REPORT ON THE ACTIVITY OF NHMRC-REGISTERED HUMAN RESEARCH ETHICS COMMITTEES FOR THE PERIOD 1 JANUARY 2013 – 31 DECEMBER 2013
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, updated March 2014) (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).

The following overview of HRECs is drawn from the information provided at registration and during the reporting period from 1 January 2013 to 31 December 2013.

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 2013, 218 HRECs were registered with NHMRC and each HREC submitted an annual report on their activities to NHMRC (Table 1.1). There were 225 HRECs in the previous (2012) reporting period.

**TABLE 1.1 HRECs by Jurisdiction**

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Number of HRECs</th>
</tr>
</thead>
<tbody>
<tr>
<td>New South Wales/ACT(^2)</td>
<td>69</td>
</tr>
<tr>
<td>Victoria</td>
<td>64</td>
</tr>
<tr>
<td>Queensland</td>
<td>39</td>
</tr>
<tr>
<td>Western Australia</td>
<td>21</td>
</tr>
<tr>
<td>South Australia</td>
<td>19</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>218</strong></td>
</tr>
</tbody>
</table>

\(^2\) NSW and ACT HRECs are grouped together as some HRECs service across the two jurisdictions.

**TABLE 1.2 Roles of HRECs**

<table>
<thead>
<tr>
<th>Role of HREC</th>
<th>Number of HRECs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research only</td>
<td>141</td>
</tr>
<tr>
<td>Both research and non-research</td>
<td>75</td>
</tr>
<tr>
<td>Non-research only(^3)</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>218</strong></td>
</tr>
</tbody>
</table>

\(^3\) Non-research HRECs undertake reviews of clinical practice and/or clinical policy matters.
2. HRECs by type of institution

HRECs can be associated with universities, higher education institutions, private or public hospitals, state health services, government departments or private organisations. The data collected in the 2013 HREC annual reports indicates that the majority of HRECs are associated with public hospitals/health services and universities/higher education institutions.

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

**TABLE 2.1 Number of HRECs by institution type**

<table>
<thead>
<tr>
<th>Institution type</th>
<th>Totals</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital/Health Service (public)</td>
<td>61</td>
<td>28.0%</td>
</tr>
<tr>
<td>University/Higher Education Institution⁴</td>
<td>58</td>
<td>26.6%</td>
</tr>
<tr>
<td>Other Organisation/Institution (not for profit)</td>
<td>40</td>
<td>18.4%</td>
</tr>
<tr>
<td>Hospital/Health Service (private)</td>
<td>29</td>
<td>13.3%</td>
</tr>
<tr>
<td>Government Department/Statutory Agency⁵</td>
<td>26</td>
<td>11.9%</td>
</tr>
<tr>
<td>Other Organisation/Institution (for profit)</td>
<td>4</td>
<td>1.8%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>218</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

⁴ The University/Higher Education Institution category (n=58) includes both public (n=49) and private (n=9) institutions.
⁵ The Government Department/Statutory Agency category (n=26) includes both Government only (n=16) and Government Statutory Agency (n=10) categories.
3. HREC membership

The minimum membership of an HREC is eight members, comprising of one from each core membership category described in paragraph 5.1.30 of the National Statement. This includes two individuals assigned to each of the 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’.

Thirteen (13) of the 218 HRECs reported that they did not meet the minimum membership requirements during the reporting period. Issues identified were:

- Only one member with current research experience that is relevant to the research proposals to be considered (n=4);
- No member with knowledge of, and current experience in, the professional care, counselling or treatment of people (n=1);
- No member who performs a pastoral care role in a community (n=3);
- No layman (n=5) and no laywoman (n=3); and
- Layperson that is affiliated with the institution (n=1).

