



**Australian Government**

**National Health and Medical Research Council**

## **National Health and Medical Research Council**

### **Report on the Activity of Human Research Ethics Committees and Certified Institutions for the period: 1 January 2020 to 31 December 2020**

October 2021

## Background

ORIMA Research was commissioned to design and conduct the 2020 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 2020 ('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 2020 reporting period opened in February 2021 and closed in June 2021.

*This project was conducted in accordance with the international quality standards ISO 20252 and ISO 27001, and in accordance with the Australian Privacy Principles contained in the Privacy Act 1988. ORIMA Research also adheres to the Privacy (Market and Social Research) Code 2021.*

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# I. Report on the Activity of NHMRC-Registered Human Research Ethics Committees for the Period 1 January 2020 – 31 December 2020

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 2020 to 31 December 2020.

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

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<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 2020, 195 HRECs were registered with NHMRC (see **Table 1**). All registered HRECs submitted an annual report on their activities to NHMRC, including five HRECs which indicated that their institution had closed the HREC (i.e. the HREC no longer operates or conducts meetings) in 2020, or in 2021 prior to submitting their annual report.

There were 204 HRECs in the previous reporting period (2019), of which 201 submitted an annual report.

**Table 1: Reportable HRECs by Jurisdiction (2020)**

Jurisdiction	Number of HRECs
Victoria	57
New South Wales	50
Queensland	31
South Australia	24
Western Australia	18
Australian Capital Territory	10
Northern Territory	3
Tasmania	2
<b>Total</b>	<b>195</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'.

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

- ◆ No male layperson (n=8)
- ◆ No members who perform a pastoral care role in a community (n=4)
- ◆ No female layperson (n=3)
- ◆ 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=3), 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 2020 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
- ◆ Deputy / pool / co-opted members
- ◆ Executive representatives (e.g. CEO, Director, General Manager)
- ◆ Ex-officio members
- ◆ Graduates
- ◆ Health service representatives
- ◆ Lived experience members
- ◆ Medical professionals
- ◆ Members experienced in reflecting on and analysing ethical decision making (National Statement 5.1.32)
- ◆ Nominees
- ◆ Non-sitting members
- ◆ Regional representatives
- ◆ Scientific advisors
- ◆ Student representatives or trainees
- ◆ Sub-committee chair
- ◆ Support staff (e.g. secretary, executive officer)
- ◆ Youth representatives, and
- ◆ Members with expertise in:
  - Aboriginal and Torres Strait Islander research
  - Clinical coding
  - Clinical trials
  - Communications and media
  - Data analytics
  - Education
  - Ethics
  - Epidemiology
  - Forensic pathology
  - Governance

- Information technology and security
- Mental health
- Microbiology
- Midwifery
- Neurology
- Nursing
- Oncology
- Pathology
- Pharmacy
- Philosophy
- Policy
- Primary and community services
- Psychology and moral deliberation
- Radiation safety
- Serology
- Statistics and mathematics
- Toxicology, and
- Workforce development

During the reporting period, one-in-three HRECs (30%; 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.<sup>2</sup> Just under one-in-ten HRECs (8%; n=15) reported less than the desired one-third of membership from outside the institution.

### **Gender balance**

As per paragraph 5.1.29(a) of the National Statement, as far as possible, there should be equal numbers of men and women on the HREC. The rationale for this guidance is that decision making, or perceptions about decision making, may be affected in situations where there is a significant imbalance in either direction. It is recognised that this may not always be achievable and that, in any event, the National Statement's distinction between 'men' and 'women' members does not give consideration to the full diversity of identities (including trans and intersex members).

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

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<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

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### Terms of reference and procedures

During the reporting period, all but six HRECs (97%; n=189) indicated that their terms of reference met the requirements of National Statement 5.1.27. The remaining HRECs reported that:

- ◆ Their terms of reference were under review
- ◆ The minimum membership requirements were not met, and
- ◆ Their terms of reference did not outline (b) the HREC's 'relationship to other processes of research review' or (c) 'its relationship to non-affiliated researchers'; however, their standard operating procedures did outline that the HREC accepts external research projects.

All but ten HRECs (95%; n=185) 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 were under development / review
- ◆ The HREC closed, or did not receive research proposals for review, during the reporting period
- ◆ The HREC did not meet in the first half of 2020 due to COVID-19 restrictions; however, out-of-session discussion was carried out in May to ensure urgent business and appropriate project approval was undertaken
- ◆ The HREC did not require researchers to report annually to the HREC; however, as part of their standard operating procedures, researchers were required to regularly report to the institution's Deputy Director of Research regarding the progress of approved research projects
- ◆ Some elements for processes for handling complaints needed further elaboration, and
- ◆ Their standard operating procedures did not outline (h) 'managing conflicts of interest'; (i) how researchers can communicate with the REC (including face to face, telephone and in writing); (j) reporting 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 of observers at meetings; and (t) confidentiality of content of applications and deliberations of review bodies.

