



**Human Research
Policy and Procedures**

ALC Human Research: Policy and Procedures

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Published by

Australian Lutheran College
104 Jeffcott Street
North Adelaide SA 5006
Australia

Ph: + 61 (0)8 8267 7400
Fax: + 61 (0)8 8267 7350
Email: alc@alc.edu.au
www.alc.edu.au

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Preamble

This handbook has been prepared by the Postgraduate Studies Committee of Australian Lutheran College [ALC] as a guide for all students and staff considering research involving human participants. It should be read in conjunction with the *National Statement on Ethical Conduct in Research Involving Humans* issued by the National Health and Medical Research Council in accordance with the *NHMRC Act 1992* at <http://www7.health.gov.au/nhmrc/publications/humans/contents.htm>.

It applies consistent national standards to research conducted through ALC.

The purpose of the Supplement is to provide a statement of ethical principles adopted by ALC and to lay out the research guidelines to protect the welfare and rights of participants in research.

This document, apart from providing practical guidelines for ethical considerations in field research, serves to highlight:

- a) that research involving human participants demands that we respect the interests, rights and welfare of the human beings involved in the research; we dare not use other human beings as mere objects of analysis;
- b) that good research is more than the collection and analysis of data; how we relate to those involved in our research is fundamental to good contemporary research;
- c) that the ethical dimensions of research are often complex and multiple; careful adherence to the guidelines, therefore, is necessary to avoid injuring a participant in some way and thereby incurring legal liability.

Finally, we encourage all who undertake research while studying at ALC to subscribe to the basic principles outlined in the following statement.

Researchers motivated by the gospel of God's love should:

- have a concern for the personal welfare of participants in the research process as a matter of priority,
- take all reasonable steps to make sure that the integrity and rights of the participants as human beings are respected and protected,
- take all reasonable steps to make sure that any potential or actual physical, psychological or spiritual harm to the participants from any research intervention is avoided.

Principles of Ethical Conduct

(Based on National Statement on Ethical Conduct)

Integrity

1. The guiding value for researchers is integrity, which is expressed in a commitment to the search for knowledge, to recognised principles of research conduct and in the honest and ethical conduct of research and dissemination and communication of results.
2. When conducting research involving humans, the guiding ethical principle for researchers is respect for persons which is expressed as regard for the welfare, rights, beliefs, perceptions, customs and cultural heritage, both individual and collective, of persons involved in research.

Beneficence

1. In research involving humans, the ethical principle of beneficence is expressed in researchers' responsibility to minimise risks of harm or discomfort to participants in research projects.
2. Each research protocol must be designed to ensure that respect for the dignity and well being of the participants takes precedence over the expected benefits to knowledge.

Justice

1. The ethical value of justice requires that, within a population, there is a fair distribution of the benefits and burdens of participation in research and, for any research participant, a balance of burdens and benefits.
2. Therefore, a researcher must ensure that particular groups are not subject to over researching. A researcher should design research so that the selection, recruitment, exclusion and inclusion of research participants is fair, and does not discriminate on the grounds of race, age, sex, disability or religious or spiritual beliefs, except where the exclusion or inclusion of particular groups is essential to the purpose of the research.

Consent

1. Before research is undertaken, whether involving individuals or group, the consent of the participants must be obtained, except in specific circumstances.

The ethical and legal requirements of consent have two aspects: the provision of information and the capacity to make a voluntary choice. So as to conform to ethical and legal requirements, obtaining consent should involve:

- provision to participants, at their level of comprehension, of information about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research (including the likelihood and form of publication of research results); and
- the exercise of a voluntary choice to participate.

Where a participant lacks competence to consent, a person with lawful authority to decide for that participant must be provided with the information and exercise that choice.

2. A person may refuse to participate in a research project and need give neither reason nor justification for that decision.
3. Where consent to participate is required, research must be so designed that each participant's consent is clearly established, whether by a signed form, return of a survey, recorded agreement for interview or other sufficient means.
4. The consent of a person to participate in research must not be subject to any coercion, or to any inducement or influence which could impair its voluntary character.
5. It is ethically acceptable to conduct certain types of research without obtaining consent from participants in some circumstances, for example the use of de-identified data in research, observational research in public places, or the use of anonymous surveys.
6. A participant must be free at any time to withdraw consent to further involvement in the research. If any consequences may arise from such withdrawal, advice must be given to participants about these before consent to involvement in the research is obtained.