Additional membership

In addition to members from the required core categories, other members appointed to HRECs during the 2013 reporting period included:

- Aboriginal and Torres Strait Islander Peoples representatives;
- Academic staff;
- Affiliated representatives for other health services;
- Clinical adviser;
- Clinicians from a range of specialties such as psychology, anaesthetics, geriatric medicine and mental health;
- Consumer representative;
- Coroner;
- Departmental, faculty and other institutional representatives;
- Donors (bone marrow and blood);
- Executive staff (Head of Institution, Chief Health Officer, Chief Financial Officer, Chief Operating Officer, Board member, Vice president, Deputy Vice Chancellor, Director, Manager);
- Graduates (medical and health);
- Nominee of Registrars of Births, Deaths and Marriages;
- Pharmacist;
- Practitioner (Allied Health, General and Medical);
- Registrar Research Development Officer;
- Student representatives or trainees;
- Sub-committee Chairs and members;
- Support staff (executive, research or governance officers as well as other research, medical or administrative staff); and
- Members with expertise in:
  - Aboriginal and Torres Strait Islander research and/or health
  - Bio-statistics
  - Bone and tissue banks
  - Chemistry
  - Clinical trials
  - Corporate governance

Of the 13 HRECs, one (1) reported that it did not have any members appointed. However, this HREC closed on 13 April 2013 and did not consider any proposals during the reporting period. The NHMRC will remind the other 12 HRECs of the membership requirements under paragraph 5.1.30 of the National Statement, particularly where an HREC had more than one issue identified with its core membership.
- Data handling and data linkage
- Diagnostic services
- Disability and disability services
- Ethics (applied, professional, research and bio-)
- Forensic pathology
- Hospital administration
- Information security
- Microbiology
- Midwifery
- Medical administration
- Medicine
- Nursing
- Organ donation/tissue typing
- Pharmacy
- Philosophy
- Privacy issues
- Public health
- Qualitative research
- Rehabilitation
- Research governance
- Social science, services and policy
- Sociology
- Statistics
- Theology

Institutional and non-institutional members

Twenty-four (24) HRECs reported less than the desired one-third of membership from outside the institution (as per paragraph 5.1.29 of the National Statement); with one (1) HREC reporting that all members were affiliated with the institution (see page 4 for detail regarding lay members).

Gender balance

The desired gender balance of an HREC is 50:50 (as per paragraph 5.1.29 of the National Statement). Twenty (20) HRECs reported a less than a 70:30 gender balance (in either direction).

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7 This does not include the one (1) HREC that reported no appointed members for the reporting period. This HREC closed on 13 April 2013 and did not consider any proposals during the reporting period.
4. HREC Meetings

Two hundred and seven (207) of the 218 HRECs reported that the HREC had considered research proposals during the reporting period. Of these, 97 (46.9%) 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, all but six (6) HRECs reported that all members were given the opportunity to comment on a proposal before a decision was reached.\(^8\)

**Number of meetings**

The distribution of the number of meetings held by HRECs during the reporting period is shown in Figure 1.\(^9\)

Ninety-eight percent (98.1%) of HRECs (n=203) that considered research proposals during the reporting period reported that they had between one (1) and 15 meetings during 2013. The maximum number of meetings held by any one HREC during the reporting period was 59 (n=1). This HREC also reported a total of 14 HREC members, with 576 proposals considered.

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\(^8\) One (1) HREC did not report on whether all members were given the opportunity to comment on a proposal before a decision was reached.

\(^9\) Eleven (11) HRECs reported that they did not hold any meetings during the 2013 reporting period and they also did not consider any research proposals during this time.
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 1613 (n=1) and the lowest number of proposals was one (1) (n=1). The HREC that reported considering 1613 research proposals met 23 times and consisted of a pool of 56 members.

Figure 2
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></th>
<th></th>
<th></th>
<th></th>
<th></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>
<td>24,882</td>
</tr>
<tr>
<td>Total research proposals approved</td>
<td>22,203</td>
<td>23,283</td>
<td>24,540</td>
<td>22,551</td>
</tr>
<tr>
<td>Total research proposals denied ethical approval</td>
<td>1,493</td>
<td>1,739</td>
<td>1,717</td>
<td>2,331</td>
</tr>
<tr>
<td>Highest number of proposals approved by an HREC</td>
<td>1,351</td>
<td>1,341</td>
<td>1,344</td>
<td>885</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>
<td>153</td>
</tr>
<tr>
<td>Total number of LNR proposals considered by HRECs&lt;sup&gt;10&lt;/sup&gt;</td>
<td>Not recorded</td>
<td>13,830</td>
<td>15,050</td>
<td>15,569</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>
<td>137</td>
</tr>
</tbody>
</table>