### Record keeping and reporting

Of the 195 HRECs, 188 (96%) reported that the HREC had considered new<sup>3</sup> research proposals during the 2020 reporting period. All but one of these HRECs (99%; n=187) 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 HREC reported that "researchers were not provided with relevant sections of the National Statement in relation to approvals, amendments or rejections as required by section 5.2.28".

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<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.

## 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 2020 reporting period, almost three-in-four HRECs (73%; n=137) reported that they accepted the use of the HREA for some or all submissions, of which:

- ◆ 52 HRECs (38%) required the use of the HREA for **all** submissions
- ◆ 45 HRECs (33%) required the use of the HREA for **some** submissions, and
- ◆ 40 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

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Among the 188 HRECs that considered new research proposals during the reporting period, over two-in-five (43%; n=81) reported that at least the minimum membership (as per paragraph 5.1.30 of the National Statement) was present at all meetings where a decision was made on a research proposal.

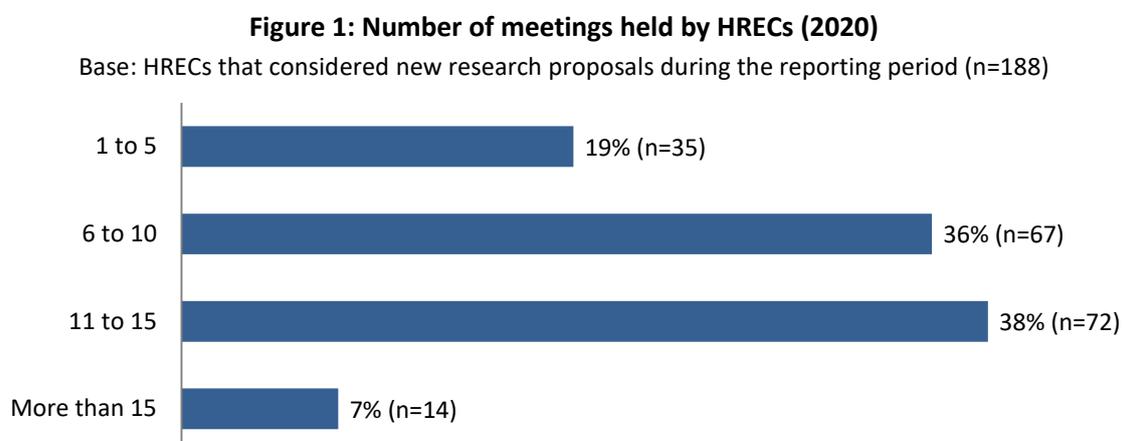
In the instances where the minimum membership was not present at all meetings, all but four HRECs (96%; n=103) reported that the chairperson was satisfied that the absent members who belong to the minimum membership had received all papers, had an opportunity to contribute their views, and that these views were recorded and considered before a decision was reached. The primary reason reported as to why the absent members did not have an opportunity to 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 (74%; n=139) reported that they held between 6 and 15 meetings during the 2020 reporting period. The maximum number of meetings held by any one HREC during the reporting period was 28 (n=2). These two HRECs also reported a total of 23 members each, with 191 to 368 new research proposals considered during the reporting period.

## E. Training

During the 2020 reporting period, around three-in-four HRECs (74%; n=145) indicated that one or more members participated in training relevant to their work on the HREC (not including induction training).

A similar proportion (73%; n=142) reported that all new members were provided with induction training (as per paragraph 5.1.28(b)(i) of the National Statement). Around one-in-four HRECs (24%; n=47) 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 15,575 new<sup>4</sup> research proposals considered<sup>5</sup> in the 2020 reporting period. Of these new research proposals, 234 (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 2016 to 2020.

**Table 2: Research proposals reviewed by HRECs (2016 to 2020)**

Details of research proposals	2016	2017	2018	2019	2020
Total number of new research proposals <b>considered</b>	18,039	16,446	16,314	15,320	15,575
Total number of new research proposals <b>approved</b> <sup>6</sup>	16,191	14,721 <sup>7</sup>	14,678	13,736	13,477
Percentage of new research proposals <b>approved</b>	90%	90%	90%	90%	87%
Highest number of proposals <b>approved</b> by a single HREC	880	399	469	442	417
Number of HRECs that accepted <sup>8</sup> the ethics approval of an external HREC	113	112	115	121	119

<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 2020 reporting period.

