Document Name

POLICY FOR THE ETHICAL REVIEW OF RESEARCH

Document Number

PO-RES-02

Document Status

<table>
<thead>
<tr>
<th>Author</th>
<th>Director of Research</th>
<th>November 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorisation</td>
<td>Academic Board</td>
<td>December 2014</td>
</tr>
<tr>
<td>Publication</td>
<td>Issue 1E</td>
<td>March 2015</td>
</tr>
<tr>
<td>Review Date</td>
<td>Review of Issue 1E</td>
<td>December 2017</td>
</tr>
</tbody>
</table>
Preamble

In developing its Policy for the Ethical Review of Research, Excelsia College (Excelsia) recognises its responsibility for ensuring that research conducted under its auspices is:

(a) designed and conducted in accordance with the Australian Code for the Responsible Conduct of Research; and
(b) ethically reviewed and monitored in accordance with the National Statement on Ethical Conduct in Human Research.

Standards and Instruments consulted in the development of Excelsia College’s Policy for the Ethical Review of Research include the following:

- Australian Code for the Responsible Conduct of Research (ACRCR) 2007
- The Joint NHMRC/ARC/AHCC National Statement on Ethical Conduct in Human Research (National Statement) 2007 (updated December 2013)
- Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research 2003.

Guiding principles for the governance of research include overall responsibility for the quality, safety and ethical acceptability of research sponsored by an institution or permitted to be carried out under its auspices (National Statement p 4). In addition to responsibility as a guiding principle, governance with respect to the conduct of ethical research also includes respect and integrity (ACRCR, 1.3), research merit, justice, and benevolence (National Statement p 11). Hence, Excelsia College is committed to fostering responsible research, protecting the dignity, safety, rights and welfare of research participants, researchers, supervisors and all persons involved in the research process.

Scope

The Policy for the Ethical Review of Research comprises policies for the:

1. Formation and terms of reference of the Excelsia College Human Research Ethics Committee (HREC)
2. Management of Research Applications
3. Monitoring of activities of the HREC.

This policy should be read in conjunction with the policies and procedures for Ethical Scrutiny, Research Misconduct, Intellectual Property, HDR Supervision, and related Higher Degree policies and procedures.

Definitions

Research involving humans includes, but is not restricted to, the use and/or collection of personal, collective or cultural data from participants or from their records, and may include their oral testimony or observed cultural activities and the testing of responses to conditions devised by researchers as set out in the National Statement on Ethical Conduct In Human Research (2007, updated 2013). It is not expected
that students, staff, or associates of Excelsia College would be conducting research involving animals or substances posing a threat to safety or security.

**Research under the auspices of Excelsia College** is defined as:

- research projects conducted by: undergraduate students enrolled in honours programs undertaking research as a component of their program at Excelsia; postgraduate students undertaking research as a component of their program at Excelsia; or Excelsia staff or students undertaking research as part of their teaching or learning activities, whether alone or jointly with others, and whether the staff member is full-time, part-time or an adjunct.
- Research carried out using equipment, facilities or premises owned by Excelsia or otherwise under the control of Excelsia.
- Research that involves human participants who are students or staff members of Excelsia, or are otherwise connected with Excelsia in any way.

**Ethics Officer** is the person who holds the office of Ethics Officer at Excelsia from time to time.

**HREC** refers to the Excelsia College Human Research Ethics Committee.

**Purpose**

This *Policy for the ethical review of research* has been formulated to ensure appropriate ethical scrutiny of any research involving humans in which Excelsia College is involved. The institutional processes for assessing and approving research processes are intended to ensure that Excelsia College complies with the Australian Code for the Responsible Conduct of Research (ACRCR). The requirements for applying for ethics approval outlined in this Policy are intended to ensure that any research involving humans complies with the requirements of the National Statement on Ethical Conduct in Human Research (National Statement) and that the welfare and rights of participants in research and the community in general are protected. Further, compliance with the Policy is intended to safeguard the reputation of Excelsia and its researchers.

**General Principles**

- Any research under the auspices of Excelsia College and involving humans requires ethics approval in accordance with this Policy before the research can be undertaken.
- Funding for any research under the auspices of Excelsia College will not be released until appropriate ethics approval has been given.

**Formation and Terms of Reference of the HREC**

1. **Formation and membership of the HREC**

The Committee responsible for the ethical scrutiny and approval of research proposals developed under the auspices of Excelsia College is the Excelsia College Human Research Ethics Committee (HREC).
Excelsia College will form an HREC in two stages:

Stage 1: An initial Human Research Ethics Committee comprising five members will be appointed to conduct ethical reviews at Excelsia during its transition to a University. This initial HREC will be a sub-committee of the Research Committee.

