Preamble

These procedures relate to:

- the formation of an Excelsia College Human Research Ethics Committee (HREC);
- the terms of reference of the HREC;
- procedures for the operation of the HREC; and
- reporting of the HREC.

They apply to all proposals relating to research conducted by Excelsia College staff and students, and research involving Excelsia College staff or students as research participants.

Formation of the HREC

In the first instance Excelsia College will establish a form of HREC that meets most, but not all, of the requirements of a full Human Research Ethics Committee. However, this initial HREC will be supplemented over the next five years to the point where a separate HREC will operate in accordance with the National Statement. (See Table below: Initial HREC membership is indicated by unshaded rows, additional members for the final HREC are indicated by shaded rows).

Initially, five members will comprise the HREC. Of these, four will be internal appointments and one will be external. Nominees for appointments to the HREC will be assessed for their qualifications for each specific role and approved by the Academic Board. Appointments will be made for a three year term which may be renewed.

Membership of the Initial HREC, final HREC, and Qualifications for Membership

<table>
<thead>
<tr>
<th>Role</th>
<th>Requirements for appointment</th>
<th>Appointee</th>
<th>Qualifications for appointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair</td>
<td>Experience in ethics</td>
<td>Director of Research</td>
<td>Experience, teaching and publications in professional ethics</td>
</tr>
<tr>
<td>Counsellor</td>
<td>Nurse, counsellor or allied health professional</td>
<td>Senior lecturer, School of Counselling</td>
<td>Counselling experience</td>
</tr>
<tr>
<td>Current researchers (2)</td>
<td>Currently conducting and publishing academic research</td>
<td>Head of Integrative Studies; Researcher in School of Education</td>
<td>Current research activity</td>
</tr>
<tr>
<td>Minister or pastoral carer</td>
<td>Gender to balance genders of internal appointees</td>
<td>Minister of religion</td>
<td>External: Experience as minister</td>
</tr>
<tr>
<td>Role</td>
<td>Requirements for appointment</td>
<td>Appointee</td>
<td>Qualifications for appointment</td>
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<tr>
<td>Lawyer</td>
<td>External. Gender to balance genders of appointees</td>
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<tr>
<td>Lay person</td>
<td>External. Gender to balance gender of appointees</td>
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<tr>
<td>Lay person</td>
<td>Can be internal or external</td>
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Terms of Reference of the HREC

A) Functions of the HREC

The Committee will:

a. assess all proposals for research to be conducted under the auspices of WI;
b. determine whether each research application is approved, rejected, or approved subject to specified amendments;
c. monitor the ethical conduct and outcomes of approved research;
d. provide confidential advice to both staff and students on ethical issues in research matters, including potential conflict of interest in research funding and sponsorship; and
e. advise the Chief Executive on issues of integrity in research

The Committee may consult with experts in specified research areas as required.

B) Procedures of the HREC

1. Frequency of meetings
   - Initially, meetings will be scheduled at quarterly intervals, to be held in the first week of March, June, September and December.
   - Further meetings will be scheduled as required.

2. Attendance at meetings
   - A quorum to a HREC meeting will comprise at least one person from each category. A member of the HREC will be deemed to be present if he/she submits written reflections on each proposal/agenda item to the Chair prior to the scheduled meeting.
   - Experts in particular fields of research and/or research ethics may be invited to attend the HREC from time to time in order to give advice on specific research proposals.
   - Researchers whose applications are being assessed may request to attend the HREC, but may only be present while their own application is being discussed.

3. Risk Assessment Sub-committee of the HREC
   - A sub-committee of the HREC, comprising three members, will assess the academic merit and risk of all proposals submitted for ethical review.
   - The sub-committee will comprise the Chair, one researcher, and one counsellor or lay person.
• The academic merit of the proposal will be assessed according to criteria for academic argument as applied to the rationale for the proposed research in light of scholarly literature.

• The research merit will be assessed by its potential benefits, use of recognized research methodologies, its basis in a thorough study of the research literature, the competency of the researcher/s, the appropriateness of its research resources, and its capacity to maintain respect for research participants.

• Risk will be assessed according to Procedures for the Assessment of Risk in Research Proposals submitted for Ethics Approval.

4. Agendas and minutes

• The call for agenda will occur four weeks prior to the meeting; the deadline for applications two weeks prior; distribution of papers to the HREC at least 10 days prior to the meeting data; and feedback to applicants sent within 10 days of the meeting.

• Preparation of the agenda, minutes and other record keeping, will be the responsibility of the WI Ethics Officer.