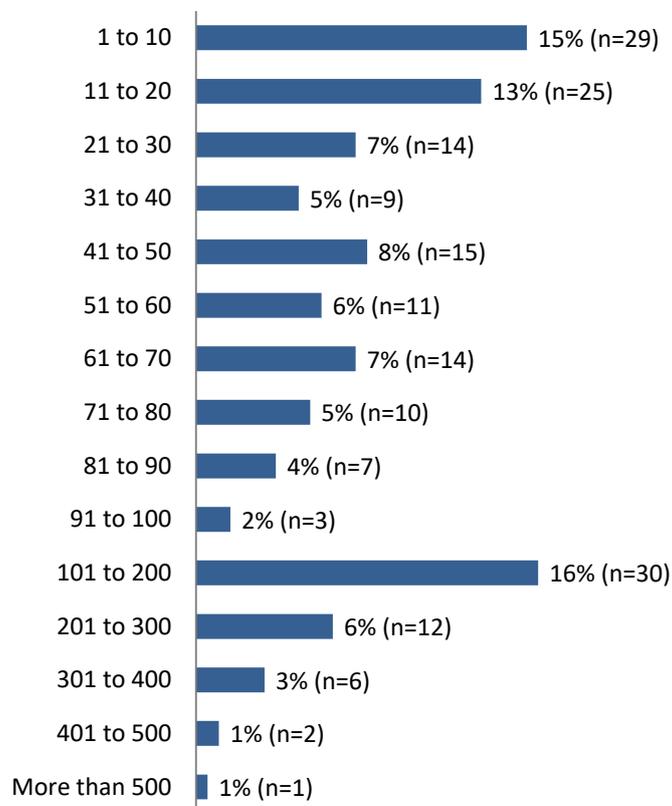
<sup>7</sup> One HREC incorrectly included proposals that were not new for the 2017 reporting period.

<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 (2020)**

Base: HRECs that considered new research proposals during the reporting period (n=188)



The highest number of new research proposals considered by any single HREC during the reporting period was 537 (n=1), and the lowest number was 1 (n=2). The HREC that reported considering 537 proposals met 21 times, and comprised a pool of 43 members.

### Types of research proposals considered by HRECs

In the 2020 reporting period, 119 HRECs (63%) considered a total of 2,314 new clinical trial<sup>9</sup> research proposals. In the previous reporting period (2019), 2,056 research proposals involving clinical trials were considered.

Five 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 188 HRECs that considered new research proposals during the reporting period, almost half (47%; n=88) considered health-related research proposals involving Aboriginal and Torres Strait Islander peoples. Of these HRECs, all but four (95%; n=84) reported that they used the [Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018](#) in considering these health research proposals. Other guidelines reported to have been used in considering health-related research proposals involving Aboriginal and Torres Strait Islander peoples included:

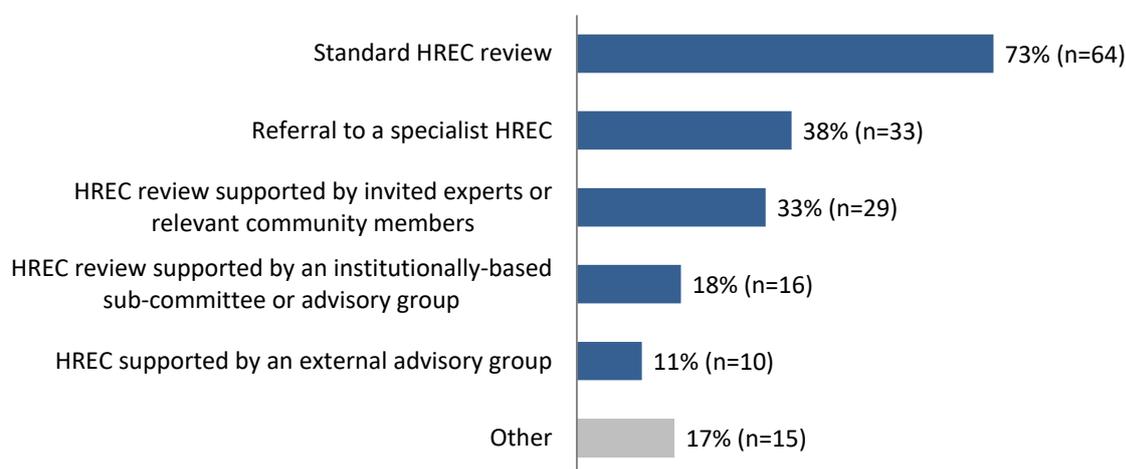
- ◆ The *National Statement on Ethical Conduct in Human Research (2007) – Updated 2018*, and
- ◆ The Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) *Guidelines for Ethical Research in Australian Indigenous Studies (GERAIS)*, which was superseded by the *Code of Ethics for Aboriginal and Torres Strait Islander Research (the AIATSIS Code)* in October 2020.

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

Mechanisms used by HRECs for the review of health research proposals involving Aboriginal and Torres Strait Islander peoples are shown in **Figure 3**.

**Figure 3: Mechanisms used by HRECs for the review of health research proposals involving Aboriginal and Torres Strait Islander peoples (2020)**

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



Fifteen HRECs (17%) 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
- ◆ HREC is specialised in Aboriginal and Torres Strait Islander health research
- ◆ Requirement to demonstrate community consultation and support
- ◆ Review sought from a HREC that specialises in assessing Aboriginal and Torres Strait Islander health research, and
- ◆ Support from an Aboriginal Community Controlled Organisation.

