Human Research and Ethics Review Project
Office of the PVC (Research and Innovation)
RMIT University

Consultant’s Report

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Abbreviations

AHEC – Australian Health Ethics Committee
HREC – Human Research Ethics Committee
LHREA – Local Human Research Ethics Advisor
NEAF – National Ethics Application Form
NH&MRC – National Health and Medical Research Council
PHRESC – Portfolio Human Research Ethics Sub-Committee
PVC (R&I) – Pro Vice Chancellor (Research and Innovation)
1. Introduction

The PVC (R&I) engaged the Consultant for up to 15 days to review existing arrangements regarding:

- governance of human research ethical review and committee practice at both levels of ethical review (HREC and PHRESCs);
- support for researchers, and research training, about human research ethics; and
- administration practices related to human research ethical review.

The Terms of Reference for the Consultancy are at Appendix A, on page 33.

Management of the Consultancy rested with the Project Steering Committee. (The Committee’s membership is listed at Appendix B on page 35).

Discussions between the Consultant and the Project Steering Committee during the course of the Review resulted in some fine-turning to the original Terms of Reference. This fine-tuning included reconsideration of the Sub-Committee model for second level ethics review.

The Consultant met with 17 people who are involved in ethical review, or who have submitted (or whose students have submitted) applications for ethical review. In addition, one written submission was received. Those consulted included

- Postgraduate and Research Co-ordinators
- members of the RMIT University HREC (including two external members);
- Chairs of PHRESCs;
- general staff responsible for research administration and for secretariat support to PHRESCs.

Consultation involved academic and general staff from each of three Portfolios.

Staff providing secretariat support to PHRESCs provided specific assistance by reviewing applications for ethical review dealt with by PHRESCs over recent months. This work formed the basis for an estimate of how many of applications in future would require review by the HREC under the categorisation of risk in the National Statement on Ethical Conduct in Human Research (2007). The outcomes of this work are incorporated in Section 6 of this Report.

While some inquiries were made of institutions which support HRECs, time limitations did not allow for systematic or detailed inquiries. Internet searches were conducted for relevant information.
2. Context for the RMIT University Human Research and Ethics Review Project

This Review project was prompted by several matters.

First, in 2005 organisational responsibility for support to the HREC moved from the Chancellery to the Office of the PVC (R&I).

Second, the National Statement on Ethical Conduct in Human Research (2007), prepared by the NH&MRC, was tabled in the Commonwealth Parliament in late March 2007. The National Statement (2007) replaces the 1999 National Statement. It provides explicit guidance on aspects of human research ethics, and on the responsibilities of institutions which undertake ethical review. This Report is primarily concerned with Section 5 of the National Statement (2007) – ‘Processes of Research Governance and Ethical Review’ (pp. 77-96).

Third, in May 2006 the NH&MRC released the NEAF for public use. Revision of the NEAF, to reflect the provisions of the National Statement (2007), is scheduled for completion by July 2007. Decisions about use of the NEAF in RMIT University’s ethical review processes were deferred pending finalisation of the National Statement (2007).

Fourth, RMIT University is seeking to expand its research output. Expansion may result in more research involving humans and, consequently, increased numbers of applications for ethical review. Changes to risk categorisation in the National Statement (2007) could increase the number of applications that must be reviewed by the HREC, but it is as yet unclear how the balance will alter between HREC and non-HREC levels of review. Both anticipated expansion and changes to risk categorisation suggest a need to establish a flexible basis for ethical review so that RMIT University can respond effectively to variation in the numbers of applications for ethical review.

In addition, the new Australian Code for the Responsible Conduct of Research, still in draft form, is expected to be finalised in coming months. While the provisions of the new Code are as yet unclear, the draft issued for consultation in February 2006 covers many matters closely related to the provisions of the National Statement (2007). The draft Code makes numerous references to ethics in human research and ethical review, and both documents refer to matters such as data storage and protection, and complaints handling.
3. Views on, and attitudes towards, human research ethical review within RMIT University

It is important to capture the breadth of views about, and attitudes towards, ethical review current within RMIT University. It is acknowledged that the perceptions presented below are based on interviews with a small number of people. However, common threads can be identified. The extensive engagement of interviewees in research, research administration, research training, and human research ethical review, suggests that the views are reliable enough as a basis for generalisation.

The nature of these views has guided the formulation of many of this Report’s recommendations.

There are five salient observations.

First, most interviewees indicated that a view exists amongst many academics and students that ethical review is an irritant, as something separate from research rather than an integral part of high quality research design and practice. The view expressed might be summarised in this way: many staff and students see ethical review as a bureaucratic and pedantic process that gets in the way of research, or slows research down, or discourages people from doing research involving human subjects – the ethical review process is regarded as disproportionate to the risks involved.

Second, those involved in ethical review are dedicated to their roles. They see ethical review as important. By and large, they do not feel well-supported in this role through either training or adequate recognition via workload allocations.

Third, it seems clear that most staff are unfamiliar with the 1999 National Statement, now superseded by the National Statement 2007. Few interviewees were familiar with the draft National Statement 2007, and fewer had read the final version.

Fourth, there are some complaints about the timeliness of ethical review processes within RMIT, but in general this is not a problem. There are more frequent complaints about other matters, including: limited expertise on some committees regarding research in the disciplines from which ethics applications come; the straying of some ethical review committee members into commentary and decision-making about research methodology rather than focussing on ethics; confusing application forms; uncertainty about the basis on which risk assessments are made.

Fifth, and closely related to the last point, it seems some aspects of ethical review about which people complain are seen as being imposed unnecessarily by RMIT University. In fact, they are mechanisms the university required in order to respond to the requirements of the 1999 National Statement.

The presence of these perceptions suggests a need for leadership in ethics, training and support for those involved in ethical review, and adequate advisory mechanisms and training/information for researchers, supervisors, and students.
4. Existing RMIT University model for human research ethical review

4.1 Structure of the existing model

RMIT operates two levels of ethical review related to research involving humans. These are:

- the HREC, registered with the AHEC;
- five PHRESCs (two each in DSC and SET, and one in Business).

Three categories of risk were identified under the 1999 National Statement – Risk Level 1 (low risk), Risk Level 2 (medium risk) and Risk Level 3 (high risk). In general terms, the HREC reviews high risk research proposals and PHRESCs review medium and low risk research proposals. Research proposals involving human subjects, and which are considered to have negligible or no risk, are exempted from review. There is no formal process whereby exemption is granted.

Some committees have mechanisms in place which provide for expedited review. However, this avenue is not available to all researchers/students, and the mechanisms vary.

The Chair of each PHRESC serves as a member of the HREC.

PHRESC Chairs, and some PHRESC members, provide advice about applying for ethical review, and most PHRESC chairs offer training in varied forums and formats. The Ethics Executive Officer, located in the Office of the PVC (R&I) also provides advice to researchers on applications for ethical review. There is wide variation in the extent to which advice is sought by researchers and students, and in the nature and extent of advice and training available to them.

4.2 Reported time commitment to the existing RMIT University ethical review model

PHRESCs – time commitment by academics

Under existing arrangements, each PHRESC comprises a minimum of six ordinary academic members, and another academic who acts as Chair. Each PHRESC has secretariat support provided by general staff.

Reported time commitments for PHRESC Chairs are shown in Table 1 – the hours shown include the involvement of Chairs on the HREC. It is noted that the hours required change from month to month, depending on demands for training, expedited review and informal advice. In addition, there are spikes in
demand due to the flow of coursework applications which are governed by academic program timelines.

