



University of Prince Edward Island

Department of Psychology

Research Ethics Committee

Student Guide to Completing the Research Ethics Proposal

1. Introduction

Conduction of research is premised on a commitment to advancing welfare, knowledge and understanding (TriCouncil Policy Statement, 1998). Research projects may use either human or animal participants. Although some research projects involving human and animal participants have produced substantial benefits, other projects have posed some troubling ethical issues. Consequently, Research Ethics Boards have been established to examine the impact that a researcher=s activities could have on any humans or animals who take part in a research project (Lougheed, 2003). Research Ethics Boards safeguard the public and scholarly reputation of the institution, and foresee any legal problems that might arise from a research project in addition to protecting the rights of human or animal participants in research projects (Lougheed, 2003).

1.1 Research Using Animals

The Canadian Council on Animal Care is the body that has been established to safeguard the rights of animals used in research. At the University of Prince Edward Island, all research involving the use of animals must first be approved by the Animal Care Committee, which is answerable to the Canadian Council on Animal Care. For information about the use of animals in research projects, please see the guidelines published by the University of Prince Edward Island Animal Care Committee, <http://www.upei.ca/research/ethics/ethics.html>

1.2 Research using Human Participants

In 1998, a common ethics policy for the conducting of human research was approved by Canada's three major research funding councils - the Canadian Institutes for Health Research (formerly the Medical Research Council), the Social Sciences and Humanities Research Council, and the Natural Sciences and Engineering Research Council. This common policy is the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (Lougheed, 2003). The Tri-Council Policy advocates eight principles that should guide and evoke thoughtful actions in the research process. These eight principles are:

1.2.1 Respect for Human Dignity

This principle is fundamental to modern research ethics and attempts to protect the multiple and interdependent interests of the individual - from physical to psychological to cultural integrity.

1.2.2 Respect for Free and Informed Consent

This principle assumes that individuals have the capacity and right to make free and informed decisions.

1.2.3 Respect for Vulnerable Persons

Respect for human dignity entails high ethical consideration for vulnerable persons - to those whose diminished competence and/or diminished decision-making capacity make them vulnerable. Children, institutionalized persons, or others who are vulnerable are entitled on the grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination.

1.2.4 Respect for Privacy and Confidentiality

Respect for Human dignity implies the principles of respect for privacy and confidentiality. Standards of privacy and confidentiality protect the access, control, and dissemination of personal information. In so doing, such standards help to protect mental or psychological integrity.

1.2.5 Respect for Justice and Inclusiveness

Justice connotes fairness and equity. Procedural justice requires that the ethics review process have fair methods, standards, and procedures for the review of research projects, and that the process be effectively independent. Justice also concerns the distribution of the benefits and burdens of research. Therefore, no one segment of the population should be unfairly burdened with the harms of research, nor should any group who may benefit from advances in research be neglected or discriminated against by the research process.

1.2.6 Balancing Harms and Benefits

The analysis, balance, and distribution of harms and benefits are critical to the ethics of human research. Therefore, research projects require a favourable harms-benefits balance - that is, the foreseeable harms should not outweigh anticipated benefits. These concerns are

particularly evident in biomedical and health research; they are also pertinent in areas such as economics, political science or modern history (e.g., biographies) where research may ethically result in the harming of the reputations of organizations or individuals in public life.

1.2.7 Minimizing Harm

Research involving human participants has a duty to avoid, prevent or minimize harms to others. Research participants must not be subjected to unnecessary risks of harm, and research projects must involve the smallest numbers of human participants and the smallest numbers of tests on these participants that will ensure scientifically valid data.

1.2.8 Maximizing Benefit

Research involving human participants has a duty to benefit others, society as a whole, and the advancement of knowledge. This principle has particular relevance for research in areas such as social work, education, health care, and applied psychology.

(Principles adopted from the Tri-Council Policy, 1998).

In practice, these principles translate into certain dialogues, procedures, and requirements that each proposed research project must meet. These dialogues, procedures, and requirements are the basis of the Research Proposal that is prepared for review by the Research Ethics Committee before the research project is commenced. An explanation of these dialogues, procedures, and requirements is presented in the next part of this guide

2. Dialogues, Procedures, and Requirements

2.1 PROFESSIONALISM

Local and federal funding for all research projects is contingent upon the proposed project meeting the approval of the Research Ethics Committee. Preparing a Research Proposal for approval by the Research Ethics Committee is therefore an important part of professional training for a career in psychological. It is imperative, then, that your Research proposal be presented in a professional manner. To this end, adhere to the following guidelines:

Before submitting your proposal, ensure that:

1. It is typed in black ink, using a 12 point font.
2. It contains no grammatical or spelling errors.
3. It contains a statement of all personnel involved in the research project, and the contact details of the Principal Investigator.