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

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During the reporting period, three-in-four HRECs that considered new research proposals (75%; n=141) 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, 78 HRECs indicated that their organisation had an established alternative mechanism, but the HREC also reviews some low or negligible risk research.

Of those who reported that the HREC reviews low or negligible risk research, almost nine-in-ten (87%; n=109) reported that the HREC had actually considered these research proposals during the reporting period.

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

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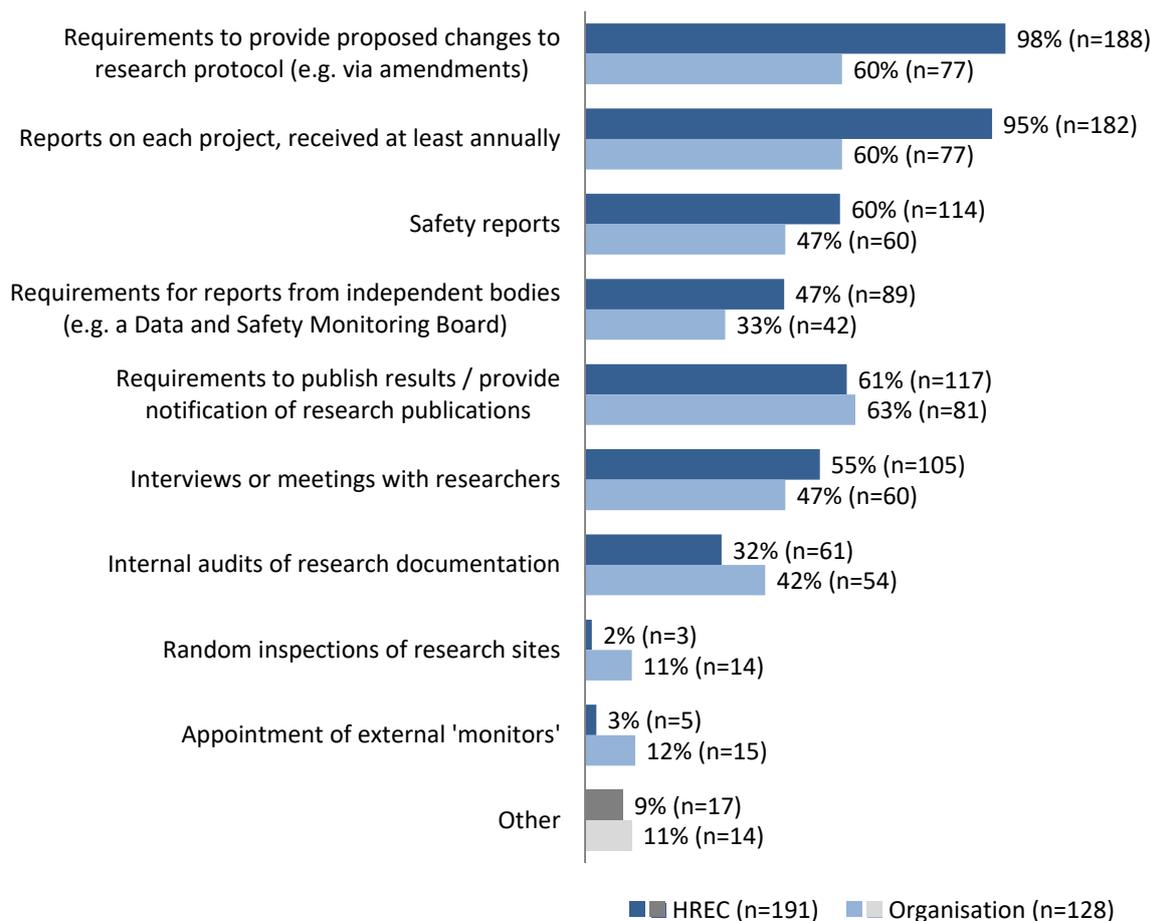
<sup>10</sup> An alternative mechanism could include review by the HREC chairperson or delegate, review by a sub-committee of the HREC, review by another institutional group or delegated individual etc. (see paragraph 5.1.18-5.1.21 of the National Statement).

## I. Monitoring of research

All 195 HRECs (100%) indicated that the organisation and/or the HREC had procedures in place for monitoring approved research. Of these HRECs, all but three (98%; n=192) reported that the organisation and/or the HREC undertook monitoring of approved research. **Figure 4** provides information on the reported monitoring processes in 2020.