Stage 2: Excelsia College will establish a final Human Research Ethics Committee comprising eight members and separate from the Research Committee once it achieves full University status.

- All the provisions of this Policy will apply to the initial HREC.
- Members of the HREC will be appointed to ensure a balance of genders, with at least three external members in the final HREC (according to the National Statement 5.1.29).
- The roles and qualifications of appointees to the HREC will comply with the National Statement 5.1.30, and a schedule documenting roles and qualifications of appointees will be certified by the Chief Executive as so complying.
- Appointments to the HREC will be reviewed every three years.

2. Appointments to the HREC

- Members of the HREC will be appointed by the Academic Board upon recommendation by the Director of Research in consultation with the Academic Director and other senior members of Excelsia College.
- Members will be appointed for a term of three years, with a maximum of two additional terms of appointment.
- Members will be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion. Members will be provided with a letter of appointment from the Director of Research (on behalf of the Academic Board) which will include: the date of appointment; the length of tenure; an assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as an HREC member; HREC meeting attendance responsibilities; and general responsibilities as an HREC member.
- Appointees must agree to their name and category of membership being made available to the public, including being published on the Excelsia website.
- Members will sign a statement undertaking that: all matters brought to their awareness during the course of their work on the HREC will be kept confidential; any conflicts of interest, which exist or may arise during their tenure on the HREC will be declared; the member has not been subject to any criminal conviction or disciplinary action for serious academic misconduct which may prejudice their standing as an HREC member.

3. Liability Coverage

- Excelsia College will provide indemnity for members of the HREC for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith.
4. Functions of the HREC

The functions of the HREC are to:

- Provide independent, competent, and timely ethical review of research projects involving humans.
- Ensure that research protocols comply with the principles of ethical conduct outlined in the National Statement, and relevant legislative requirements.
- Ensure that all researchers comply with the relevant guidelines on the conduct of human research, including the Australian Code for the Responsible Conduct of Research and the Excelsia College Research Code of Practice.
- Monitor research projects involving humans to ensure that appropriate ethical standards are maintained in order to protect the interests of research participants, researchers, WI, and the general community.
- Receive complaints, on a confidential basis, on the conduct of human research projects, and deal with these in accordance with Excelsia policies and procedures.
- Protect the privacy and confidentiality of research participants by ensuring that researchers appropriately manage the security, storage and disposal of confidential data collected during the conduct of research involving humans.
- Promote awareness and understanding of human research ethics within the College and the broader community.

5. Status of the HREC within Excelsia College

The HREC operates under delegated authority from the Board of Directors to: give approval on behalf of Excelsia to the conduct of ethical research; approve modifications to previously authorised research protocols on behalf of Excelsia; and temporarily suspend or withdraw approval to previously authorised research protocols on behalf of Excelsia.

6. Accountability of the HREC

- The HREC is accountable to the Board of Directors through the Academic Board in the conduct of its business.
- The Chair of the HREC will provide an annual report to the Academic Board on their operations of the previous calendar year (National Statement 5.7.5).
- The HREC will be registered with the NHMRC and will report annually to the NHMRC through the Excelsia Chief Executive (National Statement Section 5).

7. Specific Responsibilities of the HREC

- Each member of the HREC is responsible for deciding whether, in his or her judgement, a proposal submitted to the HREC meets the requirements of the National Statement and is ethically acceptable (National Statement 5.2.2).
- Members will be familiar with the National Statement and other published materials relevant to the ethical scrutiny of proposals.
• Members will provide ethical opinions on the ethical suitability of proposals at scheduled meetings, or if absent from a meeting, in writing to the Chair, unless incapacitated.
• Members will also provide advice to researchers from time to time on ethical issues as researchers develop research proposals and ethics applications.
• Members will attend training sessions or otherwise demonstrate current familiarity with ethical issues relevant to research every three years.
• Members will disclose any actual or potential conflict of interest with respect to any proposal submitted for ethical review.
• Members will strive for general agreement in their deliberations through open and full discussion.
• The HREC will approve, reject or request amendments to a research proposal on ethical grounds.