4. It contains a clear statement of the purpose of the research, complete rationale for the proposed project, including research questions or hypotheses, a complete explanation of the procedure to be followed in the study. Without this information, it is impossible for the Research Ethics Committee to determine if your project meets ethical guidelines.
5. It has been signed by ALL personnel on the project, and by the research supervisor, if applicable.

2.2 PARTICIPANTS

Information on Participants is required so that the Research Ethics Committee can ensure that:

1. An inclusive sample is being recruited for the study (no one group in the population is burdened with the harms of the research, or discriminated against in terms of benefits of the research);
2. Participation of individuals in the study is completely voluntary (not coerced in any way);
3. The smallest number of human participants is being used in the study in order to minimize harm;
4. Vulnerable persons are respected in the proposed research project.

NOTES:

Special Participant Requirements

Information on special participant requirements is sought to determine that an inclusive sample is being recruited for the study (no one group in the population is burdened with the harms of the research, or discriminated against in terms of benefits of the research).

Participants who are children

Information on child participants is sought to ensure that vulnerable persons are respected in the research project.

In some cases, participant of the child is deemed sufficient for the research project. In this case, the researcher(s) will not need a parent or guardian=s consent. For minimal risk protocols only (e.g., anonymous surveys), persons greater than or equal to 14 years of age and less than 18 years of age may in some cases consent to participate in a research project in the absence of parental consent, subject to specific approval by the Research Ethics Committee in that instance. Persons under the age of 14 may not be participants in research projects, in either minimal or non-minimal risk protocols, without parental consent. In this situation, a separate consent form, entitled PARENT/GUARDIAN CONSENT FORM must be included in your Research Proposal. Persons greater than or equal to 18 years of age are considered adults and may consent to

participate in both non-minimal and minimal risk protocols. For children for whom parental or guardian consent is required, seeking the children=s *ASSENT* is ***recommended***. In such cases, their assent is not binding, but their declining to participate must be honoured despite their parent=s or guardian=s prior consent.

Other vulnerable participants

Information on vulnerable participants is sought to ensure that these persons are respected in the research project. If vulnerable participants are used in research projects, any institution from which they are drawn must authorize the use of these persons as participants in a research project. Therefore, you must attach a letter from the Institution to your Research Proposal. Evidence must also be provided that these persons are competent to give their informed consent to participate in the study. If they are not deemed competent to consent, parental or guardian consent must be sought. In this situation, a separate consent form, entitled PARENT/GUARDIAN CONSENT FORM must be included in your Research Proposal.

Participant Recruitment

Participation in a research project must be fully voluntary. Consequently, persons who are intended participants must not feel coerced to take part in any research project. Therefore, all advertisements and scripts that relate to the recruitment of participants for the research project must be attached to the Research proposal for perusal by the Research Ethics Committee.

The special case of participants who are University students

Universities provide researchers with a ready pool of research participants - students. There are ***three*** problems with student participation in research conducted at Universities. First, there is the possibility that agreement to participate will not be freely given. Students may volunteer to participate out of a belief that doing so will place them in good favour with faculty (e.g., that participating in research will result in receiving better grades, and so on), or that failure to participate will negatively affect their relationship with the investigator or faculty generally (e.g., by appearing unco-operative). Second, requiring participation in research for course credit might mean that participation in the research is not free and voluntary. Third, involvement of students as participants might compromise student confidentiality, particularly in research involving the collection of data on sensitive topics such as mental health, sexual activity, or use of illicit drugs or alcohol.

Solutions to these problems have been suggested as follows.

Problem 1: Voluntary Consent

First, faculty and student investigators can advertise for participants generally (e.g., through notices posted in the Department or School). This approach is specifically suggested if the Faculty member has a conflict of interests, e.g., is an Instructor of a 100 level psychology course, where credit is offered for participation in research projects run by the faculty. Second, if a specific approach is to be made by a student researcher to a class, ensure that the approach is made either at the beginning or the end of the class, when the professor is not present. This

approach ensures that the Professor has no knowledge of who has chosen to participate in the project, and the possibility of students feeling coerced to participate in order to be perceived more positively by the professor is eliminated.