**Figure 4: Monitoring processes (2020)**

Base: HRECs that reported that the organisation and/or the HREC undertook monitoring of all approved research, multiple responses accepted (n=192)



Other processes used to monitor research included:

- ◆ A requirement for researchers to provide regular progress updates and reports, including:
  - Adverse event reports
  - Amendment updates for any change in a study (not just protocol changes)
  - Breach reports
  - Investigator change reports
  - Notifiable event reports
  - Protocol deviation / violation reports, and
  - Safety notifications.
- ◆ Audits – including self-audits, sponsor initiated audits, external audits, and informal audits by the HREC chair

- ◆ Establishing monitors and/or Data and Safety Monitoring Boards for clinical trials and projects, where required
- ◆ 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
- ◆ Presenting results during a virtual Research Week
- ◆ Providing annual reports and regular updates to the Deputy Vice Chancellor (Research)
- ◆ Reminder emails
- ◆ Review of the organisational Research Strategy
- ◆ Start-up meetings, and
- ◆ System of review for scientific merit of all projects submitted to the HREC, whereby evidence of two independent reviews must be supplied with the ethics application.

Of the three HRECs that did not undertake monitoring, one reported that there was no approved research to monitor. The remaining two HRECs reported that the organisation and/or HREC did not undertake monitoring of approved research as:<sup>11</sup>

- ◆ Progress reports were not provided due to the institutional Scientific Director being unavailable for an extended period of time, and
- ◆ The process was under review for implementation in 2021.

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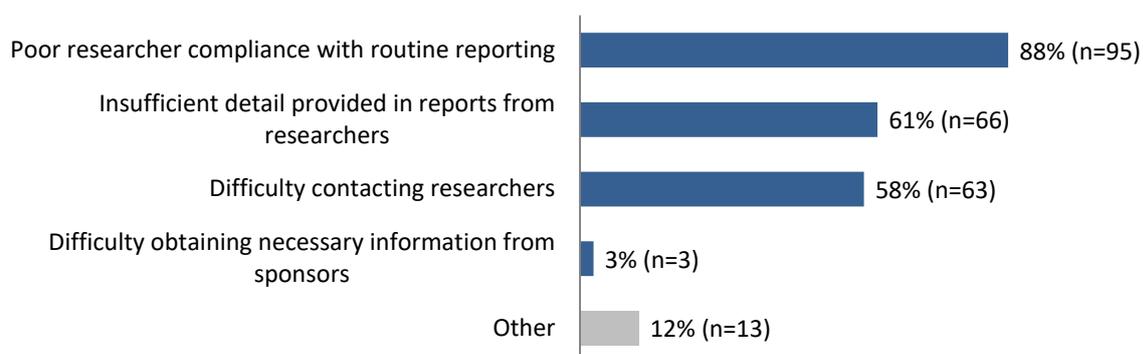
<sup>11</sup> The HRECs that did not undertake monitoring were advised that organisations and/or HRECs should undertake monitoring for approved research, as required by Chapters 5.1 and 5.5 of the National Statement.

## Problems encountered in monitoring approved research

Of the 192 HRECs that undertook monitoring of approved research during the reporting period, over half (56%; n=108) 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 (2020)**

Base: HRECs that reported that they or their organisation encountered problems in monitoring research during the reporting period, multiple responses accepted (n=108)



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

- ◆ COVID-19 related difficulties and challenges
- ◆ Limited resources to undertake regular monitoring
- ◆ Ongoing plans for the establishment of a database which will allow for greater efficiencies in monitoring
- ◆ Staff changes, and
- ◆ Timely submissions of annual reporting.

Of the 108 HRECs that reported that they encountered problems in monitoring research, all but two (98%; n=106) 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 195 HRECs, all but four (98%; n=191) 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 five HRECs (97%; n=190) 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 not publicly available due to website upgrades and/or review of the procedures themselves, and
- ◆ Complaints procedures were provided internally within the institution, as research projects were mostly internal.

### Types of complaints received

During the reporting period, two-in-five HRECs (40%; n=78) received a combined total of 229 complaints **about researchers or the conduct of an approved research project**, while under one-in-ten HRECs (8%; n=15) received a combined total of 31 complaints **from researchers about the consideration of their research proposal(s) by the HREC** (see Table 3).

**Table 3: Number of complaints or concerns received by HRECs (2020)**

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	229	21
Complaints received about researchers or the conduct of an approved research project that involved Aboriginal and Torres Strait Islander peoples	14	2
Complaints received from a researcher about the consideration of their research proposal by the HREC	31	10

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

- ◆ Administrative errors

<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.

- ◆ Adverse events
- ◆ Advertising of research
- ◆ Annual reports
- ◆ Conflict of interest
- ◆ Consent and opt-out processes
- ◆ Consumer engagement
- ◆ Data security / access / integrity
- ◆ Departmental consultation
- ◆ Difficulty contacting researchers
- ◆ Effects caused by research (including distress, injury)
- ◆ Engagement with Aboriginal and Torres Strait Islander peoples / communities
- ◆ Food
- ◆ 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 coercion, 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
- ◆ Researcher changes
- ◆ Risk assessment
- ◆ Time commitment, and
- ◆ Waiting times / delays.

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

- ◆ Dissatisfaction or disagreement with the HREC's feedback or decision
- ◆ HREC's lack of relevant expertise
- ◆ Requests for clarification / additional information
- ◆ Review processes, requirements, and timelines, and
- ◆ Risk assessment.

