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POLICY FOR THE MONITORING OF APPROVED RESEARCH

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Purpose and Context

This Policy applies to all research involving human participants under the auspices of Excelsia College and approved by the Excelsia College Human Research Ethics Committee (HREC). The purpose of the Policy is to ensure appropriate regulation of research so that the welfare of researchers, participants and others involved in the research process is safeguarded. This Policy is also intended to ensure that approved research involving humans complies with the Australian Code for the Responsible Conduct of Research and the National Statement on Ethical Conduct in Human Research.

Definitions

For the purposes of this Policy:


*Ethics Officer* means the person who holds the position of Ethics Officer at Excelsia College from time to time.

*HREC* means the Human Research Ethics Committee of Excelsia College.

*National Statement* means the National Statement on Ethical Conduct in Human Research (2007, updated December 2013) published by the NHMRC.

*NHMRC* means the National Health and Medical Research Council.

Policy Statement

1. 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.
   - The HREC may, at its discretion, request more frequent reports or require additional surveillance to ensure that the project continues to conform to ethical standards.

2. 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. The HREC may require the researcher to take steps to ameliorate the situation and/or modify research procedures in order to mitigate future risk.

3. Complaints

- 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 (Chapters 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 Chapter 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 Excelsia College Chief Executive for independent review.

- Complaints about HREC, and their resolution, will be reported to the Chief Executive for communication to the Board of Directors.

References Consulted

Policy: Monitoring of Approved Research Projects, Notre Dame University, 2011,  

Australian Code for the Responsible Conduct of Research