Problem 2: Course Credit

For research involving course credit for participation, students should be informed in the Information Letter and/or Consent Form that:

1. If they choose not to participate in this particular research project, there will be other opportunities for them to select other research projects in which to participate for course credit;
2. They can withdraw from the Research Project at any time without losing the extra course credit.

Problem 3: Confidentiality

Students who are requested as participants in research projects collecting data on sensitive issues should be fully informed as to the risks that involvement in the research entails, and they should be informed that, if they can be identified from any of their responses, their data is confidential **ONLY WITHIN THE LIMITS OF THE LAW**.

2.3 INFORMED CONSENT

Informed consent normally requires two components - the information to potential participants, and the consent form, both of which should be in lay language. If the research project uses participants who are deemed vulnerable (e.g., children below the age of 14 years), an Information Letter and Consent form for Parents/Guardians may also be required in addition to the Participant Information letter and Consent Form (these may have to be written in languages appropriate to the audience).

Information Letter

The following elements should be described, **WHERE RELEVANT**, in the information to potential participants.

1. A statement that the person has been invited to participate in a research project investigating (whatever is being investigated)
2. A statement of who is conducting the study, under whose supervision, and for what purpose (Honours Project, Course Project, or other)
3. Brief outline of the rationale of the study
4. Aims of the study
5. The procedures and/or therapy involved
6. Potential benefits of the research
7. A statement that the study poses no harm to the individual **OR** if the study proposes more than minimal harm to the participant, a statement of the potential risks of participation
8. Anticipated time duration
9. Voluntary nature of the study

10. Statement that the participant may withdraw from the study without any adverse consequences
11. Statement regarding confidentiality of records
12. Statement of any limitations of confidentiality
13. Statement of who will have access to the data and how long the data will be retained
14. Statement of steps taken to protect anonymity of the participant, and the limitations of the research project with respect to anonymity
15. Details of any compensation - financial or otherwise (e.g., course credit)
16. If compensation is course credit, a statement that if the individual chooses not to participate in this project, there will be opportunities for participation in other research projects for the equivalent amount of credit
17. The participant may consult with the Research Supervisor or Principal Investigator/s Investigator or the Head of the Department at any time, and provision of telephone numbers and email addresses of these individuals
18. If participation in the project raises psychological issues, the participant can contact the Supervisor of the research project, who can direct him/her to a relevant professional in the field
19. For access to the full results of the study once these are available, the name and contact details of the Primary Investigator/s.

19. A statement that the research has been approved by the Research Ethics Committee of the Department of Psychology as a subcommittee of the UPEI Research Ethics Board, and that any concerns regarding involvement in this study may be directed to the Chair of the Ethics Committee, Department of Psychology, with the telephone number and email address of this person provided.

A template of the Information Letter has been provided for adaptation in the Research Proposal Form.

Consent Forms

Where applicable, the following elements must appear in both the Participant and Parental/Guardian Consent Form (if applicable).

1. A statement that the individual has read and understood the material in the Information Letter;
2. A statement that he/she consents to participating in research on (statement of topic of research);
3. A statement that he/she understands that participation is voluntary;
4. A statement that he/she has the freedom to withdraw from the research at any time, without any adverse consequence;
5. A statement that he/she has the freedom not to answer any question;
6. A statement that he/she understands that the information will be confidential within the limits of the research and law;
7. A statement that once all data have been submitted and identifiers removed, he/she will no longer have the opportunity to request that his/her data be removed from the study;
8. A statement outlining limits to anonymity;
9. A statement that he/she understands that he/she can keep a copy of the signed and dated consent form;
10. A statement that he/she understands that he/she can contact the Chair of the Research Ethics Committee in the Department of Psychology (Telephone number and email address) if he/she has any concerns about the ethical conduct of this study;
11. Signature and date.

A template of the Participant Consent Form and the Parental/Guardian Consent Form has been provided for adaptation in the Research Proposal Form.

NOTES:

Survey Research

If you are conducting an *anonymous survey/questionnaire* with a population aged 18 years and over, a Consent Form DOES NOT need to be provided to the participants. Only an

Information Letter and the actual Survey needs to be provided to participants. Participant Consent is assumed if the survey is returned.

All other forms of research must provide BOTH an Information Letter and Consent Form to the participants.