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 2020 – 31 December 2020

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 2020 – 31 December 2020.

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 2020, 42 organisations operated as certified institutions under the NHMRC National Certification Scheme. These 42 organisations included 54 HRECs (see **Table 4**). In the 2019 reporting period, there were 43 certified institutions.

**Table 4: HRECs by jurisdiction (2020)**

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

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

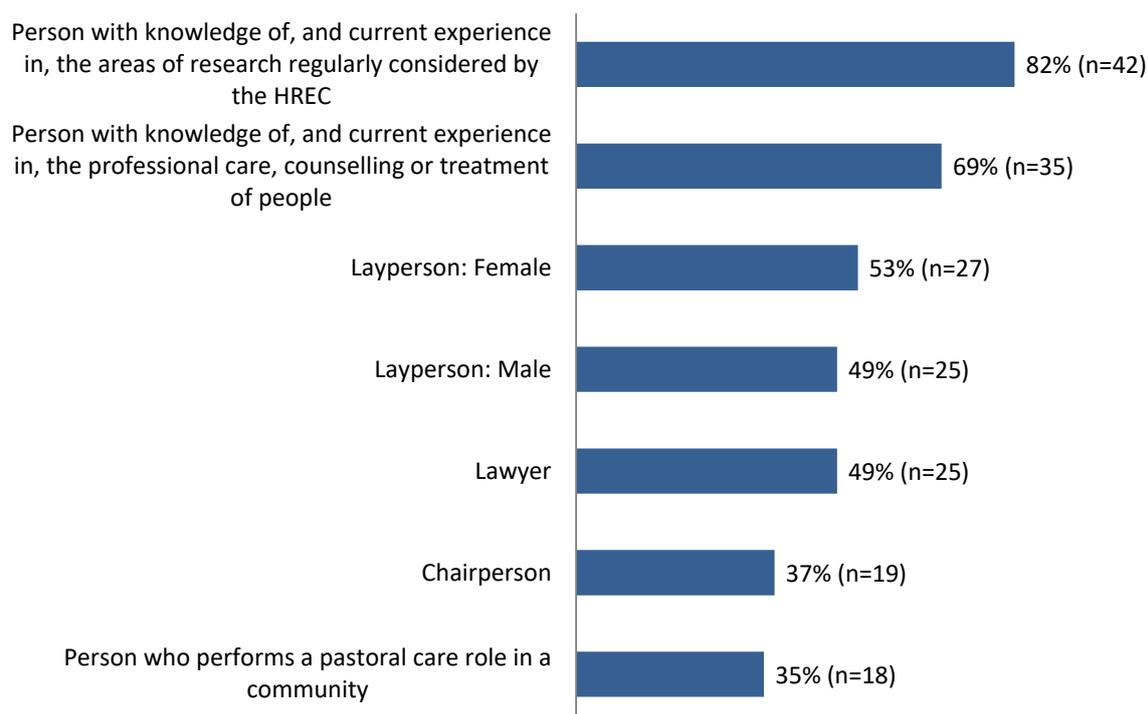
## B. HREC composition

### Membership

All but three certified HRECs (94%; n=51) reported a change to committee membership during 2020. 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 (2020)**

Base: Certified institutions 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

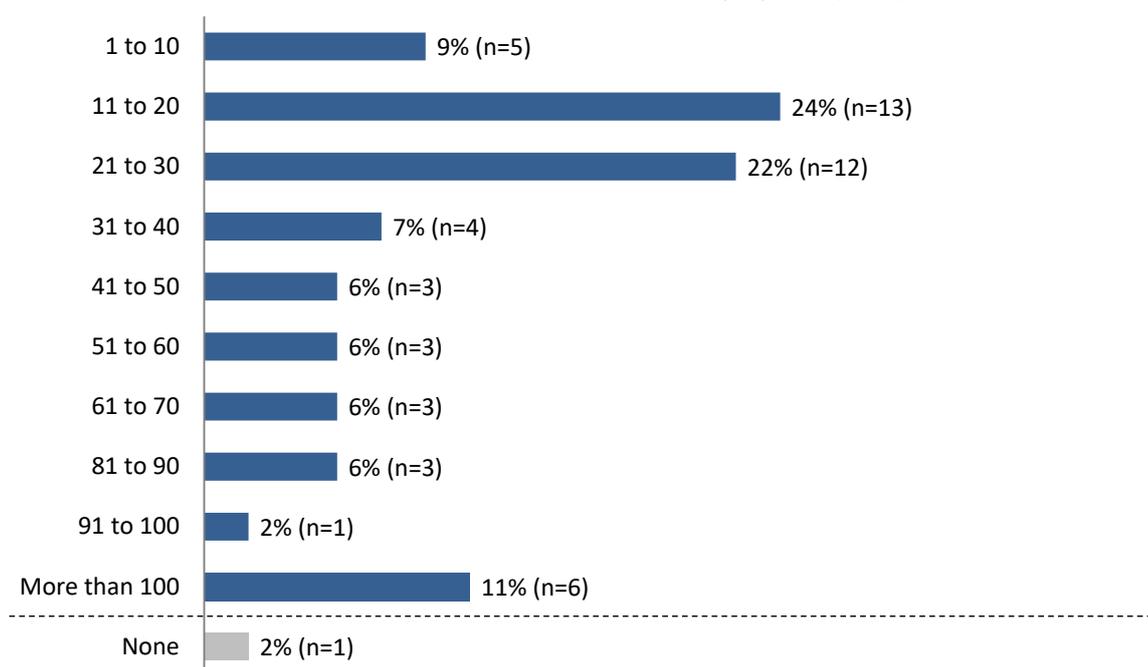
All 54 HRECs from certified institutions reported that they had considered new<sup>14</sup> research proposals during the reporting period. Of these HRECs, all but one (98%; n=53) reported that they had reviewed new multi-centre<sup>15</sup> research proposals during 2020.