Table 1  Reported time commitment to ethical review by PHRESC Chairs

<table>
<thead>
<tr>
<th>Portfolio PHRESCs</th>
<th>Number of PHRESCs</th>
<th>Hours per month per Chair</th>
<th>Total hours per month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business</td>
<td>1</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>DSC</td>
<td>2</td>
<td>40</td>
<td>80</td>
</tr>
<tr>
<td>SET</td>
<td>2</td>
<td>40</td>
<td>80</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>5</strong></td>
<td></td>
<td><strong>190 hours per month</strong></td>
</tr>
</tbody>
</table>

Approx. full time equivalent of 190 hours\(^2\) 1.2 positions

1. These hours include PHRESC Chair hours committed to HREC membership.
2. A 36 hour week is used to calculate full time equivalent positions.

Reported time commitments for ordinary academic members of PHRESCs are shown in Table 2.

Table 2  Reported time commitment to ethical review by ordinary PHRESC members

<table>
<thead>
<tr>
<th>Portfolio PHRESCs</th>
<th>Number of PHRESCs</th>
<th>Number of ordinary academic members by Portfolio</th>
<th>Hours per month - ordinary members</th>
<th>Total hours per month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business</td>
<td>1</td>
<td>6</td>
<td>5</td>
<td>30</td>
</tr>
<tr>
<td>DSC</td>
<td>2</td>
<td>12</td>
<td>7</td>
<td>84</td>
</tr>
<tr>
<td>SET</td>
<td>2</td>
<td>12</td>
<td>7</td>
<td>84</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>5</strong></td>
<td><strong>30</strong></td>
<td></td>
<td><strong>198 hours per month</strong></td>
</tr>
</tbody>
</table>

Approx. full time equivalent of 198 hours\(^1\) 1.3 positions

1. A 36 hour week is used to calculate full time equivalent positions.

The reported commitment of hours to PHRESCs made by academics across RMIT University – both for Chairs and ordinary members – amounts to 2.5 full time equivalent academic positions.

Time commitment of general staff to HREC and PHRESCs

The reported time committed to ethical review by general staff is shown in the Table 3. It is noted that the hours required can change over time depending on demands for expedited review and informal advice. In addition, there are spikes in demand due to the flow of coursework applications which are governed by academic program timelines.
Table 3  Reported time commitment to ethical review by general staff

<table>
<thead>
<tr>
<th>Level of ethical review</th>
<th>Hours per month - general staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business PHRESC</td>
<td>60</td>
</tr>
<tr>
<td>DSC PHRESC (x2)</td>
<td>90</td>
</tr>
<tr>
<td>SET PHRESC (x2)</td>
<td>84</td>
</tr>
<tr>
<td>HREC</td>
<td>72</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>306 hours per month</strong></td>
</tr>
</tbody>
</table>

Approx. full time equivalent of 306 hours (36 hour week) 2.1 positions

Time commitment of external HREC members

The reported hours noted above do not include the hours committed by external members of HREC.

The HREC Chair indicates that her role involves approximately 8-8.5 hours per month. This includes meeting preparation, meeting attendance, meeting follow-up and travel time.

One external member reports a time commitment of 5-6 hours per month. This includes meeting preparation, meeting attendance, meeting follow-up and travel time.

The attendance of external members at HREC meetings has been patchy in recent months so it is difficult to generalise about the total number of hours involved for them. Nonetheless, the reported hours noted here represent a substantial commitment to RMIT University on a voluntary and unpaid basis.
5. Ethical review under the National Statement (2007)

5.1 Why respond to the National Statement (2007)?

The *National Statement (2007)* does specify dates by which institutions must complete transition from the 1999 National Statement. The *National Statement (2007)* is a set of guidelines issued by the NH&MRC as part of its statutory requirement. It is not a set of prescriptive regulations.

Nonetheless, there are compelling reasons for adopting them as soon as possible – for example:

- the NH&MRC requires that organisations receiving NH&MRC funding have, or have access to, an HREC registered with it;
- the ARC requires that, to qualify for its funding, research proposals involving humans have approval from an HREC established and operating in accordance with the *National Statement (2007)*;
- to ensure that annual reporting to the AHEC indicates substantial progress in the transition to the new Statement and to ensure that HREC registration is maintained;
- adoption is a clear demonstration to the wider research and general community that the institution abides by the highest ethical standards for human research;
- multi-centre applications can be compromised where a participating centre does not have ethical approval from a HREC established and operating in accordance with the *National Statement (2007)*.

**Recommendation 1**

That the Office of the PVC (R&I) adopts a specific date, and preferably one not later than November 30, 2007, by which it intends that RMIT University will meet the organisational requirements of the *National Statement (2007)*.

5.2 Important changes under the National Statement (2007), and their effects on RMIT University’s model of ethical review

Three changes under the *National Statement (2007)* impact significantly on the existing RMIT University’s model of ethical review. They are:

- changes to risk categorisation;
- determining exemption from ethical review; and
- specifying that research of certain kinds must be reviewed by a HREC.

Important effects of these changes include:

- a likely shift in the balance of work between the levels of ethical review;
• in the case of exempting research from ethical review, expansion of the work which must take place in the formal domain of ethical review;
• the need to develop or redevelop a range of policies and procedures regulating ethical review;
• the need to provide adequate training and support to academic and general staff, and to students, about the requirements of the National Statement (2007).

5.3 How the changes impact on HREC and PHRESC workloads

Categorisation of risk

The National Statement (2007) alters the categorisation of risk. Risk is now assessed as follows:
• High risk – potential for harm (defined widely and including physical, psychological, financial, legal and social harms);
• Low risk – where the only foreseeable risk is one of discomfort;
• Negligible risk – where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.

At Appendix D is an extract from the National Statement (2007) which provides examples of how risk is categorised.

High risk research proposals must be reviewed by an HREC. Low risk proposals can be considered at a lower level of ethical review. Lower levels of review must be overseen by an HREC.

Determining exemption from ethical review

It is important to note that proposals entailing only negligible risk may be exempted from ethical review. However, it is equally important to note the following section from the National Statement (2007):
• 5.1.23 Institutions must recognise that in deciding to exempt research from ethical review, they are determining that the research meets the requirements of this National Statement and is ethically acceptable.

In effect, where a proposal is granted exemption from ethical review by RMIT University, that exemption is considered to be a formal warrant on behalf of RMIT University that the research proposal entails no more than negligible risk.

In risk management terms, it is in RMIT University’s interests to ensure any exemption from ethical review is granted only by a person who has delegated authority to provide such a warrant.
Kinds of research which must be reviewed by an HREC

While there are exceptions relating to research using non-identifiable data, section 5.1.6 of the *National Statement (2007)* provides a list of types of research that require review by an HREC. Of these, there are three groups of human subjects who are involved often in RMIT University research, and each of these three groups are listed in section 5.1.6. The three groups are:

- people with a cognitive impairment, an intellectual disability, or a mental illness;
- Aboriginal and Torres Strait Islander People;
- and some categories of research involving people who may be involved in illegal activities.

Until now, most RMIT University research proposals involving the first two of these groups have been reviewed by PHRESCs. Under the *National Statement (2007)*, all such proposals must be reviewed by an HREC.
6. Impact of key changes on RMIT University’s existing ethical review model

6.1 Impact of changes on HREC and PHRESC ethical review workloads

It is important to assess the impact of the changes identified in 5.2 above on the operation of the existing RMIT University model for ethical review.

