



**UNIVERSITY OF PRINCE EDWARD ISLAND**

## **Research Ethics Board**

**Guidelines for submitting an application for Research Ethics Review**

*MARCH 2009*

## Guidelines for Submitting an Ethics Application

Graduate Students submitting an application for ethics Review must also submit a completed and signed “Confirmation of Supervisor’s Review” form.

### General

1. The information in this guidance document must be used to ensure that sufficient detail is included in the Application Form. Please ensure that you follow the guidelines. Incorrect or incomplete submissions may be returned without being reviewed. The numbering of the sections and subsections below corresponds to the numbering on the Application Form.
2. All pages in the application **MUST** be numbered sequentially from start to finish including any Appendices or Addenda submitted with the form. This enables the reviewers to precisely reference their comments for revision purposes. Revised documents **MUST** show the date of the re-submission and note that it is a revision.
3. Your submission **MUST** include **(1) completed application (1) copy of your research proposal, grant application or contract proposal, PLUS (2) TWO COPIES** of (as applicable):
  - Recruitment materials
  - Information letters
  - Consent Forms
  - Research instruments
  - Debriefing materials
  - Letters of permission

These should be attached as Appendices to the Application form. A list of Appendices should also be included.

4. Each application must be submitted as a **STAND-ALONE** document. Previous submission may be mentioned, but all required content must be included in the submission (i.e., do not refer to another submission to provide details needed in this one).
5. If you have a “**Release of Funds Agreement**” associated with this study, you **MUST** attach a copy of it to this submission so that access to funding will not be interrupted.
6. Please ensure that all text is printed in a font size that is no smaller than 11 pts.
7. Please complete the form, print it, sign page 1, and submit 1 original and 2 copies (including attachments) to Lynn MacPhee in the Office of Research Development (ORD) Room 229 Kelley Building. (**Only 1 copy of the proposal is to be included with the original.**) **NOTE:** For more than minimal risk you are required to submit 1 original and 12 copies.

## Section 1. ADMINISTRATIVE INFORMATION

### 1.1 **Local Principal Investigator (PI)**

Graduate students are considered to be Principal investigators for their thesis research projects.

#### **Signature of Local PI**

It is the responsibility of the researcher to ensure that all those engaged in conduction the research project have read the Tri-Council Policy Statement (TCPS).

#### **Address**

Campus address and email are important for contacting the PI.

#### **Co-investigators**

List ALL faculty members that will be working with you on this research project.

#### **\*\*\* For Student Submissions**

Signature is required by Supervisor along with the **Confirmation of Supervisor's Review Form.**

### 1.2 Attestation.

## Section 2. PROJECT DESCRIPTION

### 2.1 **Introductory Summary**

This is a brief summary of the rationale, purpose and methods to orient the reviewers to the study. It should be written in plain language and should be no longer than 250 words.

### 2.2 **Study Design**

This section provides the rationale for the research. It should include sufficient references to the literature to substantiate the researcher's description of why it is necessary to do this research. It must be written in plain language, suitable for readers who may not be experts in your field. It should not exceed three pages in length (not including references). To the original copy of this form attach **ONE** full version of your proposal.

2.2.1 Some studies are intended to test hypotheses or address specific research questions. These should be articulated clearly. Other studies are more exploratory in nature, or

involve methodologies which are more inductive in nature. This should similarly be described.

2.2.2 Justification for the study (address scholarly/scientific validity of study and the appropriateness of utilizing human participants).

2.2.3 A brief description of the plans for data analysis (including any software that will be used should be included

2.2.4 Fully-developed versus pilot studies

A fully-developed study is one that is intended to be a stand-alone piece of work whereas a pilot study is one that is intended to test the feasibility of a methodology through data collection and analysis, or is a preliminary investigation intended as the basis for a larger work.

The Tri-Council Policy Statement requires that human participant research projects that are defined as 'pilot studies' undergo ethics review. However, researchers often engage in what might be considered exploratory investigations of methodology that are often referred to as 'pilot work'.

The following criteria distinguish a pilot study from pilot work:

- A research plan (even if it is rudimentary) is being followed, e.g., a discrete set of questions will be used in survey fashion, or a series of behavioural manipulations will be followed repeatedly with a number of participants (even if it is only a few individuals)
- The application of the plan, and collection of information, will involve the participation of individuals other than the researcher
- Data will be collected
- This data will be analyzed (even if it is only a preliminary way)
- This information will be used to guide future work, or will be published in some fashion.