### 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 (2020)**

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



The total number of new multi-centre research proposals reviewed during the reporting period was 2,254 (2,066 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 145 (n=1), and the lowest was 0 (n=1).

<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.

## Reduced duplication and timeliness

Of the 53 HRECs that reviewed new multi-centre research proposals in 2020, all but four (92%; n=49) had reviewed at least one proposal as the lead HREC<sup>17</sup>. Around one-in-five HRECs (19%; n=10) reviewed at least one new multi-centre research proposal where it was not the lead HREC.

During the reporting period, around one-quarter of HRECs (26%; n=14) reported that they were aware of instances where the HREC's approval had not been accepted by another institution. Four HRECs (7%) 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
- ◆ No executive support
- ◆ No site staff
- ◆ Proposals involved perceptions of professionals not employed by the institution
- ◆ Proposals were not approved by a certified HREC
- ◆ The institution was not part of the National Mutual Acceptance (NMA) scheme, and
- ◆ The National Mutual Acceptance (NMA) guidelines had not been followed.

Of the new multi-centre research proposals reviewed during the reporting period, over nine-in-ten reviews (94%; n=2,116) were completed within 60 calendar days<sup>18</sup>. Furthermore:

- ◆ Just over half (52%; n=1,167) were intended for conduct within one Australian state or territory only, and
- ◆ Almost half (48%; n=1,087) were intended for conduct in two or more Australian states or territories.

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<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.

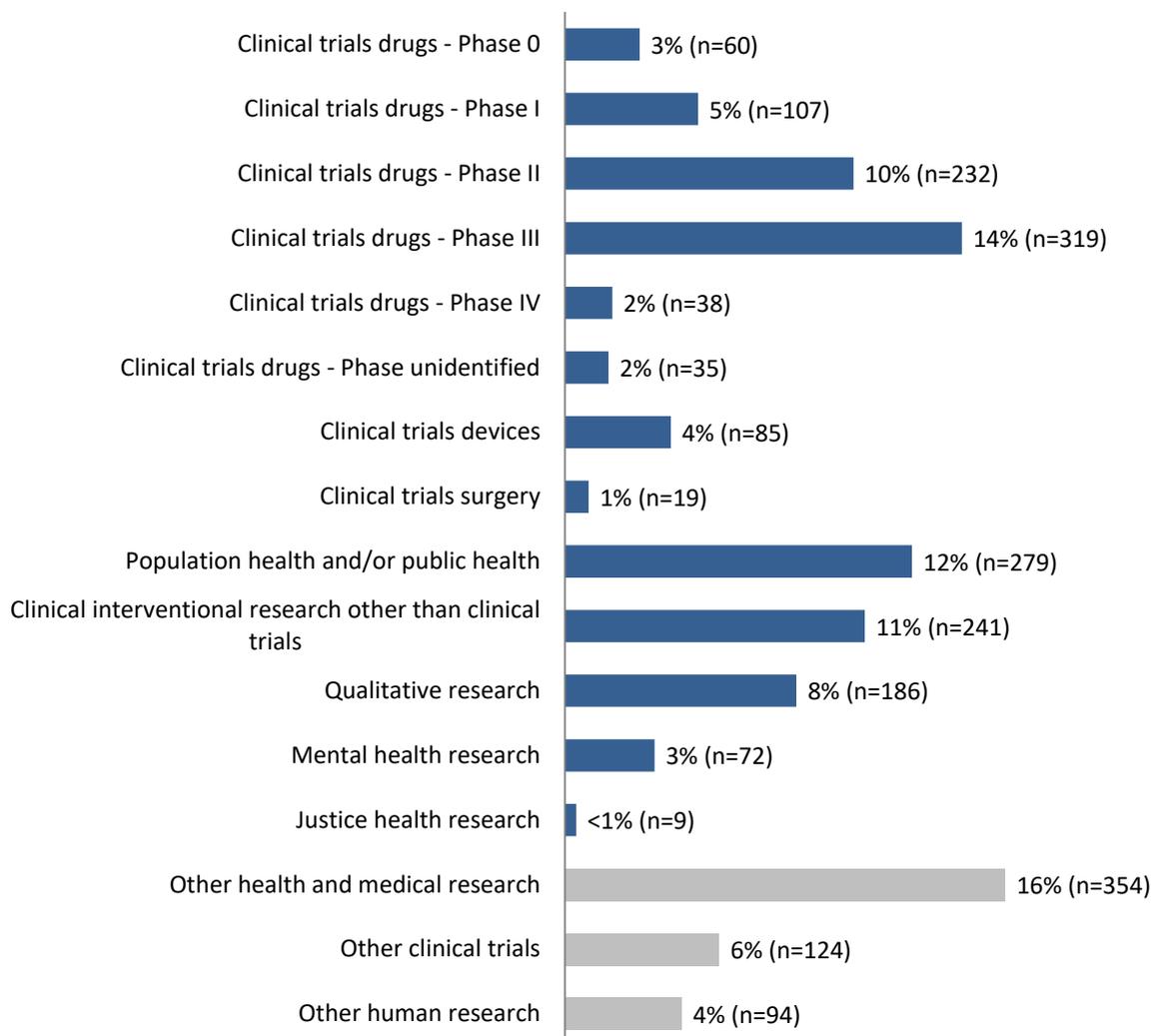
<sup>18</sup> Further information on the 60 calendar day timeframe is provided in the [National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research Certification Handbook, November 2012](#).