Focus Group Research

If you are conducting a research project that involves the use of Focus Groups, you will need to provide your participants with a copy of a Focus Group Facilitator Form in addition to the Participant Information letter and Consent Form. This letter, which must be signed by the researcher, reassures the participant that you as the Investigator will respect his/her responses, keep them confidential, and not continue with a line of questioning if any participant indicates any discomfort with the questions and/or issues being discussed.

Interview Research

If you are conducting a research project that involves the use of face to face interviews, you will need to provide your participants with a copy of an Interviewer Agreement Form in addition to the Participant Information letter and Consent Form. This letter, which must be signed by the researcher, reassures the participant that you as the Investigator will respect his/her responses, keep them confidential, and not continue with a line of questioning if any participant indicates any discomfort with the questions and/or issues being discussed.

2.4 HARM MINIMIZATION

All research conducted should pose less than minimal risk to potential participants. The standard of *minimal risk* is defined as follows: If potential participants can be reasonably expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his/her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk. Generally, research projects that pose minimal risk to the participants will include:

1. Disclosure of the aims of the research;
2. No deception of participants;
3. No psychological stress or anxiety;
4. No physical stress, fatigue, or endangerment;
5. No lingering psychological issues;

If more than minimal risk to potential participants is involved, then the risks and benefits to all parties should be discussed. Moreover, a statement should be included in the Information Letter that if participation in the project raises psychological issues, the participant can contact the Supervisor of the research project, who can direct him/her to a relevant professional in the field.

2.5 CONFIDENTIALITY AND ANONYMITY

2.5.1 Confidentiality

Confidentiality relates to the privacy of the data and addresses, and who has access to this information. In the Research Ethics Committee Research Proposal Form, you should describe the procedures that you use to preserve confidentiality of participants and explain how written records, videotapes, recordings, questionnaires, specimens, and tests will be kept, and disposed of, after the study is completed. Indicate who is responsible for data monitoring and analysis. Describe any condition in which confidentiality cannot be guaranteed or must be breached. For example, professionals disclose confidential information only as authorized by the client, unless there is substantial risk of serious harm to the client or other persons, or a legal obligation to disclose. Where disclosure is warranted, both the amount of information disclosed and the number of people informed is restricted to the minimum necessary. In rare instances it will not be possible to ensure confidentiality because of mandatory reporting laws. When this is the case, the prospective research participants should be aware of this limitation. You should also note that current regulations require you to retain records from your research for a period of five years.

2.5.2 Anonymity

Anonymity relates to all aspects of a research project where the participant=s identity might be linked to the research. Anonymity becomes a concern (even if the data are kept confidential) where mere association with a study might pose risk to participants. In research that where anonymity is important, you should describe the procedures that you use to preserve the anonymity of participants or any condition in which anonymity cannot be guaranteed or offered to participants. For example, anonymity is of particular concern in research that involves focus groups. Although the researcher may agree to keep all discussions conducted within the focus group context confidential, there is no guarantee that other participants in the focus group will maintain the privacy of the information discussed within the focus group. Therefore, in research involving focus group discussions neither confidentiality nor anonymity can be guaranteed. Potential participants need to be made aware of this possibility in the information letter, and again reminded on the Participant Consent Form.

2.6 DEBRIEFING

Debriefing concerns the closing script researchers provide participants at the end of their individual participation. This will include divulging the nature of the study and what the researcher hopes to discover. In cases where deception is involved, the real nature of the study is then to be divulged, plus adequate time is to be given to ensure participants are not harmed by this new information. In all cases, it is expected that researchers sincerely thank participants and respond to any questions they may have.

Full debriefing should also include some indication of the way in which the results of your research will be communicated to your participants after the research project has been completed.

3. Checklists

To ensure that your application to the Department of psychology Research Ethics Committee is complete, please refer to the checklist that fits the protocol for your research, and attach the listed documents to your Research proposal. It is assumed that **UNLESS EXPLICITLY STATED**, your research proposal satisfies the requirement of posing less than minimal harm to the participant.

