REPORT ON THE ACTIVITY OF NHMRC-REGISTERED HUMAN RESEARCH ETHICS COMMITTEES FOR THE PERIOD 1 JANUARY 2012 – 31 DECEMBER 2012
Introduction

Human Research Ethics Committees (HRECs) play a central role in the Australian system of ethical oversight of research involving humans. HRECs review research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.

The National Health and Medical Research Council (NHMRC) requests annual reports from HRECs registered 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 and requirements of the *National Statement on Ethical Conduct in Human Research, 2007* (National Statement) including:

- the composition of the HREC;
- processes for the consideration of research proposals;
- reporting arrangements with the host institution; and
- monitoring of approved research and mechanisms for handling complaints.

The annual reports also collect information on behalf of the Australian Information Commissioner, concerning the privacy of health information and the application of the two NHMRC guidelines approved under Section 95 and 95A of the *Privacy Act 1988*.¹

The purpose of collecting the information is to gather an annual overview about the Australian HREC system. This information assists NHMRC, including the Australian Health Ethics Committee (AHEC), to formulate policy advice, provide support to HRECs and respond to requests for information about HRECs, particularly from the Parliament or the Minister for Health.

The following overview of HRECs is drawn from information provided during the reporting period from 1 January 2012 – 31 December 2012.

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¹ *Guidelines under Section 95 of the Privacy Act 1988* and the *Guidelines approved under Section 95A of the Privacy Act 1988*
1. Number of HRECs

During 2012, 225 HRECs were registered with NHMRC, with 221 submitting an annual report on their activities to NHMRC (Table 1.1)\(^2\). There were 227 HRECs in the previous (2011) reporting period.

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Number of HRECs</th>
</tr>
</thead>
<tbody>
<tr>
<td>New South Wales/ACT(^3)</td>
<td>73</td>
</tr>
<tr>
<td>Victoria</td>
<td>67</td>
</tr>
<tr>
<td>Queensland</td>
<td>40</td>
</tr>
<tr>
<td>Western Australia</td>
<td>21</td>
</tr>
<tr>
<td>South Australia</td>
<td>18</td>
</tr>
<tr>
<td>Northern Territory</td>
<td>3</td>
</tr>
<tr>
<td>Tasmania</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>225</strong></td>
</tr>
</tbody>
</table>

\(^2\) ONHMRC was unsuccessful in contacting the remaining four (4) HRECs – three (3) of which had closed during 2012.

\(^3\) NSW and ACT HRECs are grouped together as some HRECs service across the two jurisdictions.

\(^4\) Non-research HRECs undertake reviews of clinical practice and/or clinical policy matters.
2. HRECs by type of institution

HRECs can be associated with higher education providers (e.g. universities), private or public hospitals, state health services, government departments or private organisations. The data collected in the 2012 HREC annual reports indicates that the majority of HRECs are associated with public hospitals and universities.

The breakdown of HRECs by the type of institution is represented in Table 2.1.

<table>
<thead>
<tr>
<th>Institution type</th>
<th>Totals</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital/Health Service (public)</td>
<td>66</td>
<td>29.3%</td>
</tr>
<tr>
<td>University/Higher Education Institution</td>
<td>56</td>
<td>25%</td>
</tr>
<tr>
<td>Other Organisation/Institution (not for profit)</td>
<td>41</td>
<td>18.2%</td>
</tr>
<tr>
<td>Hospital/Health Service (private)</td>
<td>30</td>
<td>13.3%</td>
</tr>
<tr>
<td>Government Department/Statutory Agency</td>
<td>27</td>
<td>12%</td>
</tr>
<tr>
<td>Other Organisation/Institution (for profit)</td>
<td>5</td>
<td>2.2%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>225</td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
3. HREC membership

The minimum membership of an HREC is eight members, comprising one from each core membership category described in paragraph 5.1.30 of the National Statement; with two individuals assigned to each of the categories ‘persons with knowledge of, and current experience in the areas of research regularly considered by the HREC’ and ‘lay people who have no affiliation with the institution and do not currently engage in medical, scientific or academic work’.