**Specific types of research (as identified in Section 3 of the National Statement)**

| Number of proposals approved involving clinical trials          | 2,617               | 2,564               | 2,471               | 2,522               |
| Number of proposals considered involving research and/or innovations involving human gametes or excess assisted reproductive technology (ART) embryos | 12                  | 17                  | 22                  | 19                  |

<sup>10</sup> This data is considered unreliable, as it is evident that the questions relating to LNR research were interpreted differently by different institutions (See also Section 7, page 12 of this report). This will be addressed in the HREC annual report for the 2014 reporting period.
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></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>
<td>2,732</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>
<td>1,111</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>
<td>367</td>
</tr>
<tr>
<td>Number of proposals approved involving people in dependent or unequal relationships</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>2,659</td>
<td>3,670</td>
</tr>
<tr>
<td>Number of proposals approved involving people highly dependent on medical care who may be unable to give consent</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>647</td>
<td>907</td>
</tr>
<tr>
<td>Number of proposals approved involving people who may be involved in illegal activities</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>194</td>
<td>363</td>
</tr>
<tr>
<td>Number of proposals approved involving people in other countries</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>1,476</td>
<td>1,588</td>
</tr>
</tbody>
</table>

11 See Section 6 (page 11) of this report for a discussion on research involving Aboriginal and Torres Strait Islander Peoples.
Figure 3

Number of HRECs that considered specific types of research / participants in 2013

- Children/young people: 71.6%
- Cognitive impairment/intellectual disability/mental illness: 64.7%
- Dependent/unequal relationships: 60.1%
- Pregnant women & the human foetus: 33.5%
- Highly dependent on medical care: 58.1%
- Illegal activities: 31.2%
- People in other countries: 33.5%
- Clinical trials: 61.9%
- Excess ART embryos & human gametes: 5.0%
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.

During the reporting period, 111 HRECs (50.9%) considered research involving Aboriginal and Torres Strait Islander Peoples. Of these HRECs, 105 reported that they used the Values and Ethics Guidelines when considering proposals. The total number of health research proposals involving Aboriginal and Torres Strait Islander Peoples considered during the reporting period was 859. Of these, 832 were approved and 27 were denied ethical approval. This data is shown in Table 6.1.

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Total number (2011)</th>
<th>Total number (2012)</th>
<th>Total Number (2013)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of health research proposals considered involving Aboriginal and Torres Strait Islander Peoples</td>
<td>917</td>
<td>877</td>
<td>859</td>
</tr>
<tr>
<td>Health research proposals involving Aboriginal and Torres Strait Islander Peoples approved</td>
<td>890</td>
<td>844</td>
<td>832</td>
</tr>
<tr>
<td>Health research proposals involving Aboriginal and Torres Strait Islander Peoples denied ethical approval</td>
<td>27</td>
<td>33</td>
<td>27</td>
</tr>
</tbody>
</table>

The highest number of health research proposals involving Aboriginal and Torres Strait Islander Peoples considered by any one HREC was 131.

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

- Absence of additional information requested by the HREC;
- Flawed, inappropriate or unclear research design and methodology;
- Inadequate information included in the application;
- Inadequate justification for conducting the research;
- Lack of community consultation, engagement and support;
- Lack of cultural appropriateness;
- Research not satisfying the principles and requirements of the National Statement;
- Researcher requested retrospective approval; and
- Researcher withdrew their application.

Fifty-one (51) HRECs (23.4%) included at least one person who identified as Aboriginal and/or Torres Strait Islander in its membership.

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12 Of the six (6) HRECs that did not use the NHMRC Values and Ethics Guidelines; three (3) HRECs used guidelines developed by the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS); two (2) HRECs reviewed proposals that had already been approved by a specialised Aboriginal Health and Ethics Committee; and one (1) HREC reviewed a proposal that was being conducted by researchers from an Aboriginal community and the community was well consulted and represented on the project steering group.
7. Non-HREC levels of ethical review for low risk research proposals

The data collected on the number of low or negligible risk (LNR) proposals considered by HRECs during the 2013 reporting period is listed in Table 5.1 (page 8). However, as identified previously (in Table 5.1), 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 issue will be addressed in the HREC annual report for the 2014 reporting period. For this reason, this report will not further analyse the available data in relation to the number of LNR applications.