If the activity can be characterized in the above fashion, then the Board considers it to be a 'pilot study' which must undergo ethics review.

By comparison, the following are examples of activities which, in the view of the Board, constitute pilot work and do not need to be reviewed.

- A researcher asks a group of colleagues to go through a behavioural exercise to see whether it is feasible to conduct it in a given way (no data is collected).
- A researcher asks a group of friends or colleagues to complete a questionnaire to determine the length of time it takes to do so (no data is retained)

When in doubt about whether or not a particular activity constitutes a pilot project requiring ethics review, the researcher should contact the Office of Research Ethics Administration (620-5104).

2.2.5 Where later phases of work are contingent on the interpretation or output of earlier stages, it may be sensible to request a 'phased review.' Phased reviews involve an initial presentation of the overall research plan, including the rationale and study design and plans for data analysis. At the time of their submission, however, it may only be possible to submit research instruments (e.g., questionnaires, interview guides) that relate to the initial phase of work. The researcher should clearly indicate what is being submitted for initial review and approval and what will be submitted later to complete the review and approval of later phases. Phased reviews are not appropriate for studies which can be presented in their entirety at the outset, even if there are several sequential steps of data collection. (See also Phased review of Research, Page 36.)

## 2.3 **Detailed Methodology**

2.3.1 The physical location of the study (e.g., where testing will be conducted, or interviews held) must be described. It is important to provide sufficient detail such that any limitations to confidentiality, or any safety concerns, can be identified.

Researchers should discuss any cultural, social or environmental contexts that pose specific ethical challenges – whether it be risk to participants, additional permissions that must be sought, or culturally-specific practices that must

be observed in conducting the research (see also, International Research, page 36).

- 2.3.2 A full protocol describing the procedures, tasks or activities that the research participants will be asked to take part in must be presented so that the Board can clearly understand what they will experience. Where many procedures are planned, a stepwise flowchart or table (indicating procedures and their duration) should be submitted. This is especially important where multiple interactions are planned with some or all of the participants. Plans for how participants will be re-contacted need to be described, where applicable. Any safety measures that are deemed necessary should also be described. Where there is a phased review requested, the details of the initial phase(s) for which approval is being sought should be presented (see Phased Reviews, 36).
- 2.3.3 The researcher should describe what data will be collected and how it will be done. All research instruments should be described (eg. questionnaires, focus group/interview guides, psychometric tests) along with their validity and reliability (where appropriate). Ethical principles require that researchers only collect the data needed to address the research questions. Therefore, where a number of instruments or highly detailed demographic questionnaires are to be used, each must be justified in relation to the objectives of the study. Where permission is needed to use research instruments developed by others, this should be described along with how permission will be obtained. Where video recording or audio recording is planned, the researcher should describe why this is necessary and how it will be done.
- 2.3.4 All members of the research team must have the appropriate training and qualifications in relation to their role and duties in the study. Both roles and qualifications should be described.
- 2.3.5 The researcher should estimate the time that participants will be asked to commit to the study. This will include travel time, time to review the Consent Form, time to complete the study measures, and any post-data collection activities, such as member-checking or data verification.

The researcher should provide a total time for participation

as well as a time estimate for each task.

## **2.4 Recruitment/Participants**

The description of the study population should include any and all characteristics or attributes of potential participants that are relevant to the research. Specific attention should be paid to those attributes that would suggest a level of vulnerability in the potential participants; e.g., literacy limitations, mental or physical impairment, extreme youth or age.

Recruitment instruments would include such items as posters, media advertisements, brochures, email text or letters. Copies of these should be appended to the application. Where oral recruitment is proposed, scripts guiding this process should be presented. Basic information that should be included in a recruitment instrument would include: study title (in plain language), a short description of what the study is about, inclusion/exclusion criteria, total length of time commitment required, compensation if any, and not prominently featured) and contact information that participants can use to reach the researcher.

Researchers should describe how they, or others on their behalf, will be pursuing these recruitment methods (e.g., members distributing recruitment brochures, IT managers circulating an email). Researchers should be careful to address issues surrounding recruitment that might relate to the voluntariness of participation. For example, faculty wishing to involve students as participants in research must clearly demonstrate how they have mitigated any coercive influences. Where an intermediary is to be used (i.e., a research assistant, or teacher in a school classroom) this should also be addressed.