5. Presentation of applications for review

• See Guidelines for submission of applications for ethics approval: Procedures for applications to HREC.

6. Conflicts of interest

• Members of the HREC will be asked to declare potential or actual conflicts of interest with respect to each application e.g., personal involvement (such as status as supervisor of student research); financial interest e.g., as researcher of a funded, linked study; or involvement in competing research.

• Where there is a conflict of interest the member will be excluded from deliberations about that matter.

7. Stages of ethical review

• Proposals will be submitted in the first instance to the HREC sub-committee for assessment of academic merit and risk.

• The sub-committee will then make a full ethical scrutiny of proposals deemed to be of negligible or low risk.

• Proposals deemed to be of greater than low risk will be referred to the full HREC for ethical deliberation.

• In addition, proposals that involve any of the following will be considered by the full HREC: interventions and therapies, people highly dependent on medical care who may be unable to give consent, people with a cognitive impairment, an intellectual disability, or a mental illness, Aboriginal and Torres Strait Islander Peoples, children, people who are culturally and linguistically diverse, people who may be unduly distressed due to past traumatic experiences, studies involving active concealment or deception, research that could jeopardize a participant’s employment and some categories of research related to the study and exposure of illegal activities.
8. **Method of decision making**

- Members of the HREC will carefully read applications and associated material prior to the scheduled meeting.
- All members will be invited to speak to each application, with particular attention to any ethical concerns. The advice of HREC members who are unable to attend a scheduled meeting will be conveyed by the Chair.
- Where there is disagreement amongst HREC members concerning the ethical status of any aspect of a research proposal, the Chair will invite further discussion with a view to reaching consensus. However, a decision may be made on the basis of a majority view provided all views have been considered.
- The HREC may decide to accept an application, reject an application, or request amendment/s to an application.

9. **Communication with researchers**

- Communication will be largely in writing, including email communication. However, internal members of the HREC will be available to give advice on research and associated ethical issues by phone or face to face to staff or student researchers.
- Correspondence will be signed by the Chair of the HREC and sent through the Ethics Officer.

10. **Notification of decisions**

- Decisions and associated reasoning of the HREC will be noted in minutes taken by the Ethics Officer and signed by the Chair.
- Once the minutes are signed the Ethics Officer will notify the Chief Researcher of the decision and reasons for the decision by email.

11. **Record keeping**

- The Ethics Officer will maintain minutes of the HREC meetings.
- The Ethics Office will keep one copy of every application, including any information sheets, consent forms and the like in the form in which they were approved.
- The Ethics Officer will maintain a register of all applications and include data as specified under National Statement 5.2.14, namely:
  i. name/s of the institution/s to which the research approval is provided;
  ii. project identification number/s;
  iii. name/s of principal researcher/s;
  iv. title of the project;
  v. correspondence between the review body and the researcher about the review;
  vi. acceptance or rejection of any changes to the proposal;
  vii. proposed date of completion of the proposal;
  viii. formal advice of final ethical approval or non-approval, with date;
  ix. terms and conditions, if any, of approval of any proposal;
  x. duration of the approval;
  xi. name of any other review body whose opinion was considered;
  xii. mechanisms to be used to monitor the conduct of the research; and
xiii. relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.

12. Monitoring research
- Researchers must submit an annual report to the Ethics Officer concerning the progress of their research, compliance with the proposal as approved by the HREC, and the security of research records.
- Researchers must also submit a report to the Ethics Officer at the completion or cessation of approved research covering issues of compliance, security of records, and any matters of concern to the researcher.

13. Adverse events
- Researchers must inform the HREC via the Ethics Officer immediately of any adverse event occurring during the process of research, and any steps taken to deal with the adverse event.
- Reports of adverse events will be sent immediately to the Chair of the HREC for assessment of the degree of risk or harm and urgency of response. In urgent cases the Chair will work with the Researcher to ensure that the welfare of research participants and others is not compromised.
- Where immediate action is not deemed necessary, the report of an adverse event will be discussed at the next HREC meeting.

14. Complaints about the conduct of research following HREC approval
- Explanations about approved research, such as Participant Information Sheets, will specify that complaints may be directed to the Ethics Officer whose contact details must be provided.
- On receipt of a complaint about the conduct of research the Ethics Officer will deal with the complaint in compliance with the Breaches and Research Misconduct provisions of the Australian Code for the Responsible Conduct of Research (chs.9-10).
- The complaint will be directed to the Chair of the HREC who will determine whether the complaint refers to a breach of the Code, or an allegation of more serious research misconduct (see Australian Code ch.10).
- Alleged breaches will be raised at the next HREC meeting with a view to ensuring fair treatment of all parties and remediation of any harm.
- Actions taken with respect to any breach will be recorded in HREC minutes and communicated to all parties by the Ethics Officer.
- If the complaint refers to the conduct of the HREC, the matter will be referred to the Chair of the Academic Board for independent review.
- Complaints about the HREC, and their resolution, will be reported to the Chief Executive for communication to the Board of Directors.