Conduct of Business

1. Operations of the HREC

• The HREC will operate according to the Procedures for the Establishment and Operations of the Excelsia College Human Research Ethics Committee. These Procedures cover the terms of reference, operations and reporting of the HREC.
• Operational procedures for the HREC will cover matters specified in the National Statement 5.1.37 and 5.2.24 to 5.2.27.

2. Categories of Risk and Related Ethical Process

There are three stages and related ethical processes of ethical scrutiny at Excelsia depending on the nature of the research and category of risk.

Stage 1 is the assessment of the merit of a research proposal, consistent with the guiding principle of research merit and integrity (National Statement). Research merit is assessed by the peer review process for funding proposals, and the confirmation of candidature process for HDR candidates. However, the research merit of all other research proposals by staff, students and others associated with Excelsia by their research will be assessed by the Risk Assessment Sub-committee of the HREC.

Stage 2 is the assessment of the degree of risk associated with a research proposal, according to the definitions of risk given by the National Statement (2.1.6, 2.1.7 and 5.1.6). The degree of risk associated with all research under the auspices of Excelsia College will be assessed by the Risk Assessment Sub-committee of the HREC. See the Procedures for Assessment of Risk in Research Proposals submitted for ethical approval to the HREC. In all cases degree of risk will be considered in conjunction with the extent of those affected by risk, ways to minimise risk, potential benefits of the research, and the extent of those for whom benefits are likely to accrue (National Statement 2.1.3).

Stage 3 is the assessment of justice, benevolence, safety, and integrity as evidenced within the proposal and consistent with the core values of the National Statement. Where the research is deemed to be of greater than low risk the assessment at Stage 3 will be conducted by a full HREC. A
sub-committee of the HREC will make the Stage 3 assessment of research proposals deemed to be of low or negligible risk. Stage 3 assessments of proposals involving participants who are of Aboriginal or Torres Strait Islander background will be considered in light of *Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (2003) and will be considered by the full HREC.

3. **Recording of Deliberations and Outcomes**
   - All deliberations of the HREC will be recorded as minutes of meetings, and communication with applicants will be in written form (usually via emails).
   - A record of all proposals, associated communications, and outcomes will be kept as required under *National Statement 5.2.24*.
   - Reasons for rejection or requests for amendments will reference the *National Statement*.

4. **Monitoring Ongoing Research**
   - Any unforeseen event, adverse or otherwise, that affects the conduct of research, or any change in the research procedures that may affect the ethical conduct of research must be notified immediately to the Chair of the HREC through the Ethics Officer. Such a report must include any steps taken to remedy an adverse event.
   - In the case of an adverse event that occurs during the presence of the researcher, the researcher must immediately cease gathering data, secure existing data, and if applicable, take steps to ensure the safety of all present.
   - An annual report noting the current stage of the research and any ethical issues that may have arisen will be requested of all researchers whose proposals were given ethical approval by the HREC or its sub-committee.
   - The Ethics Officer must be notified at the completion of the research project, and a report on the ethical conduct of the research must be provided to the HREC.

5. **Records**
   - The Ethics Officer will prepare and retain written records of the HREC’s activities, including agendas and minutes of all meetings of the HREC.
   - The Ethics Officer will prepare and maintain an official file for each application received (the Project File) including a copy of the application, and any relevant correspondence including that between the applicant and the HREC.
   - Files will be kept securely and confidentially in accordance with the requirements of State and Federal privacy legislation.
   - Records will be held for sufficient time to allow for future reference. The minimum period for retention will be in accordance with the *Australian Code for the Responsible Conduct of Research* and the *State Records Act*, whichever is longer.
   - The Ethics Officer will maintain a database of all applications received and reviewed in accordance with the *National Statement*.
• The Ethics Officer will maintain a record (the Complaints Log) of all complaints received regarding the activities of the HREC and the outcomes of those complaints, a record of all complaints received regarding research projects and the outcomes of those complaints, and a record of all possible breaches of the *Research Code of Practice*.

6. Monitoring the HREC

• Complaints regarding the HREC review process will be concerned with ascertaining whether the HREC acted in accordance with the *National Statement*, its Terms of Reference and Standard Operating Procedures, or if it acted in an unfair or biased manner.
• Complaints regarding the HREC will be made in accordance with Excelsia staff complaints procedures (if the researcher is a staff member) or student complaints procedures (if the principal researcher is a student).
• An external committee of three members appointed by the Academic Board having expertise in HREC operations will be convened to adjudicate any complaint that is not resolved via internal procedures.

References Consulted as Exemplars for Excelsia College Policy

UNSW SOP 1: *Complaints concerning the HREC’s review process*