Research merit and safety

1. Every human research proposal must demonstrate that the research is justifiable in terms of its potential contribution to knowledge and is based on a thorough study of current literature as well as prior observation, approved previous studies, and, where relevant.
2. All research proposals must be so designed as to ensure that any risks of discomfort or harm to participants are balanced by the likely benefit to be gained.
3. Research must be conducted or supervised only by persons or teams with experience, qualifications and competence appropriate to the research. Research must be conducted using only facilities appropriate for the research, where there are appropriate skills and resources for dealing with any contingencies that may affect participants.

Ethical review and conduct of research

1. Research projects involving humans must be reviewed by a Human Research Ethics Committee (HREC) and must not be undertaken or funded unless and until approval has been granted.
2. A researcher must suspend or modify any research in which the risks to participants are found to be disproportionate to the benefits and stop any involvement of a participant if continuation of the research may be harmful to that person.
3. The results of research (whether publicly or privately funded) and the methods used should normally be published in ways which permit scrutiny and contribute to public knowledge. Normally, research results should be made available to research participants.
4. Where personal information about a research participant or a group is collected, stored, accessed, used, or disposed of, a researcher must strive to ensure that the privacy, confidentiality and cultural sensitivities of the participant and/or the group are respected. Any specific agreements made with the participant or the group are to be fulfilled.

5. Where the records and results of research contain information of clinical significance, it is the responsibility of both the researcher and ALC to maintain the security and storage of records and results so as to enable any necessary follow-up studies to be carried out.
6. Where research is conducted in an overseas country under the aegis of ALC, the research must comply with the requirements of this Statement as well as the laws and guidelines of that country.

ALC Human Research Ethics Committee

General principles and composition

1. All research proposals involving human participants must be reviewed and approved by a Human Research Ethics Committee. Exception: In the case of professional projects the Chairman of the HREC may approve research applications that conform with the guidelines of the act.
2. ALC accepts legal responsibility for the decisions and advice of the HREC members, and will indemnify its members through the provision of indemnity insurance.
3. The chief role of the HREC is to protect the welfare and the rights of participants in research, and the primary responsibility of each member is to decide, independently, whether, in his or her opinion, the conduct of each research proposal submitted to the HREC will protect participants.
4. The HREC shall consist of:
 - a chairperson;
 - at least two members who are lay people in regard to research, a man and a woman. They can have no affiliation with ALC, and they are not currently involved in medical, scientific or legal work, and are from the community in which ALC is based;
 - at least one member with knowledge of, and current experience in the areas of research that are regularly considered by the HREC, that is, education and related fields;
 - at least one member with professional care or counselling knowledge, and current experience in the treatment of people;
 - at least one member who is a minister of religion, and
 - at least one member who is a lawyer.
5. Appointment of members:
 - Members shall be appointed by the ALC Principal in consultation with the teaching staff;
 - Appointments shall be for a minimum period of three years;
 - Appointments shall be in writing and shall include details of legal protection in the course of normal duties of the HREC.

Procedures

1. Meetings of the HREC shall occur up to twice a year, at a time appropriate for the processing of research proposals.
2. Secretarial and logistical support for the HREC shall be provided through the Office of the Dean of Studies.
3. Papers shall be distributed at least 14 working days prior to the meeting.
4. Applicants shall be notified of decisions in writing within two working days of the meeting.
5. The members present must agree to all decisions regarding approval. If agreement cannot be reached, requests for changes in the proposal should be made, so that members are satisfied and able to approve.

6. The Dean of Studies at ALC on behalf of the HREC shall monitor all research. This shall be done by the provision of an annual report of research provided by the researcher and supervisors.
7. The Dean of Studies shall be the recipient of any complaints from participants regarding the conduct of research.
8. The Dean of Studies shall notify the HREC if a review is required.
9. Should the HREC decide that a research project is putting participants at risk, the chairman shall notify the researcher and participants that a project is to be discontinued.
10. The office of the Dean of Studies will process the notification.