15. Advisor in research integrity
- A senior staff member who is experienced in research and empathic communication will be appointed as an Advisor in Research Integrity.
- The Advisor in Research Integrity will be available to discuss issues of potential research breaches and misconduct with staff who are unsure about whether to make an allegation.
• If the Advisor perceives a potential or actual conflict of interest in their role, they will refer the inquiry to another senior staff member.

16. Research Misconduct
• Allegations of research misconduct will be addressed to the Director of Research in writing.
• The Director of Research will secure all documents relevant to the allegation, and conduct a preliminary investigation to determine if there is a prima facie case of research misconduct.
• On the basis of the preliminary investigation the Director of Research will advise the Academic Director that the allegation should be dismissed, dealt with at departmental level or through other procedures, or investigated further through a research misconduct inquiry.

17. Withdrawing approval of HREC approved research
• If the researcher or any person associated with research under the auspices of Excelsia College raises doubts about the ethical conduct of that research, the matter will be considered at the next meeting of the HREC or in urgent cases, by the Chair of the HREC together with a sub-committee of two other members of the HREC.
• In urgent cases where immediate harm is anticipated, the Chair of the HREC will inform the Excelsia Chief Executive of the situation and ensure that the researcher is instructed by the Chief Executive to cease the research immediately.
• In all cases the Ethics Officer will request information in writing from the researcher, those allegedly affected adversely by the research, and all parties having interest in the research.
• If there is reason to believe that the welfare of research participants, or others associated with the research, will be compromised, the HREC will consider whether to withdraw approval for the research.
• In the event that approval for research is withdrawn, the Ethics Officer will inform the researcher, the institution and where possible, the participants, about its cessation. The researcher will be directed to cease the research immediately and implement actions as determined by the HREC to ensure the welfare of research participants and others.
• The researcher may apply for approval to resume the research once any welfare concerns have been addressed and safeguards established to protect future participants.
• The application to resume research must specify modifications to address the safety and welfare of future participants.
• Research must not be resumed until approval for the modified research is given by the HREC.

18. Joint institutional research
• Where research is conducted under the auspices of Excelsia College and another institution, the HREC will ensure that ethical approval is given for all research locations before authorizing its commencement.
• The HREC will not duplicate the ethical approval processes of the other institution.
• The HREC will cooperate with institutional research partners to exchange information and advice regarding research processes and their ethical implications.
19. Confidentiality

- Members of the HREC will keep confidential all information considered at HREC meetings.
- All copies of applications for ethical approval including associated documents, apart from the institutional copy, will be disposed of securely once the application is determined.

20. Professional development of HREC members

- Members newly appointed to the HREC will be provided with: an opportunity to meet informally with the HREC Chair and Ethics Officer to explain their responsibilities as an HREC member, the HREC processes and procedures; an opportunity to sit in on HREC meetings as an observer before their appointment takes effect; copies of the Excelsia policies and procedures relating to human ethics, and the National Statement.
- Each year members of the HREC will be invited to attend a seminar where ethical issues will be presented and discussed. All HREC members will be eligible to apply for College funds to attend conferences, training sessions and other professional development related to their work on the HREC.

C) Reporting of the HREC

1. The minutes of each HREC meeting will be forwarded to the Academic Board for confirmation.
2. Each year the Chair of the HREC will compile an Annual Report on the procedures and activities of the HREC over the previous calendar year as required under the National Statement 5.7.5.
3. The Annual Report will cover HREC composition; number of projects reviewed, approved and rejected, or managed by expedited review; time to final approval for all projects; enumeration of any complaints received and their outcome; approvals by Human Research Ethics Risk Assessment Sub-Committee; and general issues raised.
4. In addition, the HREC Annual Report Form will assess the application of the Guidelines Under Section 95 of the Privacy Act 1988 and the Guidelines approved under Section 95A of the Privacy Act 1988.
5. The Annual Report will be submitted to the Chief Executive for tabling at the next Board of Directors meeting.
6. The HREC Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public, and will be posted on the Excelsia College website.

References Consulted


### Document Status

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