Twenty-seven (27) of the 225 HRECs reported that they did not meet the minimum membership requirements during the reporting period. Issues identified were:

- One, or no members with current research experience (n=10)
- One, or no layperson(s) (n=6)
- No member who performs a pastoral care role in the community (n=5)
- Layperson(s) are affiliated with the institution (n=2)
- No lawyer (n=2)
- No member with knowledge of, and current experience in the professional care, counselling or treatment of people (n=2)

Additional membership

In addition to members from the required core categories, other members appointed to HRECs included:

- Aboriginal and Torres Strait Islander representatives;
- Academic staff;
- Chair of a sub-committee;
- Clinicians from a range of specialties such as pharmacology, anaesthetics, geriatric medicine, neonatal medicine and epidemiology;
- Consumer representatives;
- Departmental representatives;
- Executive representatives such as a Chief Executive Officer, Deputy Vice Chancellor (Research), Dean of the Graduate Research School, Medical/Clinical Director;
- Person with Rural and Remote Research experience;
- Research ethics/governance coordinators and other research/medical administrative staff;
- Secretary or observer;
- Student representatives; and
- Members with expertise in:
  - Aboriginal and Torres Strait Islander research and/or health
  - Bio-statistics
  - Clinical trials
  - Diagnostic services
  - Disability & disability services
  - Education
  - Ethics (clinical, professional, research, bio-)
  - Forensic Pathology
  - Law (access to justice, administrative law and procedural fairness, privacy)
  - Midwifery
  - Medicine
  - Organ donation/tissue typing
  - Outpatient health
  - Pharmacy
  - Philosophy
  - Policing
  - Population health

ONHMRC will remind these HRECs of the membership requirements under paragraph 5.1.30 of the National Statement.

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Average membership

There was an average of 14.7 members per HREC. Three (3) HRECs reported less than eight (8) members in total, with the lowest being four (4) members. The largest HREC consisted of 59 members.

Institutional and non-institutional members

Six (6) HRECs reported less than the desired one-third of membership from outside the institution (NS 5.1.29); with two (2) HRECs reporting that all members were affiliated with the institution (see above for compliance concern regarding lay members).

Gender balance

The desired gender balance of an HREC is 50:50 (NS 5.1.29). Twenty-Eight (28) HRECs reported a less than 70:30 gender balance (in either direction).
4. HREC Meetings

Two hundred and twelve (212) of the 225 HRECs reported that the HREC had considered research proposals during the reporting period. Of these, 97 (45.8%) reported that at least one member from each of the core membership categories were present at all meetings. In the instances where meetings were not attended by at least one member from each of the core membership categories (n=115), all but two (2) HRECs reported that all members were given the opportunity to comment on a proposal before a decision was reached.\(^6\)

**Number of meetings**

The distribution of the number of meetings held by HRECs during the reporting period is shown in Figure 1.

Over 90% of HRECs (n=205) reported that they had between 1 and 15 meetings during 2012. The maximum number of meetings held by any one HREC during the reporting period was 59 (n=1) and the minimum number was 0 (n=11).\(^7\) The HREC that reported holding 59 meetings also reported a total of 13 HREC members, with 554 proposals considered. The average number of meetings per HREC was 8.

**Figure 1**

![Number of meetings held by HRECs](image)

\(^6\) Two (2) HRECs reported cases where a committee member was absent and unable to contribute. Reasons included being out of contact while travelling and a vacant membership category.

\(^7\) Includes nine (9) HRECs who did not consider any research proposals during the reporting period.
5. Review of research proposals

Number of research proposals

The distribution of the number of research proposals considered by HRECs during the reporting period is shown in Figure 2.