A. Involves children (aged 14 years and under) or individuals not competent to consent, and recruited through a school or institution:

- Letter from School Board/Institutional Board, granting permission to conduct research at the requested school/institution
- Letter from School Principal/Institution, granting permission to conduct research at the requested school/institution
- Information Letter for Teachers
- Information Letter for Parents
- Information Letter for Children
- Participant Consent Form for Children (unless child assent is obtained)
- Participant Consent Form for Parent/Guardian
- Any questionnaires, surveys, interview questions, focus group questions, or cue stories to be used to collect data

PLUS:

If data is to be collected through the use of Interviews or Focus Groups:

- Interviewer Agreement Form/Focus Group Facilitator Form (if data is to be collected through the use of interviews and/or focus groups)

B. Involves children (aged 14 years and under) or individuals not competent to consent, and not recruited through a school or institution:

- Information Letter for Parents
- Information Letter for Children
- Participant Consent Form for Children (unless child assent is obtained)
- Participant Consent Form for Parent/Guardian
- Any questionnaires, surveys, interview questions, focus group questions, or cue stories to be used to collect data

PLUS:

If data is to be collected through the use of Interviews or Focus Groups:

- Interviewer Agreement Form/Focus Group Facilitator Form (if data is to be collected through the use of interviews and/or focus groups)

C. Involves adolescents deemed competent to consent (aged 14 years to 18 years), involving LESS THAN MINIMAL RISK, and recruited through school or institution:

- Letter from School Board/Institutional Board, granting permission to conduct research at the requested school/institution
- Letter from School Principal/Institution, granting permission to conduct research at the requested school/institution
- Information Letter for Teachers
- Information Letter for Adolescent Participants
- Participant Consent Form for Adolescent Participants
- Any questionnaires, surveys, interview questions, focus group questions, or cue stories to be used to collect data

PLUS:

If data is to be collected through the use of Interviews or Focus Groups:

- Interviewer Agreement Form/Focus Group Facilitator Form (if data is to be collected through the use of interviews and/or focus groups)

D. Involves adolescents deemed competent to consent (aged 14 years to 18 years), involving LESS THAN MINIMAL RISK, and not recruited through school or institution:

- Information Letter for Adolescent Participants
- Participant Consent Form for Adolescent Participants
- Any questionnaires, surveys, interview questions, focus group questions, or cue stories to be used to collect data

PLUS:

If data is to be collected through the use of Interviews or Focus Groups:

- Interviewer Agreement Form/Focus Group Facilitator Form (if data is to be collected through the use of interviews and/or focus groups)

E. Involves adolescents deemed competent to consent (aged 14 years to 18 years), involves GREATER THAN MINIMAL HARM, and recruited through a school or institution:

- Letter from School Board/Institutional Board, granting permission to conduct research at the requested school/institution
- Letter from School Principal/Institution, granting permission to conduct research at the requested school/institution
- Information Letter for Teachers
- Information Letter for Parents/Guardians
- Information Letter for Adolescent Participants
- Participant Consent Form for Adolescent Participants
- Participant Consent Form for Parent/Guardian
- Any questionnaires, surveys, interview questions, focus group questions, or cue stories to be used to collect data

PLUS:

If data is to be collected through the use of Interviews or Focus Groups:

- Interviewer Agreement Form/Focus Group Facilitator Form (if data is to be collected through the use of interviews and/or focus groups)

F. Involves adults (aged 18 years and above), recruited through an institution, with data collected by interview or focus group methods:

- Letter from Institutional Board, granting permission to conduct research at the requested institution
- Letter from Institutional Head, granting permission to conduct research at the requested institution
- Advertisement used to recruit participants for the research
- Information Letter for Participants
- Participant Consent Form
- Any interview questions, or focus group questions used to collect data
- Interviewer Agreement Form/Focus Group Facilitator Form (if data is to be collected through the use of interviews and/or focus groups)

G. Involves adults (aged 18 years and above), recruited through an institution, with data collected by anonymous surveys, questionnaires, or cue story completion tasks:

- Letter from Institutional Board, granting permission to conduct research at the requested institution
- Letter from Institutional Head, granting permission to conduct research at the requested institution
- Advertisement used to recruit participants for the research
- Information Letter for Participants
- Any surveys, questionnaires, or story completion tasks used to collect data

H. Involves adults (aged 18 years and above), NOT recruited through an institution, with data collected by interview or focus group methods:

- Advertisement used to recruit participants for the study
- Information Letter for Participants
- Participant Consent Form
- Any interview questions, or focus group questions used to collect data
- Interviewer Agreement Form/Focus Group Facilitator Form (if data is to be collected through the use of interviews and/or focus groups)

I. Involves adults (aged 18 years and above), NOT recruited through an institution, with data collected by anonymous surveys, questionnaires, or cue story completion tasks:

- Advertisement used to recruit participants for the research
- Information Letter for Participants
- Any surveys, questionnaires, or story completion tasks used to collect data

References

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