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POLICY FOR ETHICAL APPROVAL OF RESEARCH PROPOSALS

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Purpose

The purpose of this policy is to ensure appropriate ethical scrutiny of research proposals that are developed under the auspices of Excelsia College (Excelsia).

Definitions

**HREC** is the Excelsia College Human Research Ethics Committee.

**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 College.
- Research that involves human participants who are students or staff members of Excelsia, or are otherwise connected with Excelsia College in any way.

**Principal Researcher.** The Principal Researcher is the person who is responsible for the conduct of the research project. In the case of student research the Principal Researcher is the Supervisor (or Chair of the Supervisory Panel in the case of PhD students).

General Principles

- All research under the auspices of Excelsia College and involving human participants needs the approval of the HREC or a sub-committee of the HREC.
- No human research may be commenced until ethical approval from the HREC is granted.
- The purpose of ethical scrutiny is to safeguard the rights and well-being of all people associated with the research, and particularly of those in more vulnerable positions.
- Appropriate ethical scrutiny is evaluation of research proposals by a properly constituted HREC operating under the provisions of the *National Statement*.

Categories of Ethical Scrutiny

There are two forms of ethical scrutiny depending on the type of research and level of risk to those involved in the research.
Negligible and low risk research will be considered by the Risk Assessment Sub-committee of the HREC.

Research that is not deemed to be negligible or low risk will be considered by the full HREC.

The category of scrutiny will be decided in the first instance by the Risk Assessment Sub-committee of the HREC and reviewed, as required, by the full HREC.

Guidelines and procedures relating to each category of ethical scrutiny can be found in the Procedures for Assessment of Risk in Research Proposals.

Responsibility for Providing Ethical Approval

- Ethical approval is provided by the HREC or the Risk Assessment Sub-committee of the HREC, depending on the level of risk and nature of the proposed research.
- In assessing applications the following principles will be applied by the HREC or the Risk Assessment Sub-committee of the HREC:
  - Research involving human participants must meet established ethical, professional and cultural norms;
  - All research involving human interventions must balance the cost of the human interventions to those participating in them (e.g. in terms of discomfort, personal risk, loss of privacy or other sort of harm) and the value to be achieved by carrying out the research.
- Core principles with regard to the protection of participants are: integrity, including respect for persons, beneficence and justice; consent; research merit; and safety.

Conditions of Ethical Approval

Ethics approval is granted on the basis of a number of reporting conditions to be met by the Principal Researcher.

- Any serious or unexpected adverse effects on research participants must be reported immediately to the Ethics Officer and the research suspended until appropriate action is advised by the HREC.
- Any unforeseen events which might affect the continued ethical acceptability of the research project must be reported immediately to the Ethics Officer.
- The Ethics Officer must be notified of, and approve, any amendments to the original protocol, including but not limited to changes to the membership of the research team, the research design or methodology, research tools, or research participants’ recruitment method (such changes to be notified by submission of a Request for Amendment to Approved Research Project form).
- If the research is discontinued for any reason, notification must be given to the Ethics Officer, any data already collected must be submitted to the Ethics Officer for safekeeping under the same conditions as data lodged on the completion of an approved research project.
- An annual report is required to be submitted to the Ethics Officer on the anniversary of ethics approval and a final report to be submitted upon research completion.
Special Cases for Ethical Approval

- Where a research project involved the participation of children under the age of 18 years, or the use of data relating to children, a Research Involving Children form must be attached to the application for ethics approval.
- Particular care must be given to planning research involving: people in dependent or unequal relationships; 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; people who may be involved in illegal activities; and Aboriginal and Torres Strait Islander people. In these cases, applications must refer to the National Statement Section 4, and indicate consultations that have occurred with relevant community groups, committees or agencies.
- Research involving Aboriginal or Torres Strait Islander participants must reference the NHMRC Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003).
- Where the assistance or agreement of another organisation is required to undertake the research project involving humans, the appropriate written permission is required to access staff, clients or other information of that organisation.
- Where external research involves Excelsia staff or students, written permission of the HREC is required for the research to occur, irrespective of whether or not approval has been granted by the institution where the research originates.

References Consulted

Australian Code for the Responsible Conduct of Research


Notre Dame University (Australia) Policy on Ethical Approval for Research Involving Humans