In 2006, the RMIT HREC considered 23 high risk applications. Will the changes to risk categorisation contained in the National Statement (2007) change the number of applications that must be considered by the HREC?

One way of responding to this question is to estimate how many applications lodged for PHRESC review in the last 12 months would require HREC review in future. Staff providing secretariat support to PHRESCs undertook this task. The outcomes are shown in Table 4.

**Table 4  Reported time commitment to ethical review by general staff**

<table>
<thead>
<tr>
<th>Portfolio PHRESCs</th>
<th>Risk Level 2 applications considered over last 12 months</th>
<th>Estimated Increase in number of applications referred for HREC review under provisions of the National Statement (2007)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business</td>
<td>117</td>
<td>0</td>
</tr>
<tr>
<td>DSC</td>
<td>140</td>
<td>11</td>
</tr>
<tr>
<td>SET</td>
<td>141</td>
<td>15-20 (possibly higher than 20)</td>
</tr>
<tr>
<td><strong>Total estimated increase in number of applications requiring HREC review</strong></td>
<td><strong>26-31 (possibly higher than 31)</strong></td>
<td></td>
</tr>
</tbody>
</table>

While this work cannot be precise about future demands, it seems very likely there will be significant growth in the number of ethical review applications flowing to the HREC. RMIT University’s intention to lift research output may further add to that growth.

Based on past performance, it is unlikely that the RMIT University HREC will be able to perform its review functions in a timely manner.

Should there be overall growth in the number of research proposals involving human subjects, most of the additional applications will flow to the PHRESCs, imposing additional workloads on them, and particularly the Chairs.

The need formally to exempt a research proposal from ethical review must also be dealt with through the ethical review model. Under the existing RMIT University model for ethical review, it is most likely that formal delegation to grant exemption would be vested in a PHRESC member, possibly the Chair.
7. Proposed model for ethical review

7.1 Overview of the proposed model

Section 7 of this Report outlines a proposed model for ethical review at RMIT University. The model seeks to:

• deliver high profile leadership for ethical review;
• support smooth implementation of the *National Statement (2007)*;
• target advice and support to those applying for ethical review;
• respond flexibly to potential growth in applications for ethical review.

Key aspects of the proposed model are:

• significant adjustments to the composition of the HREC;
• establishment of Local Human Research Ethics Advisors at the school level;
• application of a systematic and comprehensive monitoring, quality assurance and audit model to ensure the practice and governance of ethical review is conducted in accordance with the provisions of the *National Statement (2007)*.

7.2 Preliminary rethinking of the allocation of existing resources

There is an existing resources platform for the proposed model.

The current RMIT University model of ethical review costs the equivalent of 2.5 academic and 2.1 general staff positions, as reported by interviewees. The 2.5 equivalent academic positions comprise fractional time contributions by up to 35 academics (see section 4.2). The majority of this time is spent in committee. A standard two hour monthly PHRESC meeting involving seven academics is, in fact, a 14 hour meeting (7 academics x 2 hours = 14 hours). There are five PHRESC meetings held in 11 months of each year.

The proposed model will assist in removing redundancy from those 14 hours per PHRESC meeting. In addition, general staff supporting committees will have time released from committee secretariat functions to support the maintenance of the proposed model.

Considerable work is required before RMIT University can meet the requirements of the *National Statement (2007)*. Resources will be required:

• to respond to changes in the number of applications requiring HREC review;
• to respond to changes in the number of applications requiring non-HREC review;
• to determine and grant exemptions from ethical review;
• to meet the need in the short term to implement the organisational requirements contained in the *National Statement (2007)*;
• to provide additional levels of support and advice to academics and students in the transition to the provisions of the National Statement (2007).

The dot point list above identifies both long term (first three dot points) and short term (last two dot points) resource implications.

Time constraints applying to this Review have not allowed detailed exploration of either the short term or long term resource implications. It is recognised that it is not ideal to propose a new model without some clarity about resource implications. That work needs to be done.

**Recommendation 2**

That the Office of the PVC (R&I) undertake modelling to assess the resource implications of the proposed model and implementation of the provisions of the National Statement (2007), both for short term transitional activity, and for longer term maintenance.

### 7.3 First tier ethical review under the proposed model – composition of the RMIT University HREC

**Overview**

The rules determining composition of the HREC are cited in sections 5.1.29-5.1.33 of the National Statement (2007). Within these rules there is considerable room for an institution to establish an HREC which meets its particular needs.

The proposed model incorporates five key changes in the composition of the HREC. These changes are set out in this section under the following headings:

- Chair and Deputy Chair of the RMIT University HREC;
- Establishment of a pool of inducted HREC members;
- External members of the RMIT University HREC;
- Appointment of HREC members.

Proposed changes to the composition of the HREC are no reflection on the significant service provided by existing members of the HREC. Indeed, in the interests of continuity, it would be wise for some existing HREC members to continue their service.

**Minimum requirements for composition of the RMIT University HREC**

The National Statement (2007) (see sections 5.1.29-5.1.33) sets out the minimum requirements for composition of an HREC. Amongst other things, the requirements are for a membership of no fewer than eight, and that this number must include:
• a chairperson, with suitable experience, whose other responsibilities will not impair the HREC’s capacity to carry out its obligations under this National Statement;
• at least two 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;
• at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people, for example, a nurse or allied health professional;
• at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
• at least one lawyer, where possible one who is not engaged to advise the institution; and
• at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

Optional elements in HREC composition

The National Statement (2007) (see sections 5.1.29-5.1.33) states that as far as possible:
• there should be equal numbers of men and women; and
• at least one third of the members should be from outside the institution for which the HREC is reviewing research.

In addition:
• institutions are encouraged to establish a pool of inducted members in each category who may attend meetings as needed to meet minimum HREC requirements, and may also be available to provide expertise for the research under review; and
• wherever possible one or more of the members should be experienced in reflecting on and analysing ethical decision-making.

Chair and Deputy Chair of the RMIT University HREC

This Report suggests that visible, accessible, hands-on leadership of ethical review within RMIT University is essential at this time for two reasons:
• first, to guide, and play an integral role in, the transition (within a tight timeframe) from existing arrangements for ethical review to arrangements which meet the requirements of the National Statement (2007), and then to secure the maintenance of the new arrangements;
• second, to support the adoption of a set of attitudes within the RMIT University research community that positively adopts ethical review as an integral part of high quality research design and practice where human subjects are involved.
It is suggested that RMIT University researchers will be well-disposed to ethical review leadership if the leaders are drawn from their own number, have a strong background in research and/or research administration, and are both accessible and visible in their conduct of their leadership roles. It is also suggested that leaders who are intimately familiar with the university’s culture and processes will be able to use their influence most effectively.

Recommendation 3
That both the HREC Chair and the Deputy Chair roles are filled by RMIT University academic staff, with the Chair being a member of the professoriate who has a strong research record and/or a strong background in research administration.

It may be appropriate to consider the appointment of a Chair and/or Deputy Chair drawn from disciplines that frequently engage in research involving high risk to human subjects.

Recommendation 4
That in the first instance, the HREC Chair be appointed on a specified time fraction of 0.4 and the Deputy Chair be appointed on a specified time fraction of 0.3.