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

Non-HREC level review

Approximately 74% of HRECs that considered research proposals during 2013 reported that the host institution had established a mechanism for ethical review other than by an HREC for research that carries only low or negligible risk (n=153). These mechanisms included:

- Approved by Access Request - site approval accepted and project approved following site approval;
- Checklist completed by the HREC Chair and secretary and reported to the HREC;
- Flowchart process for consideration as per national standards;
- Low risk applications reviewed by trained ethics reviewers within the institution and a sample of these applications are called in for further review by request of the HREC. All low risk proposals are noted by the HREC;
- Online Expedited Ethical Review system;
- Peer reviewed, then assessed by an appropriate expert reviewer and the HREC Chair;
- Reciprocal approval between state health sites, HREC approval accepted and project approved following site assessment;
- Researcher completes and signs an ethics checklist to retain as an auditable record with their project documents;
- Review by an institutional committee (advisory, research, faculty, school, departmental, executive, expedited review committee or working party)*;
- Review by HREC Chair and institutional representative (such as the Operations Manager, Director of Medical Services and Manager Social Responsibility and Ethics)*;
- Review by HREC Chair (or delegate), with reference to a sub-committee if deemed necessary;
- Review by HREC Chair (or Deputy Chair), as well as HREC member/s and/or HREC support officer/s*;
- Review by HREC convenor;
- Review by HREC executive committee or panel*;
- Review by institutional executive (head of institution or director)*;
- Review by non-HREC panel, reviewer or advisor*;
- Review by senior scientists;
- Review by staff of the institution’s Research Governance and/or Research Ethics Department (secretariat, HREC coordinator or executive officer)*; and
- Sub-committee, or panel set up specifically to review LNR applications (sometimes via email)*.

* Some institutions reported that the outcome is then ratified by the institution’s HREC and/or 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(^{13})</th>
<th>Percentage of HRECs(^{14})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Established reporting mechanism between institution and HREC</td>
<td>206</td>
<td>99.5%</td>
</tr>
<tr>
<td>Minutes of HREC meetings provided to management level of institution</td>
<td>135</td>
<td>65.2%</td>
</tr>
<tr>
<td>Regular (at least annual) HREC reports provided to management level of institution</td>
<td>170</td>
<td>82.1%</td>
</tr>
<tr>
<td>Other</td>
<td>47</td>
<td>22.7%</td>
</tr>
</tbody>
</table>

The ‘Other’ reporting mechanisms reported by HRECs included:

- A committee has been established involving the institution (executive staff/board members) and the HREC (HREC Chair and executive officers);
- Ad hoc communication between the HREC Chair, head of the institution (or delegate) and executive officer regarding complaints or other issues arising;
- All HREC research protocols are recommended for approval to institution's management (and/or legal team);
- Annual joint meeting of the institution’s HREC and board;
- Any issues requiring management action are bought to the executive's attention via email or more formal notification where required;
- Approved projects are selected for audit and educative purposes at HREC meetings;
- Articles provided for institutional newsletter on HREC activity;
- Each school committee provides a list of projects approved to the HREC;
- Executive staff approves payments to external independent committee members;
- Executive staff review and approve annual reporting provided to NHMRC and other areas;
- HREC Chair is a member of an institutional advisory group, committee, executive management group, or annually attends the institutional board meeting;

\(^{13}\) HRECs may select more than one reporting mechanism.

\(^{14}\) Based on the 207 HRECs that reviewed research proposals during the reporting period.
• Institutional representative (such as an executive staff member, board member or their nominee) is either a member of the HREC or is invited to attend HREC meetings;
• Meetings between executive staff, board of the institution, HREC Chair and HREC support staff on a regular or as required basis;
• Minutes from HREC meetings are stored on official organisational files;
• Provision of briefing papers, research material or advice to the institution (executive staff, board members, council, committees or sub-committees) advising of issues requiring attention or action on a regular basis or upon request; and
• Provision of monthly, bi-monthly, quarterly, half yearly and/or annual reporting to the institution on HREC activities.
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 (Chapter 5.5: Monitoring Approved Research). Some HRECs have monitoring requirements that are additional to these minimum requirements. Table 9.1 and the subsequent list provides information on the reported processes used to monitor research during the reporting period.