The highest number of research proposals considered by any one HREC during the reporting period was 1367 (n=1) and the lowest number was 0 (n=10, 4.5%). The HREC that reported 1367 research proposals met 23 times and consisted of a pool of 59 members. The average number of research proposals considered by an HREC was 124. Approximately one-fifth of HRECs (n=46) reviewed between one (1) and ten (10) research proposals.

Of these ten (10) HRECs, one (1) HREC is known to have reported incorrectly. There is a discrepancy between the HREC Annual Report and the Certification Annual Report for this HREC, which will need to be resolved.
Types of research proposals considered by HRECs

Table 5.1 shows the types and number of research proposals considered by HRECs. The number of HRECs considering various types of research proposals is shown in Figure 3.

TABLE 5.1 Research proposals reviewed by HRECs

<table>
<thead>
<tr>
<th>Details of research proposals</th>
<th>Total number (2010)</th>
<th>Total number (2011)</th>
<th>Total number (2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of research proposals considered</td>
<td>23,696</td>
<td>25,022</td>
<td>26,257</td>
</tr>
<tr>
<td>Total research proposals approved</td>
<td>22,203 (93.7%)</td>
<td>23,283 (93.05%)</td>
<td>24,540 (93.5%)&lt;sup&gt;9&lt;/sup&gt;</td>
</tr>
<tr>
<td>Total research proposals denied ethical approval</td>
<td>1,493</td>
<td>1,739</td>
<td>1717</td>
</tr>
<tr>
<td>Highest number of proposals approved by an HREC&lt;sup&gt;10&lt;/sup&gt;</td>
<td>1,351</td>
<td>1,341</td>
<td>1344</td>
</tr>
<tr>
<td>Number of Institutions that have a non-HREC reviewing process for low or negligible risk (LNR) proposals</td>
<td>134</td>
<td>157</td>
<td>149</td>
</tr>
<tr>
<td>Number of LNR proposals reported&lt;sup&gt;11&lt;/sup&gt;</td>
<td>Not recorded</td>
<td>13,830</td>
<td>15,050</td>
</tr>
<tr>
<td>Number of HRECs that accept reviews for multi-centre research approved by an HREC / Institution outside its State/Territory Jurisdiction</td>
<td>133</td>
<td>139</td>
<td>140</td>
</tr>
</tbody>
</table>

Specific types of research (as identified in NS Section 3)

<table>
<thead>
<tr>
<th>Details of research proposals</th>
<th>Total number (2010)</th>
<th>Total number (2011)</th>
<th>Total number (2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of proposals approved involving clinical trials</td>
<td>2,617</td>
<td>2,564</td>
<td>2,471</td>
</tr>
<tr>
<td>Number of proposals considered involving research and/or innovations involving human gametes or excess assisted reproductive technology (ART) embryos</td>
<td>12</td>
<td>17</td>
<td>22</td>
</tr>
</tbody>
</table>

Vulnerable participant groups (as identified in NS Section 4)<sup>12</sup>

<table>
<thead>
<tr>
<th>Details of research proposals</th>
<th>Total number (2010)</th>
<th>Total number (2011)</th>
<th>Total number (2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of proposals approved involving children and young people</td>
<td>2,707</td>
<td>2,683</td>
<td>2,889</td>
</tr>
<tr>
<td>Number of proposals approved involving people with a cognitive impairment, intellectual disability or a mental illness</td>
<td>1,281</td>
<td>968</td>
<td>1,017</td>
</tr>
<tr>
<td>Number of proposals approved involving women who are pregnant and the human fetus</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>270</td>
</tr>
</tbody>
</table>

<sup>9</sup> There are suspected discrepancies in this data. Refer to page 10 of this report for details.

<sup>10</sup> This item reports data from the same HREC across the three (3) years. The 2012 approval rate for this HREC was 98.3%.

<sup>11</sup> This data is considered unreliable, as it is evident that the questions relating to LNR research were interpreted differently by different institutions. This question set in the HREC Annual Report requires refinement to enable greater analysis of the data collected (See also Section 7 (page 12) of this report).