The time fractions would be open to review as transition to the new arrangements is completed.

It is suggested that the Chair is tasked with two particular tasks:
- oversight of the development of a plan to provide training and information related to ethical review; and
- the development of the policies and procedures required to align RMIT University with the provisions of the National Statement (2007).

It is suggested that the Deputy Chair is tasked with overseeing implementation of arrangements for establishment of LHREA roles and to support the implementation of those roles.

Establishment of a pool of inducted HREC members

A reported cause of some concern amongst the RMIT University research community is the lack of familiarity by members of the HREC and PHRESCs with the nature of the research conducted within some disciplines. For low risk research, the proposal to establish LHREAs ameliorates this concern. However, for high risk research proposals (which must be considered by the HREC) it is likely that the credibility of ethical review will be enhanced by the availability to the HREC of people with relevant research expertise.
In addition, as RMIT University targets higher research outputs, it is likely that more multi-centre applications requiring HREC review will be forthcoming. The availability to the HREC of people with relevant research expertise is again likely to enhance credibility, both within and beyond the university.

The diversity of disciplines represented within RMIT University is too great to justify permanent HREC membership of people with relevant research expertise in all of them. However, research output in some disciplines is likely to grow at a greater rate than in others. This Report suggests, then, that RMIT University academics with research expertise in these disciplines become HREC members. Their presence at HREC meetings would be limited to:

- attendance when an application in their own or a cognate discipline are reviewed;
- acting as alternates for internal RMIT HREC members who cannot attend a HREC meeting.

Recommendation 5
That a pool of inducted members of the HREC be established to support ethical review in those disciplines where targeted growth in research output is greatest.

External members of the RMIT University HREC

External membership of the HREC can provide substantial benefits to RMIT University. Recruitment of highly competent external members will enhance the university’s reputation for research governance, will ensure that research activity is served by well-informed community views and perceptions, and will assist in forging connections between the university and its many publics.

To maximise those benefits it is important that some external members have a close appreciation of RMIT University’s mission and strengths, and the nature of its relationship with the community.

Recommendation 6
That at least two external membership positions on the HREC be filled by people with a close understanding of RMIT University’s mission.

Appointment of HREC members

Present arrangements for the HREC lack specific provisions for duration of membership, mechanisms for appointment, and the criteria by which potential candidates are selected.

The National Statement (2007):
- requires that open and transparent processes are used in the appointment of HREC members (see National Statement (2007), section 5.1.34);
• requires that institutions should consider reviewing appointments to the HREC at least every three years (section 5.1.34);
• explicitly states that members should be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion (section 5.1.35);
• requires institutions to provide an assurance of legal protection to all those involved in ethical review of research, for liabilities that may arise in the course of bona fide conduct of their duties in this capacity (section 5.1.9);
• publicise remuneration, if any, for members (section 5.1.27 (g)).

Taken together these provisions envisage transparency in appointments to the HREC, constant renewal of the HREC by knowledgeable and skilled individuals (both internal and external to RMIT University), and a recognition that ethical decision-making is often difficult and demanding.

Recommendation 7
That appointment to the HREC is by formal letter from the PVC (R&I).

Recommendation 8
That on formation of the new HREC, one half of the members be appointed for two years, and one half be appointed for three years (including the Chair), followed by two or three year appointments as negotiated with members.

Recommendation 9
That the PVC (R&I) seek advice from the RMIT University Solicitor concerning the nature of legal assurance that ought to be provided, under the terms of the National Statement (2007), to those involved in both HREC and non-HREC levels of ethical review.

Recommendation 10
That, in recognition of the value placed on the contribution of external members of the HREC, RMIT University offers an honorarium to those who accept appointment, at a level to be fixed by reference to any relevant RMIT University policies and precedents.

Training about ethical review for HREC members

HREC members must have access to training that supports their ethical review responsibilities. In particular, it is important that they are exposed as a group – including pool members – to differences between ethical and moral reasoning. It is also important that as a group they develop through training a capacity for ethical decision-making that manages competing standpoints. HREC members need also to define the boundaries of ethical decision-making which limit their responsibilities to the matters contained in the National Statement (2007).
This background will underpin strong ethical review, and contribute to both the efficiency and the effectiveness of the HREC. This will be an important advantage if there is growth in the number of applications the HREC must review, which appears likely.

It is suggested elsewhere (page 17) that the Chair of the newly constituted HREC be responsible for overseeing development of a plan to provide training and information related to ethical review at both HREC and non-HREC levels.

7.4 **Second tier ethical review under the proposed model - Local Human Research Ethics Advisors**

The *National Statement (2007)*, section 5.1.20, offers considerable flexibility in the mechanisms institutions may adopt for ethical review of low risk research. These include, but are not limited to:

- review or assessment at departmental level by the head of department;
- review or assessment by a departmental committee of peers (with or without external or independent members);
- delegated review with reporting to an HREC; or
- review by a subcommittee of an HREC.

The proposed model, based on the notion of delegated review with reporting to the HREC, disbands PHRESCs and in their stead establishes Local Human Research Ethics Advisors (LHREAs). The primary characteristics of LHREAs are that:

- they are academics;
- they have a workload allocation for ethical review, advice, training delivery and ethical review moderation that is based on the ethical review requirements of a school (or in some instances, two or more schools);
- all applications involving high risk would be thoroughly checked by LHREAs before progressing to the HREC as a key means of minimising HREC workload through ensuring that applications are sound in areas that frequently cause applications to be returned for amendment.

The *National Statement (2007)* requires that any non-HREC level of ethical review is appropriately monitored by the HREC and has appropriate support (see the *National Statement (2007)*, sections 5.1.7, 5.1.12, and 5.1.18-5.1.21).

It is noted again that up to 35 academics are involved in ethical review through PHRESCs, equating to 2.1 academic positions across the university. The number of LHREAs would be fewer. While it is uncertain what the long term full time equivalent would be, it is thought likely to be higher than 2.5 positions.
It is also important to note that monitoring, support and training requirements required under the *National Statement (2007)* apply to any second tier of ethical review, whether LHREAs or PHRESCs. In these matters, LHREAs do not represent an additional cost.

Again, this proposal does not imply any criticism of those who have served on PHRESCs. Indeed, it would be advantageous if many of them took up the proposed LHREA roles and some served on the HREC.

**Role of LHREAs**

LHREAs would be academics responsible for:
- ethical review of low risk applications;
- providing advice on the relevant university policy and procedures related to human research ethics and ethical review;
- issuing the formal warrant on behalf of the university that a research proposal is exempt from ethical review;
- providing advice, support and training to academics and students about the principles of ethical practice and the ethical review application process;
- thorough checking of all high risk applications to ensure that only complete and well-thought through applications are submitted for HREC consideration.

LHREAs would have, or would quickly develop, a high level of expertise in ethical review. Given the likelihood of increased application numbers flowing to the HREC, the thorough checking of them by LHREAs is critical to HREC performance. Applications for HREC review should be complete, aligned with policy, and meet known HREC expectations. Where common errors are encountered in applications reviewed by the HREC, these can be notified to LHREAs who can address them in future vetting, advice and training.

**Key reasons for establishment of LHREAs**

Establishment of LHREAs introduces leadership, advice and training for researchers and students that is accessible and flexible because it is provided as close as possible (in organisational design terms) to the researchers themselves. This has several advantages.