<table>
<thead>
<tr>
<th>Process</th>
<th>Number of HRECs using the process(^\text{15})</th>
<th>Percentage of HRECs(^\text{16})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reports on each project, received at least annually</td>
<td>200</td>
<td>96.6%</td>
</tr>
<tr>
<td>At least the minimum requirements as described in the National Statement(^\text{17})</td>
<td>194</td>
<td>93.7%</td>
</tr>
<tr>
<td>Adverse event reports</td>
<td>182</td>
<td>87.9%</td>
</tr>
<tr>
<td>Requirements to publish results/notify HREC of research publications</td>
<td>142</td>
<td>68.6%</td>
</tr>
<tr>
<td>Reports from independent agencies</td>
<td>73</td>
<td>35.3%</td>
</tr>
<tr>
<td>HREC interview with researcher</td>
<td>66</td>
<td>31.9%</td>
</tr>
<tr>
<td>Site visits/audits of research documentation</td>
<td>40</td>
<td>19.3%</td>
</tr>
<tr>
<td>Appointment of ‘monitors’ from HREC or within organisation</td>
<td>22</td>
<td>10.6%</td>
</tr>
<tr>
<td>Random inspections of research sites</td>
<td>18</td>
<td>8.7%</td>
</tr>
<tr>
<td>Other</td>
<td>18</td>
<td>8.7%</td>
</tr>
</tbody>
</table>

The ‘Other’ processes used by HRECs to monitor research included:

- Contact details for HREC included on Information Sheets and Plain Language Statements;
- Database audit of HREC approved research;
- Existing state research governance mechanisms, e.g. Site Specific Assessment (SSA);
- Feedback, comments and/or complaints from research participants or organisations and communities where research is being conducted;
- HREC requests a copy of the findings that are made available to interested participants;

\(^{15}\) HRECs may select more than one process for monitoring research.

\(^{16}\) Based on the 207 HRECs that reviewed research proposals during the reporting period.

\(^{17}\) Reasons for not meeting the minimum requirements are discussed in this section, under the heading ‘Minimum monitoring requirements’ (page 16).
- Independent safety and monitoring committees established for clinical trials where appropriate;
- Low risk approvals regularly audited by a sub-committee;
- Monthly or quarterly updates provided to the institution (committee and board);
- Ongoing contact with researchers which may include informal review;
- Publications arising from projects granted ethical approval are located and made available to the HREC;
- Quarterly reporting;
- Randomised self-audit;
- Reporting conditions included on the HREC’s approval letter to researchers (for protocol deviation, amendments or serious adverse events);
- Researchers requested to advise all sites involved in research when research is multi-site;
- Researchers required to report protocol deviations and violations;
- Researchers undertaking Masters and PhD programs have a supervisory panel;
- Sub-committee of HREC separately reviews and monitors adverse events; and
- Voluntary reporting from researcher related to a request for advice from the HREC.

Minimum monitoring requirements

Six percent (6.3%) of HRECs (n=13) reported that they did not meet the minimum monitoring requirements as set out in Chapter 5.5 of the National Statement. Of these HRECs:

- Ten (10) reported that the HREC did not encounter any problems in monitoring the research; 19
- One (1) reported that it did encounter problems in monitoring approved research (see below); and
- Three (3) reported that they do not have any monitoring procedures in place for approved research. 20

Problems encountered in monitoring approved research

Seventy-two (72) HRECs reported that they encountered problems in monitoring approved research. The reported problems included:

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

Of the 72 HRECs, one (1) reported that the problems had not been communicated to an appropriate level of management within the institution and one (1) reported that it did not have monitoring procedures in place that were at least as per the minimum requirements as described in the National Statement. 21

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18 These 13 HRECs included those that had no monitoring procedures in place at all, as well as those that did have monitoring procedures in place but were not at least the minimum requirements as set out in Chapter 5.5 of the National Statement.
19 The NHMRC will remind the institutions responsible for these HRECs of the minimum monitoring requirements.
20 The NHMRC will remind the institutions responsible for these HRECs of their responsibility to monitor all approved research.
21 The NHMRC will also raise concerns with the institutions responsible for these HRECs, to ensure that each institution is reminded of its 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.