<sup>12</sup> See Section 6 (page 11) of this report for a discussion on research involving Aboriginal and Torres Strait Islander Peoples.
<table>
<thead>
<tr>
<th>Type of research/participant</th>
<th>Number of HRECs that considered specific types in 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>children/young people</td>
<td>74.1%</td>
</tr>
<tr>
<td>cognitive impairment/intellectual disability/mental illness</td>
<td>59.7%</td>
</tr>
<tr>
<td>highly dependent/unequal relationships</td>
<td>55.7%</td>
</tr>
<tr>
<td>pregnant woman &amp; the human fetus</td>
<td>34.4%</td>
</tr>
<tr>
<td>highly dependent on medical care</td>
<td>38.5%</td>
</tr>
<tr>
<td>illegal activities</td>
<td>30.3%</td>
</tr>
<tr>
<td>people in other countries</td>
<td>30.3%</td>
</tr>
<tr>
<td>clinical trials</td>
<td>63.4%</td>
</tr>
<tr>
<td>Excess ART embryos &amp; human gametes</td>
<td>5.9%</td>
</tr>
</tbody>
</table>

**Figure 3**

| Number of proposals approved involving people in dependent or unequal relationships | Not recorded | Not recorded | 2,659 |
| Number of proposals approved involving people highly dependent on medical care who may be unable to give consent | Not recorded | Not recorded | 647 |
| Number of proposals approved involving people who may be involved in illegal activities | Not recorded | Not recorded | 194 |
| Number of proposals approved involving people in other countries | Not recorded | Not recorded | 1,476 |
Approval rates for research proposals

Table 5.2 shows the approval rates for research proposals during 2012. For example, one (1) HREC approved between 1 – 25% of the research proposals it considered during the reporting period.

### TABLE 5.2 Approval rates

<table>
<thead>
<tr>
<th>Approval rates</th>
<th>Number of HRECs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>3</td>
</tr>
<tr>
<td>1 – 25%</td>
<td>1</td>
</tr>
<tr>
<td>26 – 50%</td>
<td>2</td>
</tr>
<tr>
<td>51 – 75%</td>
<td>13</td>
</tr>
<tr>
<td>76 – 100%</td>
<td>187</td>
</tr>
<tr>
<td>&gt;100%</td>
<td>6</td>
</tr>
</tbody>
</table>

**NOTE:**

- Of the three (3) HRECs that reported a 0% approval rate:
  - One (1) HREC considered only one (1) research proposal
  - One (1) HREC reported that although the HREC met 11 times during the reporting period, no research proposals were considered\(^\text{13}\)
  - One (1) HREC considered 343 research proposals, and none were approved\(^\text{14}\).

- Of the 187 HRECs that reported a 75 – 100% approval rate, 82 reported a 100% approval rate.

- Six (6) HRECs reported a >100% approval rate, this suggests that the number of applications and/or the number of applications approved were reported incorrectly by these HRECs.

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\(^{13}\) HREC is known to have reported incorrectly. There is a discrepancy between the HREC Annual Report and the Certification Annual Report for this HREC, which will need to be resolved.

\(^{14}\) Suggest that this has been reported incorrectly. This will be queried with the HREC in question.
6. Research involving Aboriginal and Torres Strait Islander Peoples

The NHMRC publication *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003)* (Values and Ethics Guidelines) contains guidelines for ethical health research involving Aboriginal and Torres Strait Islander peoples. These guidelines were developed by an AHEC Working Party in 2003 and replace the NHMRC *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research (1991)*.

During the reporting period, 877 research proposals involving Aboriginal and Torres Strait Islander Peoples were considered by 107 HRECs\textsuperscript{15}. Of these HRECs, 103 reported that they used the Values and Ethics Guidelines when considering proposals\textsuperscript{16}. Of the proposals that were considered, 844 were approved and 33 were denied approval. This data is shown in Table 6.1.