The development of local ethical review expertise and the accessibility of advice and support at the local level is considered likely to:
- reduce substantially levels of uncertainty and insecurity about ethical review and the application process, and
- encourage researchers to explore with greater confidence research designs involving human subjects.
Access to an LHREA who has an intimate knowledge of the discourse in a researcher’s discipline is likely to:

- encourage a positive attitude to ethical review as an integral component of high quality research; and
- maximise efficiency and timeliness of ethical review by both the LHREA and the HREC.

School-based location of LHREAs

LHREAs would be located in each school and would be drawn from academics in each school. Where a school has small numbers of applications for ethical review it is proposed that it share an LHREA with another school undertaking research in related disciplines.

LHREAs would require a workload allocation related to the level of need within their schools.

A number of universities use similar models for second tier ethical review. These include the University of Technology, Sydney, Curtin University of Technology, and Griffith University. The University of Newcastle adopted a similar model early in 2007.

Flexibility of, and accountability for, ethical review

Locating LHREAs at the school level makes a direct connection between the demand for ethical review and the allocation of resources to ethical review. School-based LHREAs offer the flexibility to increase or reduce workload allocations as the number of ethical review applications rises or falls over time. LHREAs present a flexible mechanism for managing spikes in activity resulting from, for example, a predictable and large number of applications for ethical review being submitted at the same time in line with coursework requirements.

The establishment of LHREAs also provides schools with the capacity to extend the role where that is considered useful. In a school with a high number of high risk applications, the LHREA could be assigned the role of overseeing or undertaking the writing of these applications rather than providing advice alone. In a school with an express strategy of expanding the number of research proposals involving human subjects, LHREA time allocations can be adjusted upwards to allow for more training and advice.

Reasons for disbandment of PHRESCs

The disbandment of PHRESCs is proposed for a number of reasons, beyond the advantages of LHREAs.

PHRESCs are a more inflexible resource than LHREAs. As committees, they meet at a fixed time each month and are less able to deal with peaks and
troughs in demand, or to respond quickly when necessary (except by placing unusually heavy burdens on PHRESC members, and especially on Chairs). They have a fixed membership which may or may not have expertise in the disciplines from which applications come.

The membership of PHRESCs is not drawn necessarily from those schools with the highest call on the PHRESCs’ time. At some times of the year, one school may have the majority of applications before a PHRESC, and at other times of the year much less. Some schools have consistently high proportions of applications coming before the PHRESC. Some schools with a very low total number of applications annually contribute the same level of committee membership resources as other schools with a very high total. In sum, PHRESCs skew the allocation of resources away from a fair distribution of costs and benefits, and limit the development of local expertise and leadership where it is most needed.

**Maintaining a collegial perspective in second tier ethical review**

The advantages of PHRESCs raised in the course of discussions with interviewees include:

- the value of shared experience brought to bear on ethical review at PHRESC meetings;
- the capacity to manage risk better when the assessment of risks is shared;
- the breadth of perspectives and views contributed to ethical review through PHRESCs.

The basis of these propositions rests upon effective collegial sharing of experience and expertise within a committee context. The introduction of LHREAs needs to build on this notion in order to ensure that something considered important is not lost. LHREAs should be regarded as a network group and LHREAs would be encouraged to raise difficult matters with others in the network. LHREAs would be required to attend moderation meetings at least twice each year at which they compare the outcomes of their ethical reviews with others, thus aiding consistency in decision-making. In addition, ethical reviews undertaken by LHREAs would be subject to monitoring by the HREC to ensure protection of human subjects is sufficient (see National Statement (2007), section 5.1.12).

**Administrative support to LHREAs**

LHREAs will need access to general staff support for record-keeping and follow-up with applicants. Portfolios will need reporting on a Portfolio-wide basis about ethical review occurring within their areas of responsibility. The HREC and HREC Secretariat will need administrative support at the Portfolio level to ensure the effective implementation and maintenance of a systematic and integrated approach to monitoring, quality assurance and record-keeping.
There is an existing platform of administrative support at the Portfolio level – the equivalent of 2.1 full-time positions is reported as committed to ethical review by general staff at the present time.

There is the potential for an increased general staff workload in the short term as RMIT University transitions to the organisational requirements of the National Statement (2007).

With the advent of LHREAs, the long term roles of general staff supporting PHRESCs would change – committee secretariat work would reduce very markedly, or disappear. The number of people for whom they provide support would most probably fall from seven committee members per PHRESC to the number of LHREAs created in the Portfolio for which they work. For example, in both SET and DSC one general staff member provides support to two PHRESCs, or fourteen people. It is unlikely that there would be fourteen LHREAs in either SET or DSC.

The expertise developed by general staff supporting PHRESCs is clearly valuable to ethical review. The short term and long term general staff resourcing requirements need to be assessed as part of the modelling proposed in Recommendation 2 on page 15.

It is recognised that these general staff positions are located within Portfolios which are accountable for resource allocation.

Recommendation 11
That Local Human Research Ethics Advisors are introduced into RMIT University and that Portfolio Human Research Sub-Committees are disbanded.

Recommendation 12
That the PVC (R&I) open discussions with Portfolio PVCs regarding short term and long term allocation of general staff to the support of ethical review within their Portfolios.

7.5 Monitoring, quality assurance and auditing of ethical review

Monitoring and auditing of ethical review

The proposed model incorporates the implementation of an audit system for ethical review. The National Statement (2007) imposes a series of requirements about recordkeeping, development and implementation of procedures and policies, monitoring and support of HREC and non-HREC levels of ethical review, and monitoring of research approved by either HRECs or non-HREC levels of review.
The proposed model recommends the implementation of a systematic monitoring, quality assurance and audit system that spans all these requirements.

There are numerous provisions within Section 5 of the *National Statement (2007)* requiring effective monitoring of HREC and non-HREC ethical review, and the development, implementation and observance of policies and procedures.

It is beyond the limits of this Consultancy to address each of these provisions in turn. Many of them fall outside this Review’s Terms of Reference. It is recommended that these requirements are addressed systematically and in an integrated manner.

**Recommendation 13**

That the HREC Secretariat work with relevant individuals and organisational units within RMIT University to develop a plan to address systematically the *National Statement (2007)* requirements for monitoring, quality assurance, regular auditing, and policy/procedure development.
8. HREC reporting lines

The Review Terms of Reference seek recommendations on reporting lines for RMIT University ethics committees, and on communication/collaboration between ethics committees and development of consistency between committees. Following discussion with the Project Steering Committee this Report has proposed a model for ethical review that disbands PHRESCs and introduces LHREAs. Consequently, recommendations are not made in respect of the PHRESC reporting lines or on securing consistency between the PHRESCs.

The HREC is an independent body registered with the AHEC. Institutions must meet a series of HREC support requirements under the *National Statement (2007)*. These are enumerated in Section 5 of the *National Statement (2007)* (5.1.28 (a)-(j) and 5.1.37 (a)-(t)). Internal arrangements which deliver on these requirements are left to the institutions themselves.

Secretariat support to the RMIT University HREC is provided by the Office of the PVC (R&I). The transfer in 2005 of secretariat functions from the Chancellery has provided the opportunity for the HREC to become more integrated with RMIT University's research culture and administration. Nevertheless, there is some lack of clarity about HREC reporting lines.

**Recommendation 14**

That in addition to its reporting responsibilities to the AHEC, the HREC report to the Vice Chancellor through the PVC (R&I) by submission of an annual report which should be tabled at RMIT University Council.