## 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> (2020)**

Base: Total number of multi-centre research proposals considered by certified institutions' HRECs (n=2,254)



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

- ◆ Action research
- ◆ Allied health
- ◆ Ambulance / paramedicine
- ◆ Anaesthesia
- ◆ Artificial Intelligence (AI)
- ◆ Audits / quality assurance

<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.

- ◆ Autoimmune disorders
- ◆ Biobanking
- ◆ Biospecimen / biopsy analysis
- ◆ Burns
- ◆ Cancer / oncology
- ◆ Capacity building
- ◆ Cardiology
- ◆ Case series and video atlas
- ◆ Clinical medical and science research
- ◆ Cognitive paradigms
- ◆ Cohort studies
- ◆ Correlation research
- ◆ COVID-19
- ◆ Data linkage / review
- ◆ Dentistry / oral health
- ◆ Descriptive studies
- ◆ Developmental / validation research
- ◆ Diabetes
- ◆ Diagnostic validity studies
- ◆ Digital health research
- ◆ Education
- ◆ Emergency and trauma
- ◆ Epidemiology
- ◆ Genetics
- ◆ Haematology
- ◆ Health economics
- ◆ Health services
- ◆ Immunology
- ◆ Infectious diseases
- ◆ Intensive care unit (ICU)
- ◆ Laboratory research
- ◆ Maternal and foetal health
- ◆ Medical imaging
- ◆ Microbiology
- ◆ Neurology
- ◆ Neuroscience
- ◆ Nursing
- ◆ Nutrition and dietetics
- ◆ Observational research
- ◆ Occupational therapy
- ◆ Ophthalmology
- ◆ Orthopaedics
- ◆ Paediatrics
- ◆ Pain management

- ◆ Palliative care
- ◆ Pathology
- ◆ Patient satisfaction / management
- ◆ Pharmacy / pharmacology / pharmaceutical sciences
- ◆ Physiotherapy
- ◆ Prospective database
- ◆ Quantitative research
- ◆ Registries
- ◆ Renal medicine
- ◆ Reporting
- ◆ Retrospective review / data collection
- ◆ Review of medical records
- ◆ Social science
- ◆ Staff research
- ◆ Stroke
- ◆ Surgery (including general, colorectal, maxillofacial, plastic)
- ◆ Surgical and perioperative medicine, and
- ◆ Women's and children's health.

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

- ◆ Aphasia
- ◆ Application development / use
- ◆ Cancer
- ◆ COVID-19
- ◆ Education
- ◆ Gastroenterology
- ◆ Genetics
- ◆ Gynaecology
- ◆ Hepatology
- ◆ Interventions
- ◆ Method / tool development
- ◆ Mindfulness
- ◆ Models of care
- ◆ Neurology
- ◆ Nutrition and dietetics
- ◆ Observation
- ◆ Paediatrics
- ◆ Palliative care
- ◆ Physiotherapy
- ◆ Psychology
- ◆ Rehabilitation
- ◆ Standard of care

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

- ◆ Supplementation, and
- ◆ Telehealth.

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

- ◆ Audits
- ◆ Biobanks
- ◆ Biospecimens
- ◆ Clinical non-interventional research
- ◆ Data linkage
- ◆ Education
- ◆ Epidemiology
- ◆ Interviews and focus groups
- ◆ Nursing
- ◆ Social policy
- ◆ Social science, and
- ◆ Surveys.

During the reporting period, two-in-three HRECs (66%; n=35) reviewed multi-centre research proposals involving children and young people / paediatrics.

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