**TABLE 6.1 Research involving Aboriginal and Torres Strait Islander Peoples**

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Total number (2011)</th>
<th>Total number (2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of research proposals considered involving Aboriginal and Torres Strait Islander Peoples</td>
<td>917</td>
<td>877</td>
</tr>
<tr>
<td>Proposals involving Aboriginal and Torres Strait Islander Peoples approved</td>
<td>890</td>
<td>844</td>
</tr>
<tr>
<td>Proposals involving Aboriginal and Torres Strait Islander Peoples denied ethical approval</td>
<td>27</td>
<td>33</td>
</tr>
</tbody>
</table>

The highest number of proposals involving Aboriginal and Torres Strait Islander Peoples considered by any one HREC was 149; of which the approval rate was approximately 87%.

The reasons provided for denying ethical approval for a research proposal involving Aboriginal and Torres Strait Islander Peoples included:

- Flawed / inappropriate research design and methodology
- Unable to adequately address Aboriginal and Torres Strait Islander issues
- Lack of consultation and support from communities / lack of ‘expert’ and/or Aboriginal cultural input
- No evidence of a formal literature review which would justify the need for the study
- Application was unprofessional
- The application was withdrawn by the researcher due to the field work not being able to be undertaken
- Absence of additional information requested by the HREC
- Incorrect applications submitted, e.g. low risk application submitted when risk was greater than low.

Forty-six (46) of the 107 HRECs that considered research proposals involving Aboriginal and Torres Strait Islander Peoples included at least one person who identified as Aboriginal and/or Torres Strait Islander in its membership.

\textsuperscript{15} Seventeen (17) HRECs reported that they considered research involving Aboriginal and Torres Strait Islander Peoples – However, these HRECs also reported that they did not approve or deny any proposals involving Aboriginal and Torres Strait Islander Peoples. This will be queried with the HRECs in question.

\textsuperscript{16} Of the four (4) HRECs that did not use the NHMRC Values and Ethics Guidelines; two (2) HRECs used guidelines developed by the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) instead, an additional HREC considered that the AIATSIS guidelines in conjunction with Chapter 4.7 of the National Statement were more appropriate for the non-health projects reviewed; and one (1) HREC only reviewed proposals that had already been approved by a specialised Aboriginal Health and Ethics Committee.
7. Non-HREC levels of ethical review for low risk research proposals

The National Statement provides guidance on alternative methods of reviewing low or negligible risk (LNR) research. In paragraph 5.1.18 of the National Statement this is referred to as ‘non-HREC level’ review.

The data collected on the number of LNR applications considered during the 2012 reporting period is listed in Table 5.1 – however, as identified previously (on page 8 of this report), this data is considered unreliable. From the responses provided in the HREC annual reports, there is reason to believe that the questions relating to LNR research were interpreted differently by the different institutions. This question set in the HREC annual report requires refinement to enable greater analysis of the data collected. For this reason, this report will not further analyse the available data in relation to the number of LNR applications assessed by HRECs and/or non-HREC methods.

Non-HREC level’ review

Approximately 70% of HRECs who consider research proposals during the 2012 reporting period (n=149) reported that the host institutions had non-HRECs levels of review for LNR research proposals. Non-HREC levels of review reported included:

- A sub-committee set up specifically to review LNR applications*
- Review by HREC’s Chair and/or Deputy Chair, with reference to a sub-committee if necessary
- Review by head or director of the department*
- Review by the HREC executive committee*
- Review by the HREC Chair or a Deputy Chair, and a Human Research Ethics Officer.
- Review by an advisory/governance committee of the institution*
- Review by a School/Faculty committee established for reviewing LNR proposals within the institution
- Reviewed by staff of the institution’s Research Governance/Research Ethics Department in consultation with relevant members of the HREC where required*
- Out-of-session review via email with HREC members*
- Peer review, then assessment by an appropriate expert reviewer and the HREC Chair
- Review by a member of the HREC and a member of the Scientific Advisory Committee, with further consultation with other members of the HREC where required**
- Review by the Secretariat/Research Ethics/Governance Officer**
- Review by two senior scientists
- Researcher completes a ‘Research Checklist’ to identify any ethical risks associated with proposed research. This is then authorised by their manager. If no ethical risks are identified, no further ethical review is required and the manager monitors the research. The project is listed on the HREC database of projects and issued with a letter of compliance.
- Researcher submits a ‘negligible risk research declaration’ to the Faculty Associate Dean Research for review and sign-off, and then to an Expedited Review Committee for noting
- Low risk student projects reviewed by non-HREC panel/reviewer
- Researcher completes and signs an ethics checklist to retain as an auditable record with their project documents
- Requests are received via letter and the HREC discusses the content of each letter at a meeting. If questions arise, letters are directed to the author to answer them. Once a response is received a determination is made by the HREC during a meeting as to whether a formal application is required.