There is a lack of clarity also about integration between RMIT University policy development processes and the requirements of ethical review.

Interviewees raised a range of policy matters about which they believe there is a need for policy or policy review. Such policy matters include, for example, whether police checks should be mandatory for any researcher who is in direct contact through their research with young people, people who have intellectual disabilities, and other vulnerable groups. Such requirements exist at other universities (Deakin University and the University of Queensland, for example). However, it is unclear how such matters are placed on the policy development agenda through the HREC.

**Recommendation 15**

That policy issues identified by the HREC as requiring attention are notified to the PVC (R&I) who is responsible for resourcing the development of policy and procedures relating to ethical review.

The HREC, the Research Committee, the Animal Ethics Committee, and other relevant groups, should be aware of matters of common policy interest.
9. Human research ethics training and information

9.1 Introduction

Broadly it is reported that there is a great deal of information available regarding human research ethics, but that it is not easily interpreted or applied to specific research proposals. The reported requirement is not for additional information or sources of information, but ‘just in time’ support that is sensitive to a researcher’s proposed research, discipline and/or research method.

This reported requirement adds further weight to the recommended establishment of LHREAs.

The online NEAF is also a potential answer to this requirement in that it incorporates an ‘as-you-go’ interpretive and instructional functionality.

9.2 Ethics review materials available on the RMIT University website

At present, information about ethical review processes is posted on both Portfolio and Research and Innovation websites. It is preferable if the Research and Innovation website is the single source for information about ethics, whether principles or process. A single source makes it more likely that information will be consistent in content and format, and up-to-date.

Recommendation 16

That the human research ethics website maintained by the HREC Secretariat is developed as the single authoritative source for human research ethics material within the University.

Two enhancements to web-based human research ethics materials are proposed here. The purpose of these enhancements is to respond to the frequently expressed need for information that is relevant to particular disciplines and particular methodologies.

The first enhancement is the provision of brief case studies that set ethical issues and principles within a disciplinary and methodological context. The Griffith University website provides case studies of this kind at: http://www.griffith.edu.au/or/ethics/humans/

The second enhancement borrows from the University of Sydney website where samples are provided of various documents included in ethical review applications – for example, there are model participant information statements for both medical and humanities discipline groups. It would be relatively straightforward to generate samples of this kind for a number of disciplines and research methodologies. University of Sydney sample documents are at: http://www.usyd.edu.au/ethics/human/sample/sample7.html
Recommendation 17
That the HREC Secretariat develop, for posting on the human research ethics website, case studies and sample documents contextualised for a range of disciplines and research methodologies.

9.3 Information and training about ethics review

The Review Terms of Reference specifically identify primary groups for ethics training and support as researchers, early career researchers and students learning to make ethics applications. Interview outcomes confirm these as primary audiences. While most supervisors are active researchers, this group was also identified as a primary group requiring information and support.

This Report recommends the establishment of LHREAs at the school level. A key part of the role is the provision of readily accessible human research ethics advice, support and training.

Many interviewees believe that centrally provided training about human research ethics to large cross-disciplinary groups of researchers, supervisors and students is inefficient and ineffective because the inevitable level of generalisation misses the key interests of the individual members of the audience – ethics information relevant to their disciplines, their research proposals and (in the case of supervisors) their students. However, there are good reasons to conduct training and information sessions for large, cross-disciplinary groups of academics and students, given the extent of the changes associated with the National Statement 2007, and the recommended introduction of the NEAF and LHREAs.

Recommendation 18
That the HREC Secretariat develops a plan for informing researchers/academic supervisors, relevant academic managers, and relevant general staff about the National Statement (2007), and about RMIT University’s plans for transitioning to it.

Recommendation 19
That where human research ethics information and training sessions are conducted for cross-disciplinary groups of academics, academic supervisors, and students, participants are asked to complete evaluation forms that inform organisers/presenters about the relevance of the sessions, and that inform planning for future sessions.

Recommendation 20
That where human research ethics information and training sessions are conducted for cross-disciplinary groups of academics and students, that presenters have expertise in human research ethics.
A consistent theme from interviews was the inconsistency across the university in the way that information and learning opportunities are presented to higher degree students. At present it appears that some induction programs provide, for periods varying from 10-45 minutes, a mix of principles and information about applying for ethical review. Some Research Methods courses cover human research ethics closely, some do not. Students who receive exemptions from Research Methods courses may not receive any information about ethics until they come to submit an application form, usually after they have had a research proposal approved. One Portfolio offers seminars on ethical review open to researchers/academic supervisors and students.

It is generally felt that students in disciplines where human research is often conducted should be introduced to the principles of human research ethics – the emphasis is on principles rather than application processes for ethical review. However, there is no clear sense of agreement about how such information should be provided. Views expressed included the following:

- Supervisors have primary responsibility for introducing students to ethical issues and principles when research proposals are being formulated, and that this should be sufficient because many students will not require ethics review for their proposals while others will develop proposals that involve high risk;
- Mandatory attendance at a seminar dealing with human research ethics was proposed, although others disagreed strongly on the basis that the load on many higher degree students (particularly part time students) is already high;
- Research Methods courses should be reviewed with the intention of incorporating coverage of human research ethics issues and principles, although others disputed this, indicating that such courses are already crowded.

There was general agreement that providing students with a web-based package that introduced human research ethics was likely to be unsuccessful. Most interviewees cited time pressures as a disincentive to work through such a package, and some interviewees indicated that an exchange of views was central to developing an appreciation of human research ethics issues and principles.

**Recommendation 21**

That the Chair of the newly constituted HREC take responsibility for seeking a workable consensus on how best to introduce human research ethics issues and principles to higher degree students.
10. Human research ethics review application process

10.1 Introduction

The Review Terms of Reference seek recommendations on administrative support and processes associated with lodging, assessing, responding to applications and ensuring receipt of progress reports.

Limitations on time available for this Review do not permit consideration of the extensive requirements relating to these matters set down in Section 5 of the *National Statement (2007)*.

This Report recommends (Recommendation 13, page 25) that the HREC Secretariat works to develop a plan to address systematically the *National Statement (2007)* requirements for monitoring, auditing, quality assurance and policy/procedure development. Other sections and recommendations address matters such as the thorough review by LHREAs of all applications involving high risk before they are submitted to the HREC.

Two matters of note remains to be addressed – the application form used for ethical review applications, and the form used for seeking exemption from ethical review.

10.2 National Ethics Application Form

Interviewees variously report that there are between four and seven different forms on which applications for ethical review can be made. It has not been possible to secure copies of each of these. In any case, there is some confusion about which forms are current and which of the current forms should be used in which circumstances.

It is also reported that applicants have made alterations to the forms on-screen if the nature of the questions asked, for example, do not appear to relate to their research proposals.

Interviews revealed a view that the application forms are onerous, long and difficult to understand.

Under these circumstances the option of using the National Ethics Application Form (NEAF) is attractive. However, interviewees have mixed views about the NEAF, although few of those interviewed had looked at it recently or at all.