Specific inclusion and exclusion criteria (e.g., age, profession, sex) should be stated. Where a given recruitment strategy is intended to exclude those for whom the study procedures would pose a particularly high degree of risk, then this should be explained. Where possible, researchers should refer to estimations of risk reported in the literature to support the selection of particular inclusion/exclusion criteria. The sample population should be representative of your total population.

If the permission of authorities are needed (e.g., Aboriginal Band Council, School board, Director of long-term care facility) for the

researcher to be able to conduct recruitment and research activities, these should be described and letters of permission included in an Appendix to the submission.

Compensation is allowable, often recommended in fact, but the amount cannot be deemed undue enticement. The concept of undue enticement will vary between participant pools, location, nature of the experimental conditions, and other factors, but should not be deemed more than the costs incurred by participation. This better ensures that participation is truly voluntary.

## **2.5 Risk and Benefits**

Consistent with the principle of proportionate review, the more risk that is posed to research participants by a given study, the greater the care and comprehensiveness of the consent process will be required by the Research Ethics Board.

2.5.1 Doing a risk assessment of the proposed research is a vital part of the ethics submission. Researchers should be thorough but realistic in describing and estimating risks that are posed to participants in the study. Because of the inherent uncertainty in the conduct and outcomes of research, it is not appropriate to claim that there are 'no risks'. Risks may be minor or significant; however the researcher is responsible for mitigating any anticipated research-related risk to the best of his/her ability. In all cases, the researcher must disclose to participants whatever risk, discomfort, or inconveniences the research might pose, including:

- all **known** adverse effects (including physical, emotional, psychological, social or economic) to the participant
- any anticipated or **potential** risks or stressors (physical, emotional, psychological, social or economic) to the participant

The definition of minimal risk used in the TCPS is, as follows:

"If potential participants can reasonably be 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 ... his or her everyday life... then the research can be regarded as within

the range of minimal risk.”

- 2.5.2 Risk has two components: harm and the probability of that harm. In describing potential risks, the researcher should discuss both, such as “there is a high probability that participants will feel emotional distress.” Wherever possible these should be substantiated by references to prior research or to the literature.
- 2.5.3 Researchers should describe what steps are taken to mitigate the risks posed by research. These could include specific safety precautions, screening protocols, referral arrangements for counselling, etc.
- 2.5.4 Sometimes the research poses risks at the level of communities. For example, epidemiological research into the geographic prevalence of certain diseases might have an impact on insurability of people living in those communities, or where being identified as a homosexual in a homophobic community may have dire consequences. The researcher should seek to identify such risks, when they exist and to determine whether or not there are any mitigating actions that could be taken. This is not to suggest that critical research should not be undertaken, rather that the assessment of risk should consider communities, as well as individuals, and the researcher should address these either through mitigation (where possible) or disclosure where it is not possible to mitigate these risks.
- 2.5.5 Benefits must be to the participant, not to the participant group. Typically there are no direct benefits in research that do not involve medical treatment (save pedagogical benefits)

## **2.6 Informed Consent Process**

### **2.6.1**

The conduct of research involving human participants requires that participants are provided with the opportunity to give informed consent prior to their participation in the research. The process of obtaining this consent can be carried out in a number of ways, and where warranted, should be revisited during the research (where the research takes place over a protracted period, or where information

emerges during research that might influence a participant's decision to remain in the study).

The TCPS states that, except in specific circumstances, informed consent should be obtained using a written Consent Form that the researcher reviews with participants and has signed prior to the start of the research. This document must provide research participants with sufficient information about the research to ensure that they understand the procedures, tasks or activities, in which they will be involved, and the risks and potential benefits of the research. It must also inform them of their rights with respect to participation, i.e., that research participation is voluntary and that they have the right to withdraw at any time. Researchers should provide the Consent Form to participants in advance of whatever activity they will be involved in (i.e., focus group, testing) so that they have a chance to consider their participation prior to their arrival at the research venue.

Where different groups of participants will be involved in different aspects of the study, a consent form specific to each group's participation should be developed, to avoid confusion or misinterpretation.

The researcher should describe the consent process that will be used, including who will do it, when it will be done (in relation to when the research will take place) and where it will be done.

Vulnerable, participants refer to unequal power relations between recruiter and potential participants. If the participant is in a subservient relation to the researcher or recruiter, he or she may not feel the choice to participate is really voluntary. Examples include where the participant is the researcher's student or employee.