Procedures for gaining HREC approval

Staff or students planning research at ALC involving human participants are required to:

- a) Become familiar with the guidelines in this handbook and with the National Statement on Ethical Conduct in Human Research.
- b) Complete the HREC **Application for Research Approval** form, specifying the required information and design of the research to be undertaken; in complex cases the supervisor may consult with the HREC to clarify the ethical factors involved.
- c) Modify the research design in accordance with any terms of approval specified by the HREC and communicated to the supervisor.
- d) Consult regularly with their supervisor, taking into account modifications required by the HREC, any changes in circumstances and progress in the implementation of the research design.
- e) With their supervisors, submit periodic written progress reports specifying how the steps of the research design have been completed, or modified, to conform to the initial approval given by the HREC.
- f) Notify the HREC of any changes to the original research design; where, in the opinion of the supervisor, these changes are substantial, request for approval of such changes is to be submitted to the HREC.
- g) Submit a **Research Project Completion Form** within 3 months of the completion of the research program.

Research with human participants is not to commence prior to approval being given by the HREC.

Teaching staff responsibilities

1. Supervisors will be responsible for providing continuous guidance to student researchers.
2. Supervisors will ensure that the annual reports are submitted to the office of the Dean of Studies at least 21 working days prior to the September meeting of the HREC

Ethical Guidelines

Recruitment of participants

All participants must be willing volunteers who decide to participate in the research on the basis of adequate information and informed consent and are not influenced by fear that refusal to participate will affect their, or any member of their family's, legal rights, studies, employment or welfare.

People who are in a dependent relationship with the researcher (eg, students, patients, employees) or with a person, or institution whose cooperation is necessary for the research to be pursued, may be under pressure to volunteer that is not evident to the researcher. In such cases, special care needs to be taken and the nature of such dependent relationships specified in the application for approval.

Care must be taken at all times to ensure that no economic, moral, academic, personal or financial pressure is applied, however minimal, to induce potential participants to volunteer. Where possible and appropriate, it is wise to use open advertisement or open invitations to recruit participants.

Advertisements or open letters inviting participation should include the following:

- name of ALC from which the research originates;
- full title of the research proposed;
- a clear description in lay terms of how the participants will be involved in the research
- assurance of confidentiality;
- exclusion criteria in plain English;
- name and address of an independent person given in the advertisement or letter as the contact person who can discuss the research process with the potential participant. NOTE: the contact person is NOT the staff member or student pursuing the research.
- details of remuneration for any out-of-pocket expenses for participating in the project. These expenses are not to be construed as payment of any kind.

Information to participants

All potential participants and, for minors or students, those who have responsibility for them, are to receive an approved information sheet giving adequate information to assist them in their decision whether or not they or those for whom they are responsible will participate in the research program.

Sufficient time must also be given to enable people to make their decisions. Researchers need to be available to provide additional information when requested by potential participants.

Information sheets provided to potential participants should include:

Cover sheet with:

- name of ALC from which the research originates;
- full title of research proposed (including lay title where necessary);
- names and qualifications of staff or student researchers;
- name and phone/fax number of researcher and principal supervisor;
- name and phone/fax number of chairman of the HREC.

A personal invitation containing:

- an invitation to participate in the research;
- a statement of the nature and purpose of the research in plain English;
- an indication of the potential benefits of the research;
- an outline of what the participants are expected to do as part of the research;
- a declaration of complete confidentiality assuring the participants that their identities as individuals will not be released or available to any outside person or body;
- an assurance of care in case of any adverse effects;
- a statement that all data collected will be preserved by the ALC for seven years according to legal requirements;
- an assurance that participants may withdraw from the research program at any time without affecting their position or care.

Written consent

People who agree to participate in any research are to give written and informed consent that they comprehend what is required of them as participants in the research, including the precise nature of any interviews, surveys and observations. To ensure that the interests of the participants, the researcher and ALC are protected, an adequate consent procedure is to be followed and official consent forms of ALC are to be used. This includes consent to access particular records, such as class lists.

Where potential participants are in a dependent relationship with the researcher it is recommended that an independent person approach the participants to obtain written consent.

The consent form should be signed by the participant and an independent witness. Both the researcher and the participant should hold a copy of the consent form.

Participants under 16 years of age are required by law to have the consent of parents or guardians (over 18) to be part of such research.

The Research Project Consent form is to be completed.