Despite the mixed reactions, the broader issue for RMIT University to consider is that the NEAF is becoming the standard. The list of universities, who have formally adopted it is growing and cuts across characteristics like size, location, and research intensity. For example:
- Queensland University of Technology adopted the NEAF for all high risk applications from 1 January, 2007;
- Monash University adopted the NEAF for all ethical review applications from 1 March, 2007;
- Deakin University has decided that the NEAF must be used for all ethics review applications from July 1, 2007;
- University of Technology, Sydney, has decided to use the NEAF for all high risk applications and will decide on whether to extend its use during the course of 2008;
- The Menzies School of Health Research at Charles Darwin University trialled the NEAF in 2006, and the University has required its use for all applications from 1 March, 2007.
- The University of Newcastle has adopted the NEAF for all high risk applications.

The advantages of the NEAF include ease of access, automatic elision of elements of the application form not relevant to a research proposal, and the ease of generating and reviewing multi-centre applications.

Importantly, the NEAF incorporates an educative function, via hyperlinks and sidebars, explaining principles and terms, and referring directly to the principles and expectations in *National Statement (2007)*. (The NEAF is expected to be updated by July 2007 to align it with the *National Statement (2007)*).

The NEAF’s primary disadvantage is that it does not account for variations in legal and regulatory requirements between state jurisdictions. This can be overcome through the attachment of appendices and the NEAF prompts researchers to ensure those requirements are addressed.

Introducing the NEAF for, say, high risk applications only introduces the possibility that an applicant often doesn’t know at the outset which application form to use because they don’t know whether their proposal is high risk or not.

On balance, it is considered that it is better for RMIT University to adopt the NEAF for all ethical review applications from a specified date.

If the recommendation to introduce the role of LHREAs is taken up, familiarising researchers and students with the NEAF would be an early part of their role. Whatever ethical review model is chosen, using the NEAF will require training and support.

**Recommendation 22**

That, apart from ethical review applications about teaching practice, RMIT University adopts the NEAF for all applications for ethical review from 1 February 2008, or earlier if feasible.
10.2 Granting exemptions from ethical review

It should be noted that there will be two forms in any case – one that seeks exemption from ethical review, and one that applies for ethical review.

Where the LHREA is the person with delegated authority to grant exemptions, it is suggested that a researcher or student should be required only to submit a copy of their research proposal and an application form not exceeding two pages. The form should contain responses to matters concerning risk and consent, much in the form of a checklist.

(Development of the exemption application form would be addressed under activity flowing from Recommendation 13, page 25).
Appendix A

Terms of Reference

The initial Terms of Reference for the consultancy were agreed on 3 April. They are shown below in the same format as provided to those involved in the consultation (see Appendix C).

HUMAN RESEARCH AND ETHICS REVIEW PROJECT

Matters for exploration

Research governance and committee practice

- Role of committee members and chairs at central university and portfolio level, including any workload issues.
- Reporting lines for portfolio and university ethics committees.
- Communication/collaboration between ethics committees and development of consistency between committees.
- Development of a template for a standard annual report by portfolios to the university committee.

Support for researchers, and research training, about ethics requirements

- Provision of information about human research ethics requirements to researchers, especially through web communication.
- Support for early career researchers and students learning to make ethics applications.

Research administration practices

- Administrative support and processes associated with lodging, assessing, responding to applications and ensuring receipt of progress reports.
- Record keeping and security/data maintenance.

Incidental matters

Research policy – review and development

- Process for approval of clinical trials;
- Inclusion of art and design researcher proposals involving representation of human subjects into ethics processes;
• Processing applications that require additional ethics approvals external to the university, such as those involving Indigenous people and children;

• Triggers and level of review for u/grad/coursework student research involving human participants;

• Development of a process to manage applications from external organisations who wish to recruit RMIT students or staff.
Appendix B

Project Steering Committee

The members of the Project Steering Committee are listed below.

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Ms Janet Gaffey</td>
<td>Manager – Research Support</td>
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<tr>
<td></td>
<td>Office of the Pro Vice Chancellor (Research &amp; Innovation)</td>
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<tr>
<td>Mr Peter Burke</td>
<td>Ethics Executive Officer</td>
</tr>
<tr>
<td></td>
<td>Office of the Pro Vice Chancellor (Research &amp; Innovation)</td>
</tr>
<tr>
<td>Ms Fiona Nolan</td>
<td>Research Administration Officer</td>
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<td></td>
<td>Design and Social Context Portfolio Office</td>
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</tbody>
</table>

The Steering Committee met with the Consultant on three occasions during the course of the project.
Appendix C - List of those consulted during the Review

The table below (continued on the following page) lists the individuals who contributed to the consultations undertaken by the Consultant.

Contributors were invited to respond to the Review Terms of Reference (see Appendix A).

were conveyed to the Consultant by the following people during the period

Conversations with informants (either face to face meetings, or on telephone) lasted between 40 minutes and two hours. One written statement was received. Consultations were conducted between 17 April, 2007, to 15 May, 2007.

Meetings were arranged by members of the Project Steering Committee (PSC) via an email to selected RMIT staff and HREC committee members on 13 April, 2007, and via direct contact by PSC members.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position/Role</th>
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<tbody>
<tr>
<td>Ms Julie Barnett</td>
<td>Administrative Officer&lt;br&gt;Design and Social Context Portfolio&lt;br&gt;Secretariat support to Portfolio Human Research Ethics Sub-Committees</td>
</tr>
<tr>
<td>Dr Nick Blismas</td>
<td>Postgraduate Coordinator&lt;br&gt;School of Property, Construction &amp; Project Mgt</td>
</tr>
<tr>
<td>Ms Lorraine Bridger</td>
<td>Manager, Research Grants and Contracts&lt;br&gt;Design and Social Context Portfolio Office</td>
</tr>
<tr>
<td>Associate Professor Carlene Boucher</td>
<td>Chair, Human Research Ethics Sub-Committee, RMIT Business&lt;br&gt;Member, RMIT University Human Research Ethics Committee</td>
</tr>
<tr>
<td>Ms Cheryl de Leon</td>
<td>Administrative Officer&lt;br&gt;Science, Engineering and Technology Portfolio&lt;br&gt;Secretariat support to Portfolio Human Research Ethics Sub-Committees</td>
</tr>
<tr>
<td>Ms Diana Donohue</td>
<td>Chair, Human Research Ethics Sub-Committee A&lt;br&gt;Science, Engineering and Technology Portfolio&lt;br&gt;Research Fellow&lt;br&gt;School of Medical Sciences</td>
</tr>
<tr>
<td>Associate Professor David Forrest</td>
<td>Higher Degrees by Research Co-ordinator&lt;br&gt;School of Education&lt;br&gt;Design and Social Context Portfolio</td>
</tr>
<tr>
<td>Mr Don Grose</td>
<td>Lay Member&lt;br&gt;RMIT University Human Research Ethics Committee</td>
</tr>
<tr>
<td>Associate Professor Heather Fehring</td>
<td>Chair, Human Research Ethics Sub-Committee (Bundoora campus),&lt;br&gt;Design and Social Context Portfolio&lt;br&gt;Member, RMIT University Human Research Ethics Committee</td>
</tr>
<tr>
<td>Name</td>
<td>Position and Responsibilities</td>
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<tr>
<td><strong>Professor John Hawley</strong></td>
<td>Head – Exercise Metabolism Group School of Medical Sciences Science, Engineering and Technology Portfolio</td>
</tr>
<tr>
<td><strong>Ms Lyndal Jones</strong></td>
<td>Director of Research School of Creative Media Design and Social Context Portfolio</td>
</tr>
<tr>
<td><strong>Ms Prue Lamont</strong></td>
<td>Research Student Administration Officer Research Development Unit RMIT Business Secretariat support to Portfolio Human Research Ethics Sub-Committee</td>
</tr>
<tr>
<td><strong>Professor Miles Nicholls</strong></td>
<td>Director – Research Graduate School of Business Business Portfolio Former member Human Research Ethics Sub-Committee (Business Portfolio)</td>
</tr>
<tr>
<td><strong>Associate Professor Barbara Polus</strong></td>
<td>Chair, Human Research Ethics Sub-Committee B Science, Engineering and Technology Portfolio Member, RMIT University HREC Member, Higher Degrees Committee, School of Health Sciences</td>
</tr>
<tr>
<td><strong>Professor Judy Savige</strong></td>
<td>Chair, RMIT University Human Research Ethics Committee Professor of Medicine (Northern Hospital) University of Melbourne</td>
</tr>
<tr>
<td><strong>Associate Professor Geoff Shacklock</strong></td>
<td>Member, Human Research Ethics Sub-Committee (Bundoora campus) Design and Social Context Portfolio</td>
</tr>
<tr>
<td><strong>Professor Joe Siracusa</strong></td>
<td>Director, School of Global Studies, Social Science &amp; Planning Chair, Human Research Ethics Sub-Committee (City campus), Design and Social Context Portfolio Member, RMIT University Human Research Ethics Committee</td>
</tr>
<tr>
<td><strong>Associate Professor Christopher Ziguras</strong></td>
<td>Higher Degrees by Research Coordinator School of Global Studies, Social Science and Planning Senior Research Fellow, Globalism Institute</td>
</tr>
</tbody>
</table>
Appendix D - Extract from the National Statement (2007)
Chapter 2.1 - Harm, discomfort and inconvenience

