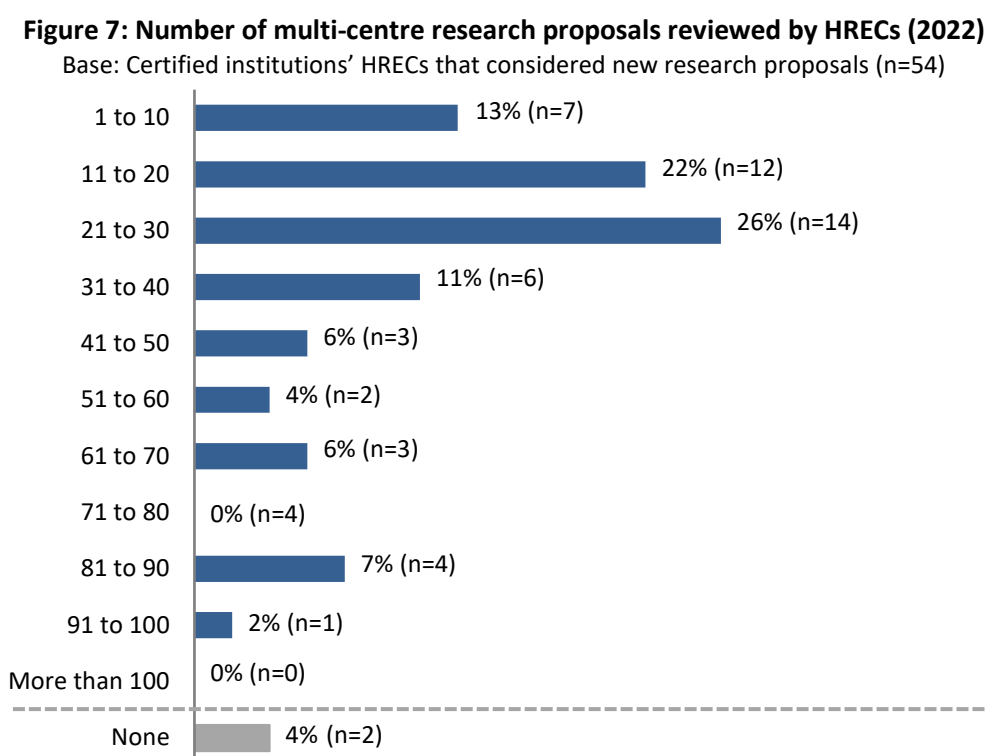
¹¹ The minimum membership categories are set out in paragraph 5.1.30 of the National Statement.

C. Review of multi-centre research proposals

All 54 HRECs from certified institutions who submitted an annual report had considered new¹² research proposals during the reporting period. Of these HRECs, 96% (n=52) reported that they had reviewed new multi-centre¹³ research proposals during 2022.

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**.



During the reporting period, a total of 1,673 new multi-centre research proposals were reviewed during the reporting period (2,254 were reviewed in the previous reporting period). The highest number of multi-centre research proposals reviewed by any one HREC was 98 (n=1), and the lowest was 0 (n=2).

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 52 HRECS that had reviewed new multi-centre research proposals in 2022, all but one (98%; n=51) had reviewed at least one proposal as the lead HREC.¹⁵ Furthermore, just over one-in-four (27%; n=14) HRECs had reviewed at least one new multi-centre research proposal where it was not the lead HREC.

During the reporting period, one quarter (25%; n=13) of HRECs that had reviewed new multi-centre research proposals in 2022 reported that they were aware of instances where the HREC's approval had not been accepted by another institution. A small number of HRECs (6%; n=3) reported that the institution had 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:

- Proposals were not approved by a certified HREC
- The institution was not a signatory on the National Mutual Acceptance (NMA) scheme
- The research related to Aboriginal and Torres Strait Islander peoples.

Of the new multi-centre research proposals reviewed during the reporting period, over nine-in-ten (91%; n=1,519) were completed within 60 calendar days.¹⁶ Furthermore, around half were:

- intended for conduct within one Australian state or territory only (47%; n=784)
- intended for conduct in two or more Australian states or territories (53%; n=889).

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.