In the completion of these consent forms it is important that the potential participants:

- understand that the ownership of the data and findings of the project lie with the student researcher, or in the case of staff members, with ALC;
- know the names of the researchers and their supervisors;
- have had ample opportunity to discuss the project and what is required of them;
- are aware of any possible risks from participating in the project;
- on their own behalf or on behalf of those for whom they are responsible, have agreed to participate in the project on the terms explained by the researcher;
- are assured they may withdraw from the project at any time without penalty;
- agree to the mode of collecting data, such as tape recording or video recording, and the method of presentation of the findings of the project so that confidentiality is guaranteed.

Duty of care

The researcher has the responsibility to exercise a duty of care towards all participants in all aspects of the research. Direct effects of the research may include emotional distress, mental stress, spiritual discomfort or even physical injury. Indirect effects may be financial, legal or social. Researchers must act appropriately to ameliorate side effects and to modify the research immediately.

In developing the application for approval researchers must consider whether:

- the venue of the research process presents any danger to the participants;
- emergency equipment is accessible at the venue;
- a context of complete confidentiality can be established;
- the duration of any research exercises is announced in advance;
- the likelihood of participants being disturbed in any way by the research process has been carefully considered;
- continuation of care and possible future referral (eg., health care or social care) has been taken into account.

Confidentiality

The researcher is required to ensure, as far as is possible, that at no time before, during or after the research program the confidentiality of the participants is breached. This applies in terms of recruitment of participants, access to records of participants, data presentation, dissemination of research results and subsequent care or future contact. All precautions are to be taken to prevent the risk of identification of participants to anyone other than the researcher(s) approved by the HREC, whether before, during or after the research project.

The Privacy Act 1988 sets out the Information Privacy Principles that govern agencies of the Commonwealth in their collection, management and use of data containing personal information. ALC accepts Principle 11, which is relevant to research as a reasonable standard for it to implement. The principle states that,

agencies may not disclose to anyone else personal information except:

- a) where the subject of the information is reasonably likely to be aware, or has been made aware, of the practice of disclosure,
- b) with the consent of the person,
- c) to prevent serious and imminent threat to a person's life or health,
- d) as required or authorised by law,
- e) where reasonably necessary for the enforcement of the criminal law or of law imposing a pecuniary penalty, or for the protection of the public revenue.

Therefore, information which identifies the participant should be physically separated from the study at the earliest possible time, so that the participant's name nowhere appears in the data or findings of the project. The study data and any code which might identify any participants is to be stored in a locked cabinet in a safe place designated by ALC authorities with access granted only to the researcher or the supervisors and, in exceptional circumstances, the Principal of ALC.

Effects on participants

Researchers should assess any likely social, religious, psychological, cultural, ecological, or political implications of their research for the participants, the researcher, and the ALC. Special considerations and approvals need to be considered in any research involving Aboriginal participants. Possible religious implications need to be considered when researching the faith of participants.

Interviews, for example, may inadvertently lead into sensitive cultural areas, sectarian social fears, deep psychological problems or unknown spiritual anxieties. Where these become apparent, the researcher must take into account the possible impact of the questions and exercise pastoral care in dealing with the situation. After immediate attention is given to the needs of the participant, the interview should be terminated and possible future care for the participant initiated.

Any researcher wishing to pursue research with participants who are mentally, physically or socially disadvantaged or research with Aboriginal people, will be subject to additional guidelines. These are contained in the Privacy Act.

Ownership of data and authorship

Intellectual property results from the intellectual activity of research projects, including information gained from participants and kept confidential. Student researchers own the intellectual property derived from their research, have unlimited access to their projects/theses and have the right to submit all or part thereof for publication.

The ALC owns the intellectual property derived from the research of staff members operating in their capacity as members of staff.

Recording of research data and findings

Where audiotapes or videotapes are used for data collection the participant must be informed in advance of the research project commencing, sight the tapes and agree to the release of any tape prior to the release of results. The participant must also be informed that the tape as raw data will be kept securely for seven years. Special considerations may apply in the use and ownership of tapes in certain minority groups in society. If for any special reason there is a mutual agreement that a tape is released, the identity of the participant must be effectively removed and masked.

Approval from other institutions

In order to do research in particular bodies, such as schools or parishes, approval of the responsible heads of these bodies is also necessary. In some cases this may also mean getting ethical clearance from the corresponding ethics committee of the institution concerned. The approval of all interested parties, such as teachers, parents or pastors, is required to ensure that all parties are informed and agreeable to the research program.