This extract from the National Statement (2007) provides examples of how levels of risk are assessed.

Harm, discomfort and inconvenience

Research may lead to harms, discomforts and/or inconveniences for participants and/or others. No list of harms can be exhaustive, but one helpful classification identifies the following kinds of potential harms in research:

- physical harms: including injury, illness, pain;
- psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease;
- devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;
- social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status;
- economic harms: including the imposition of direct or indirect costs on participants;
- legal harms: including discovery and prosecution of criminal conduct.

Less serious than harm is discomfort, which can involve body and/or mind. Discomforts include, for example, minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview.

Where a person’s reactions exceed discomfort and become distress, they should be viewed as harms.

Less serious again is inconvenience. Examples of inconvenience may include filling in a form, participating in a street survey, or giving up time to participate in research.

Examples of risks to non-participants include the risk of distress for a participant’s family member identified with a serious genetic disorder, the possible effects of a biography on family or friends, or infectious disease risks to the community. Some social research may carry wider social or economic risks; for example, research in a small community into attitudes to specific subpopulations may lead to unfair discrimination or have effects on social cohesion, property values, or business investment.

Harms that may arise from research misconduct or fraud, and harms to members of research teams from other forms of misconduct (for example, harassment or bullying) are addressed primarily in the Australian code for the responsible conduct of research. These forms of misconduct may, of course, also lead to potential harms to participants.
Low risk and negligible risk research

The expression ‘low risk research’ describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

The expression ‘negligible risk research’ describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.
Appendix E – Consolidated list of recommendations

The recommendations contained in this Report are extracted here for ease of reference. The location of each recommendation within the body of the Report is cited following each recommendation.

Recommendation 1
That the Office of the PVC (R&I) adopts a specific date, and preferably one not later than November 30, 2007, by which it intends that RMIT University will meet the organisational requirements of the National Statement (2007). (See page 10).

Recommendation 2
That the Office of the PVC (R&I) undertake modelling to assess the resource implications of the proposed model and implementation of the provisions of the National Statement (2007), both for short term transitional activity, and for longer term maintenance. (See page 15).

Recommendation 3
That both the HREC Chair and the Deputy Chair roles are filled by RMIT University academic staff, with the Chair being a member of the professoriate who has a strong research record and/or a strong background in research administration. (See page 17).

Recommendation 4
That in the first instance, the HREC Chair be appointed on a specified time fraction of 0.4 and the Deputy Chair be appointed on a specified time fraction of 0.3. (See page 17).

Recommendation 5
That a pool of inducted members of the HREC be established to support ethical review in those disciplines where targeted growth in research output is greatest. (See page 18).

Recommendation 6
That at least two external membership positions on the HREC be filled by people with a close understanding of RMIT University’s mission. (See page 18).

Recommendation 7
That appointment to the HREC is by formal letter from the PVC (R&I). (See page 19).

Recommendation 8
That on formation of the new HREC, one half of the members be appointed for two years, and one half be appointed for three years (including the Chair), followed by two or three year appointments as negotiated with members. (See page 19).
Recommendation 9
That the PVC (R&I) seek advice from the RMIT University Solicitor concerning the nature of legal assurance that ought to be provided, under the terms of the National Statement (2007), to those involved in both HREC and non-HREC levels of ethical review. (See page 19).

Recommendation 10
That, in recognition of the value placed on the contribution of external members of the HREC, RMIT University offers an honorarium to those who accept appointment, at a level to be fixed by reference to any relevant RMIT University policies and precedents. (See page 19).

Recommendation 11
That Local Human Research Ethics Advisors are introduced into RMIT University and that Portfolio Human Research Sub-Committees are disbanded. (See page 24).

Recommendation 12
That the PVC (R&I) open discussions with Portfolio PVCs regarding short term and long term allocation of general staff to the support of ethical review within their Portfolios. (See page 24).

Recommendation 13
That the HREC Secretariat work with relevant individuals and organisational units within RMIT University to develop a plan to address systematically the National Statement (2007) requirements for monitoring, quality assurance, regular auditing, and policy/procedure development. (See page 25).

Recommendation 14
That in addition to its reporting responsibilities to the AHEC, the HREC report to the Vice Chancellor through the PVC (R&I) by submission of an annual report which should be tabled at RMIT University Council. (See page 26).

Recommendation 15
That policy issues identified by the HREC as requiring attention are notified to the PVC (R&I) who is responsible for resourcing the development of policy and procedures relating to ethical review. (See page 26).

Recommendation 16
That the human research ethics website maintained by the HREC Secretariat is developed as the single authoritative source for human research ethics material within the University. (See page 27).
Recommendation 17
That the HREC Secretariat develop, for posting on the human research ethics website, case studies and sample documents contextualised for a range of disciplines and research methodologies. (See page 28).

Recommendation 18
That the HREC Secretariat develops a plan for informing researchers/academic supervisors, relevant academic managers, and relevant general staff about the National Statement (2007), and about RMIT University’s plans for transitioning to it. (See page 28).

Recommendation 19
That where human research ethics information and training sessions are conducted for cross-disciplinary groups of academics, academic supervisors, and students, participants are asked to complete evaluation forms that inform organisers/presenters about the relevance of the sessions, and that inform planning for future sessions. (See page 28).

Recommendation 20
That where human research ethics information and training sessions are conducted for cross-disciplinary groups of academics and students, that presenters have expertise in human research ethics. (See page 28).

Recommendation 21
That the Chair of the newly constituted HREC take responsibility for seeking a workable consensus on how best to introduce human research ethics issues and principles to higher degree students. (See page 29).

Recommendation 22
That, apart from ethical review applications about teaching practice, RMIT University adopts the NEAF for all applications for ethical review from 1 February 2008, or earlier if feasible. (See page 31).