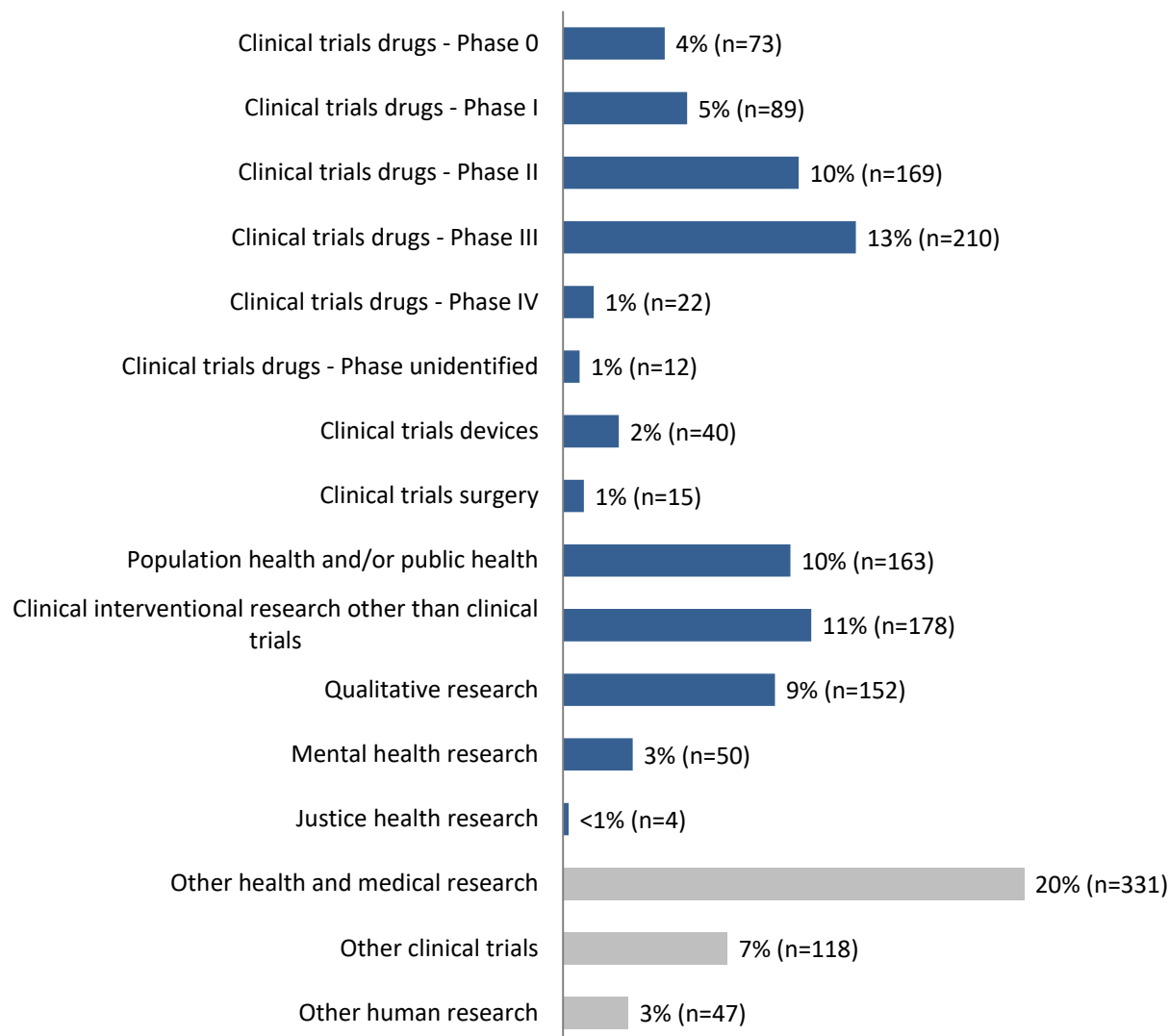
¹⁶ Further information on the 60 calendar day timeframe is provided in the [National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research Certification Handbook, November 2012](#).

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 (2022)

Base: Total number of multi-centre research proposals considered by certified institutions' HRECs (n=1,673)



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 2022 reporting period included trials involving or related to:

- Artificial Intelligence
- Biology
- Cancer (including radiotherapy)
- Child health
- Clinical Sciences
- Complementary and Alternative Medicine
- Education
- Exercise
- Gastroenterology
- Haematology
- Imaging
- Interventions
- Mindfulness
- Neurology
- Neuroscience
- Nutrition and Dietetics
- Observation
- Randomised control trials
- Prevention
- Psychological / Health Intervention
- Screening
- Standard of care
- Technology including digital health interventions and telehealth
- Virtual reality.

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

- Aboriginal and Torres Strait Islander Health (including adolescents)
- Action research
- Allied health
- Arthritis and musculoskeletal health
- Artificial intelligence
- Biobanking
- Biospecimen / biopsy analysis
- Cancer
- Cardiorespiratory health / medicine
- Child / adolescent health
- Cohort studies
- Correlational research
- Dementia
- Education
- Emergency medicine
- Epidemiological research
- Gastroenterology
- Genetics and genetic testing
- Gestational diabetes
- Haematology
- Health economics
- Health services
- Hepatology
- Imaging
- Infectious diseases / infection
- Intensive care / ICU
- Intervention
- Laboratory-based research
- Machine learning
- Medical records review
- Nephrology
- Neurology
- Neurotoxicity
- Non-clinical trials
- Nursing
- Obesity
- Observational research
- Obstetrics
- Parasitological diseases
- Pharmacology
- Psychology
- Public and population health
- Qualitative research
- Quantitative research
- Radiation therapy

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

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

- Registry and data linkage
- Retrospective review / research
- Sleep and sleep disorders
- Speech pathology / language.
- Stroke
- Surgery
- Thoracic medicine
- Tissue bank
- Women's health.

Other **human research**²⁰ considered during the reporting period related to:

- Action research
- Angioplasty
- Biospecimen
- Education
- Financial impact research
- Haematology
- Low risk research
- Neuroscience
- Nutrition
- Patient registry
- Quantitative research / surveys
- Retrospective review / research
- Workforce retention research.

During the 2022 reporting period, just over half of HRECs (56%; n=29) reviewed multi-centre research proposals involving children and young people / paediatrics.

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