A project comparing the grades, attitudes or activities of children in Lutheran and State schools would require that the project get approval from the ethics committee of the Education Department of the relevant state.

Legal considerations

Researchers should ascertain whether there are any legal implications associated with their research which may affect the participants, researchers or ALC. The insurance policy of ALC needs to cover liability in relation to research conducted by its students and staff.

Conflict of interest

Wherever a conflict of interest exists or may exist between the researcher and the participants or their employers, this must be disclosed in advance and the precise relationship of the parties involved should be specified.

Such interests would include ways in which either party may benefit from the research exercise, whether financially or otherwise.

The relationship between sponsors or funding bodies and the researcher should be specified in a written contract so that the findings of the research are not biased in favour of the funding or employing body but genuinely advance a field of knowledge.

Research involving children and young people

1. Research is essential to advance knowledge about children's and young peoples' well-being, but research involving children and young people should only be conducted where:
 - the research question posed is important to the health and well-being of children or young people;
 - the participation of children or young people is indispensable because information available for research on other individuals cannot answer the question posed in relation to children or young people;
 - the study method is appropriate for children or young people;
 - the circumstances in which the research is conducted provide for the physical, spiritual, emotional and psychological safety of the child or young person.
2. Consent to a child's or young person's participation in research must be obtained from:
 - The child or young person whenever he or she has sufficient competence to make this decision; and either
 - The parent/guardian in all but exceptional circumstances; or
 - Any organisation or person required by law.
3. The HREC is forbidden to approve, and consent cannot be given, for research that is contrary to the child's or young person's best interests.
4. A child's or young person's and/or parent/guardian's refusal to participate in a research project must be respected.

Research involving persons in dependent or unequal relationships

1. It is not possible to define exhaustively all types of dependent relationships, but they include situations where unequal power relationships exist between participants and researchers, or where participants occupy junior or subordinate positions in hierarchically structured groups. Examples include:
 - Students and teachers
 - Employees and their employers or supervisors
2. Where it is proposed to involve persons in dependent or unequal relationships in research, the possibility that the relationship may impair free consent requires additional attention from the HREC in order to ensure that consent is indeed adequately informed and voluntary.
3. Where research involves persons in dependent or unequal relationships the researcher must give an assurance that refusal to participate in, or a decision to withdraw from, the research will not result in any discrimination, reduction in the level of care or any other penalty.

Application for research approval

[Details of the Research Project]

1. Purpose of research

- 1.1 State briefly the purpose of your research project, giving a rationale indicating why this project is significant as a contribution to knowledge in a given field.
 - 1.2 Describe the professional or academic background that has led you to this research. Indicate whether this research is based on earlier studies, pilot projects or professional work in a given field.
 - 1.3 List the specific objectives or hypothesis for this research.
 - 1.4 Indicate what you consider to be the social, educational or religious implications/outcomes of this research.
-

2. Research method and design

- 2.1 Outline the basic research approach being followed and the specific steps in the research design.
 - 2.2 List appropriate references basic to your research project.
-

3. Human participant considerations

- 3.1 Describe the criteria by which human participants are to be included and excluded. Describe the group or groups of participants planned for your research project.
- 3.2 Describe the process by which recruitment of participants is planned. Include sample recruitment material as **Appendix 1**. If access to records (such as class lists) for data or personnel for referral is required please provide all proposed correspondence with the holders of the records or referral information, as **Appendix 2**.
- 3.3 Describe any interest groups or individuals (e.g. Aboriginal people, children) that you think may be affected by your research and indicate how you think they may be affected.
- 3.4 Specify the means you intend taking to ensure that potential participants, including interest groups, are informed adequately about the research project prior to their agreement to participate. Include as **Appendix 3** proposed information to be provided to these participants.
- 3.5 Describe measures planned to care for the needs of the participants, including possible psychological or other effects of the research process. This step also includes provision for an option of withdrawal from the project.
- 3.6 Indicate how consent to participate will be obtained from those participating. Attach as **Appendix 4** a copy of the proposed consent form to be used.
- 3.7 Describe any likely sociological, ecological, psychological or religious (spiritual) implications/effects of your research.