* Most institutions reported that the outcome is then ratified by the institution’s HREC
** The outcome is then reviewed by the HREC Chair
8. Recording and internal institutional reporting

The National Statement requires HRECs to record relevant information about research proposals received and reviewed including (but not limited to):

- the terms and conditions, if any, of approval;
- name of any other review body that considered the proposal; and
- the mechanism by which the approved research will be monitored.

Full details of documentation that should be recorded are listed in paragraph 5.2.24 of the National Statement. Details of the most common reporting mechanisms used between HRECs and their institution are shown in Table 8.1.

### Table 8.1 HREC reporting mechanisms

<table>
<thead>
<tr>
<th>Reporting mechanisms</th>
<th>Total number of HRECs*</th>
<th>Percentage of HRECs**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Established reporting mechanism between institution and HREC</td>
<td>212</td>
<td>100%</td>
</tr>
<tr>
<td>Minutes of HREC meetings provided to management level of institution</td>
<td>149</td>
<td>70.3%</td>
</tr>
<tr>
<td>Regular (at least annual) HREC reports provided to management level of institution</td>
<td>162</td>
<td>76.4%</td>
</tr>
<tr>
<td>Other</td>
<td>47</td>
<td>22.2%</td>
</tr>
</tbody>
</table>

*HRECs may select more than one reporting mechanism

**Based on the 212 HRECs which reviewed research proposals during the reporting period

‘Other’ reporting mechanisms reported by HRECs included:

- Provision of regular/additional reports and minutes of meetings to the Research Office/DVCR/CEO/Board/equivalent
- Regular meetings between CEO/Board/DVCR/equivalent of the institution and the HREC Chair
- Institution has a member on the HREC
- Management/CEO attends all HREC meetings
- HREC Chair attends Board meetings on an annual basis
- Annual joint meeting of the HREC and the Board
- All HREC research protocols are recommended for approval to institution’s management (and/or legal team)
- Institution receives all agenda papers and informed of all issues considered by the HREC
- Reports to Research Advisory Committees / Clinical Safety and Quality Committees
- Minutes are provided upon request from management, and when payments are processed for external committee members
- Brief report on HREC activities included in the institution’s Annual Report and newsletter
- Periodic institutional audits
- Ad hoc communication between Chair / Executive Officer and Chief Executive or delegate, as required
- Any issues requiring management action are brought to the Management’s attention via email or more formal notification where required.
9. Monitoring of Research

The National Statement sets out the minimum monitoring requirements that institutions should have in place to monitor research projects that have been given ethical approval by the HREC. Some HRECs have monitoring requirements that are additional to these minimum requirements. Table 9.1 and the subsequent list provide information on the reported processes used to monitor research during the reporting period.