Of the 207 HRECs that considered research proposals during the reporting period:

- All reported that the institution responsible for the HREC had a mechanism for receiving and handling complaints or concerns about researchers or the conduct of approved research projects; and
- All but one (1) reported that the institution responsible for the HREC had procedures for receiving and handling concerns or complaints from researchers about the conduct of the HREC in consideration of their research proposal.22

Types of complaints received

The data collected shows that 51 HRECs received a combined 145 complaints regarding the conduct of an approved research project.23 The highest number of complaints received by any one HREC was 28; of which related to poor researcher communication (manner and amount); inability to contact researchers; contact/request to be in research; access to patient information (privacy); reimbursement; respect; ethical acceptability of project; and management at another site.

The data also shows that 15 HRECs received a combined 20 complaints from researchers about the ethical review process. This data is shown in Table 10.1.

**Table 10.1 Number of complaints or concerns received by HRECs**

<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>145</td>
<td>28</td>
</tr>
<tr>
<td>Complaints received from a researcher about the consideration of their research proposal by the HREC</td>
<td>20</td>
<td>4</td>
</tr>
<tr>
<td>Complaints received about projects that involved Aboriginal and Torres Strait Islander peoples</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

22 This one (1) HREC reported that any complaints received are dealt with by the HREC and referred to a State body for consideration.
23 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 19 of this report).
Complaints received about the conduct of approved research projects related to the following issues:

- Access to treatment following completion of the study;
- Administrative errors (participant response lost in the mail and a reminder was sent, participant contacted at incorrect address, participant incorrectly charged for a cancelled appointment);
- Belief that the research was biased;
- Breach of approved protocol;
- Clinical circumstances not resolved through involvement in trial;
- Concern about a research topic as seen in an advertisement;
- Concerns about health issues of participants;
- Conduct of the researcher, research assistant or contracted interviewer;
- Confidentiality of study participant documentation and data, as well as breaches in confidentiality (contacting family members without the participant’s consent);
- Conflict of interest;
- Consent processes (including opt-out);
- Data security;
- Ethical acceptability of a research project;
- Errors in reporting individual results to participants;
- Inappropriate actions by a third party;
- Injury caused by research;
- Intellectual property dispute among co-researchers;
- Lack of information or inappropriate information given to the participant group;
- Lengthy delays for participants at study visits and in actioning steps in the research protocol;
- Modification to research methodology without prior approval from the HREC;
- Participants not informed that test results would be provided;
- Potential Serious Adverse Event not included in Participant Information Sheet and Consent Form;
- Privacy concerns and breaches;
- Receipt of unsolicited material;
- Recruitment (including contact prior to the participant receiving their diagnosis, breach of recruitment protocols, grieving families receiving correspondence about/or deceased family members, content in advertisement, unhappy about being approached to participate, family members unhappy about recruitment, coercion, identification and/or contact of potential participants, time taken to recruit, lack of information provided to participants followed by miscommunications and misunderstandings, and exclusion criteria);
- Reimbursement (including variability);
- Research conducted in an inappropriate, irresponsible, discriminatory and/or disrespectful manner;
- Research conducted without appropriate approval or misunderstandings on requirements for approval;
- Treatment of participants (including vulnerable populations); and
- Validity of research.

Complaints received from researchers about the consideration of their research proposal by an HREC related to the following issues:

- Dissatisfaction or disagreement with the HREC’s decision (relating to HREC review comments, requests for further information, research being greater than low risk, denial of ethical approval, and consent);
- HREC comments extending into methodology;
- HREC lack of expertise in reviewing research;
- HREC processes;
- HREC sub-committee terms of reference not being readily available (now rectified);
- Impact of local legislation;
- Incorrect belief that researchers cannot address the committee directly;
- Issues of consistency and criteria for the level and type of ethical review;
- Projects reviewed and then deemed not research;
- Requesting inappropriate amendments that are not feasible to implement;
- Study not approved outright without the opportunity for the researcher to respond to HREC concerns;
- Sub-committee request for additional information; and
- Time taken to attain HREC approval for research projects and amendments to protocols.
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. 24

24 www.nhmrc.gov.au
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 2013. Where HRECs have not met the minimum requirements with regard to membership and the 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 hrec.reports@nhmrc.gov.au.