4. Research data considerations

- 4.1 Outline briefly how your research data (audio tape, video tape, etc) will be recorded and stored during the project.
- 4.2 Describe briefly how your research data and findings will be reported, giving special attention to the factor of confidentiality.
- 4.3 Specify who will have access to your data and findings and indicate any conditions to be placed on that access.
- 4.4 Data must be stored safely for seven years. Specify how and with whom it will be stored.
- 4.5 Specify the ownership and authorship of the data and the findings.

5. Involvement of other institutions

- 5.1 Specify any other organisations or bodies who may be involved from whom approval is to be sought. Where ethics approval is to be obtained from an institution please provide documentation of approval (or approval in process) as **Appendix 5**.
- 5.2 Where overseas organisations are involved, please specify the nature of the involvement and provide any correspondence as **Appendix 6**.
- 5.3 If research involves areas of a sensitive cultural or spiritual nature such as interaction with Aboriginal communities or particular religious groups, please indicate the nature of this interaction and provide any relevant correspondence as **Appendix 7**.

6. Proforma

The following proforma are to be used by students as they prepare research programs or professional projects and may be photocopied as required.

Application for Research Approval Form [ALC Human Research Ethics Committee]

Cover sheet			
<i>[please type, and answer all questions on the Application fully]</i>			
Name and qualifications of researcher			
Name			
Qualification			
Name and qualifications of principal supervisor			
Name			
Qualification			
Principal supervisor's contact details			
Address line 1			
Address line 2			
Suburb		Postcode	
State		Country	
Email			
Phone			
Fax			
Title and outline of research project/thesis			
Lay title (where necessary)			
Proposed commencement date			
Principal supervisor's endorsement			
<p>This is to certify that I am the principal supervisor of this project, have consulted with the researcher, have read the research design and agree to the procedures to be followed to ensure ethical practice.</p>			
Signature of principal supervisor		Date	

Research Project Consent Form [ALC Human Research Ethics Committee]

Project			
Title			
Researcher			
Name			
Supervisor[s]			
Principal supervisor			
Co-supervisor			
Statement of consent			
1	I have read the <i>Information Sheet</i> provided and understand the nature and purpose of the proposed research.		
2	I agree to participate in this research project in the specific ways explained to me.		
3	I understand that I will not benefit directly from participating in this project.		
4	I understand that while data and findings from this research may be published, I will not be identified in person and any information I have contributed to the project will remain confidential and never be associated with my name.		
5	I have been assured that I can withdraw from this project at any time and that by doing so my position or care will not be affected.		
6	I declare that I am over 18 years of age or I declare that I am over 18 years of age and that those for whom I am responsible (eg, child, staff members, etc) understand and agree to the preceding five points.		
Details of participant or person responsible for participant			
Participant			
Person responsible for participant			
Relationship of person responsible for participant			
Name			
Address line 1			
Address line 2			
Suburb		Postcode	
State		Country	
Email			
Phone			
Fax			
Signature of participant or person responsible for participant		Date	
Researcher's endorsement			
As the researcher in this project, I hereby declare that I have explained this project to the participants, that they understand the project and their part in the project and that they have signed without any pressure on my part.			
Signature of Researcher		Date	

Research Project Completion Form [ALC Human Research Ethics Committee]

[to be completed and sent to the HREC within 3 months of completing the research and kept for 7 years]

Researcher	
Name	
Project details	
Title <i>[upon completion]</i>	
Date approved	
Date commenced	
Date completed	
Number & categories of participants	
Location[s] of project	
Modifications to research design	
Specify any modifications to the research design as originally approved <i>[use additional pages if necessary]</i>	

Modifications to research design [continued]

Were there any adverse effects reported?

If so, please specify details, how appropriate care was exercised and how the research project was modified

Brief summary of the findings of the research project

Researcher's and Principal Supervisor's endorsement

As the researcher in this project, I hereby declare that I have explained this project to the participants, that they understand the project and their part in the project and that they have agreed to their informed participation without any pressure on my part. This work represents my original work. No other person's work or ideas have been used without acknowledgment. Except where I have clearly stated that I have used some of this material elsewhere, I have not submitted it as part of any other course at this or any other institution.

Signature of researcher		Date	
-------------------------	--	------	--

This is to certify that I am the principal supervisor of this project, have consulted with the researcher, have agreed to the research design and that ethical practice was followed.

Signature of principal supervisor		Date	
-----------------------------------	--	------	--

For HREC use only

Research project number	
-------------------------	--

Date approved	
---------------	--

Date completion report received	
---------------------------------	--