**TABLE 9.1 HREC processes to monitor research**

<table>
<thead>
<tr>
<th>Process</th>
<th>Number of HRECs using the process</th>
<th>Percentage of HRECs**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reports on each project, received at least annually^17</td>
<td>203</td>
<td>95.8%</td>
</tr>
<tr>
<td>Adverse event reports</td>
<td>179</td>
<td>84.4%</td>
</tr>
<tr>
<td>At least the minimum requirements as described in the National Statement^#</td>
<td>176</td>
<td>83%</td>
</tr>
<tr>
<td>Requirements to publish results/notify HREC of research publications</td>
<td>137</td>
<td>64.6%</td>
</tr>
<tr>
<td>Reports from independent agencies</td>
<td>70</td>
<td>33%</td>
</tr>
<tr>
<td>HREC interview with researcher</td>
<td>69</td>
<td>32.5%</td>
</tr>
<tr>
<td>Site visits/audits of research documentation</td>
<td>41</td>
<td>19.3%</td>
</tr>
<tr>
<td>Random inspections of sites</td>
<td>25</td>
<td>11.8%</td>
</tr>
<tr>
<td>Appointment of “monitors” from HREC or within organisation</td>
<td>24</td>
<td>11.3%</td>
</tr>
<tr>
<td>Other</td>
<td>17</td>
<td>8%</td>
</tr>
</tbody>
</table>

^HRECs may select more than one process for monitoring research

**Based on the 212 HRECs which reviewed research proposals during the reporting period
^Reasons for not meeting these requirements are discussed below

Alternative processes used by HRECs to monitor research include:

- Existing state research governance mechanisms e.g. Site Specific Assessment (SSA)
- HREC members and ethics office staff attend research seminars/presentations
- Feedback/surveys from community members participating in the research
- Reports from subcommittees
- Quarterly reporting
- HREC requests a copy of the findings that are made available to interested participants

^17 Note: Unreliable data concerning six (6) HRECs.
• Protocol deviation reporting
• Researchers requested to advise all sites in research when research is multi-site

Minimum monitoring requirements

Seventeen percent (17%) of HRECs (n=36) reported that they did not meet the minimum monitoring requirements as set out in Chapter 5.5 of the National Statement. Of these HRECs:

• 24 reported that the HREC did not encounter any problems in monitoring the research
• 9 reported that they did encounter problems in monitoring approved research (see below)
• 3 reported that they do not have any monitoring procedures in place for approved research

Problems encountered in monitoring approved research

Nine (9) HRECs reported that they did encounter problems in monitoring approved research. The reported problems, and reasons for not meeting the minimum monitoring requirements, included:

• difficulty contacting researchers
• poor researcher compliance with routine reporting
• insufficient detail provided in reports from researchers
• lack of HREC resources to conduct monitoring

All nine (9) HRECs reported that these problems had been communicated to an appropriate level of management within the institution.

An additional 64 HRECs, who reported that they did meet the minimum monitoring requirements, also reported that they had encountered problems in monitoring approved research. Sixty-two (62) of these HRECs also reported that these problems had been communicated to an appropriate level of management within the institution.

In addition to the problems listed above, HRECS also listed ‘internal institutional restructuring’ as a problem encountered during the 2012 reporting period.

18 ONHMRC will remind the institutions responsible for these HRECs of the minimum monitoring requirements.
19 ONHMRC will remind the institutions responsible for these HRECs of their responsibility to monitor all approved research.
20 ONHMRC will also raise these concerns with the institutions responsible for these HRECs, to ensure that the institutions are reminded of their responsibility to monitor all approved research.
10. Complaints handling

The National Statement sets out the procedures that institutions with HRECs should have in place to receive and handle complaints or concerns about the conduct of an approved research project, or about the consideration of a research project by the HREC (Chapter 5.6 of the National Statement). In addition, the *Australian Code for the Responsible Conduct of Research, 2007* describes ‘research misconduct’ and specifies institutional processes for dealing with it.

One (1) HREC reported that the institution responsible for the HREC did not have a mechanism or a procedure in place to receive and handle complaints or concerns about the conduct of approved research projects. However, it was noted that ‘a formal mechanism will be established and documented at the next meeting of the HREC’.

Although the remaining 211 HRECs that considered research proposals during the reporting period reported that the responsible institutions did have a *mechanism* in place to receive and handle complaints or concerns about the conduct of approved research projects, one (1) HREC reported that there was no *procedure* in place.\(^{21}\)

### Types of complaints received

The data collected show that 53 HRECs received 161 complaints regarding the conduct of an approved research project.\(^{22}\) The highest number of complaints received by any one HREC was 22; of which 17 related to the same research project.

The data also shows that 15 HRECs received 19 complaints from researchers about the ethical review process. This data is shown in Table 10.1.

<table>
<thead>
<tr>
<th>Nature of concerns and complaints</th>
<th>Total number of complaints</th>
<th>Highest number received by any one HREC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complaints received about the conduct of an approved research project.</td>
<td>161</td>
<td>22</td>
</tr>
<tr>
<td>Complaints received from a researcher about the consideration of their research proposal by the HREC</td>
<td>19</td>
<td>3</td>
</tr>
<tr>
<td>Complaints received about projects that involved Aboriginal and Torres Strait Islander peoples</td>
<td>4</td>
<td>1</td>
</tr>
</tbody>
</table>

\(^{21}\) This HREC reported that it would disband in early 2013. As of 2 September 2013, no notice of closure has been received by NHMRC. ONHMRC will follow this up with the HREC in question.

\(^{22}\) This does not include any complaints received which relate to the *Guidelines approved under Section 95A of the Privacy Act 1988* which are reported in a separate report prepared for the Australian Information Commissioner (see Section 11 (page 18) of this report).
Issues raised in complaints received about the conduct of approved research projects included:

- Access to treatment/care following completion of study or withdrawal of consent
- Breach of approved protocol
- Conduct of International research
- Conduct of participants
- Conduct or qualifications of researcher/research assistant
- Conflict of interest
- Consent processes (incl. opt-out)
- Data security and/or Identifiability of data
- Inappropriate actions by third party
- Inappropriate survey/questionnaire (design/content/terminology)
- Injury/medical condition caused by research (or exacerbation of pre-existing conditions)
- Lack of information or inappropriate information given to the participant group (e.g. school children)
- Modification to research methodology or Participant Information Sheet without prior approval from HREC
- Privacy concerns/breach
- Recruitment (incl. unhappy about being approached to participate, family members unhappy about recruitment, recruitment method not approved by HREC/institution, coercion, how potential participants were identified and/or contacted, eligibility criteria, participation not followed up after consent provided, parental consent not sought)
- Reimbursement
- Reporting of individual results to participants
- Research conducted without HREC approval
- Scope of participant-researcher relationship
- Treatment of participants
- Validity of research
- Withdrawal of consent

Issues raised in complaints received from researchers about the consideration of their research proposal by an HREC included:

- Conflict of interest (incl. personal and professional bias)
- Contractual arrangements of research staff
- Dissatisfaction/disagreement with the decision of an HREC (incl. denial of ethical approval, amendments requested by HREC)
- Ethical consideration of non-medical projects
- General HREC administration/processes
- Impact of local legislation
- Perceived lack of opportunity by Sponsor to present information to the HREC
- Time taken to attain HREC approval
- Withdrawal of HREC approval
11. Privacy, Medical Research and Health Information

The use of the *Guidelines under Section 95 of the Privacy Act 1988* and the *Guidelines approved under Section 95A of the Privacy Act 1988* is required by HRECs when reviewing research proposals which involve access to health information. HRECs registered with NHMRC report to NHMRC in the annual report on this process.

A separate report is prepared for the Australian Information Commissioner for each annual reporting period. This report is also published on the NHMRC website for the information of HRECs and other interested parties.  

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12. Summary

The annual report process provides NHMRC with a snapshot of HREC activities and the application of the National Statement during a calendar year.

For those aspects on which the report form collects information, the majority of HRECs have been assessed as meeting the minimum requirements in 2012. Where HRECs have not met the minimum requirements with regard to membership and monitoring of research, staff of the NHMRC will contact the relevant institutions to address these issues and remind the institutions of their responsibilities under the National Statement.

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