## 2.6.2 Oral Consent

In some very specific instances, written and signed consent forms may not be culturally appropriate, may actually constitute a risk to research participants, or may not be sensible where literacy limitations of participants are a concern. In these cases, oral consent may be appropriate and the procedures to be used in obtaining it and documenting it, along with the reasons why written consent

is not appropriate, should be stated in the research protocol. In such cases, an information letter provided to the participant can ensure the accuracy and consistency of conveying necessary information to participants. This information would consist of the same elements found in a Consent Form, however, without the requirement for participant signature.

It should be noted that oral consent is not permitted for research that involves the use of a medical intervention. Similarly, the greater the risk to participants, the greater the need for fully informed, voluntary, and signed consent.

### 2.6.3 Waiver of Consent

In accordance with the Tri-Council Policy Statement (Article 2.1 c) there are specific situations where the Research Ethics Board may waive the requirement for obtaining informed consent (written or oral).

This may only be done when **all** of the following conditions pertain:

1. where the risks to participants are minimal,
2. where obtaining consent is extremely impractical,
3. where obtaining written consent violates the norms of the culture/community,
4. where the waiver does not violate the rights or well-being of the participants,
5. where no therapeutic intervention is involved in the research.

The researcher must demonstrate in writing that these conditions exist for the REB to grant such a waiver.

### 2.6.4 Third-party Consent Process

Where it is not clear that potential participants have the capacity to provide informed consent, or if the research participants are of a population recognized as lacking the capacity to provide informed consent (e.g., young children, adults under the influence of judgment-impairing drugs), informed consent must be obtained from an individual who bears responsibility for decisions concerning the well-being

of the participant (e.g parent, guardian, care-giver). Where this impairment is temporary, researchers should describe how consent will be obtained from the participant when they are deemed to have regained decisional capacity. Where a participant lacking decisional capacity is able to provide assent for the research (i.e., demonstrate their willingness to cooperate with the researcher and take part in the research), this should also be sought. Researchers should provide a description in the protocol of the criteria that they will use to judge either assent or dissent of a participant.

**NOTE:** Persons under the age of 14 may not participate as research subjects, in either minimal or non-minimal risk protocols, without parental consent. Persons greater than or equal to 14 years of age and less than 18 years of age may consent to participate as a research subject in the absence of parental consent, subject to specific approval by the REB in that instance. Persons greater than or equal to 18 years of age are considered adults and may consent to participate as research subjects without seeking parental consent. 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.

#### 2.6.5 On-going Consent

The process of consent is not limited to the initial discussion and signature of the consent form. During the course of the research, new information about the study, or knowledge regarding the risks of study procedures may be learned that should be disclosed to participants. **It is the responsibility of the researcher to ensure that this is done.** This would be achieved through:

- submitting an amendment to the Research Ethics Board describing the changes to the recruitment/consent process, and
- informing and reconfirming consent of those currently involved in the study, and
- modifying the consent process / form for new participants

### 2.6.6 Community Consent

In some circumstances (e.g., aboriginal research) it may be important to seek consent from the community as a whole in addition to getting consent from individual participants. It is the responsibility of the researcher to determine whether or not this is needed, and if so, to describe how such consent will be sought.

### 2.7 **Deception / Incomplete Disclosure** (if applicable)

2.7.1 Researchers should describe what misdirection or deception will be used in the study. They should discuss why this is necessary in order to achieve the study objectives. The Board may request that alternative methods be considered if it appears that the study's objectives can be achieved without the use of deception.

2.7.2 Researchers sometimes wish to withhold information about the study that would normally be available to participants; for example, what the true intent of the researcher is or what the purpose of the study is. This must be discussed in the protocol along with the rationale for doing so.

2.7.3 Where deception/misdirection/non-disclosure is used, the researcher must debrief participants regarding the true circumstances surrounding their participation in research. This would include disclosing what the deception or misdirection consisted of along with explaining what the reasons for it were. Similarly information that has been withheld should be disclosed. Researchers should be sensitive to the possibility that the revealed deception may be unnerving to the participants. A plan should be in place for such instances. Also, participants should be given the opportunity to withdraw their data from the study. A debriefing script should be submitted as an Appendix.

### 2.8 **Confidentiality and Anonymity**

Confidentiality relates to the privacy of the data and addresses who has access to it.

Anonymity relates to all aspects of the study whereby the

participant's identity might be linked to the research. Anonymity becomes a concern (even if data is kept confidential) where mere association with the study might pose a risk to participants. For cases where anonymity is important, describe the procedures for preserving anonymity of participants, or any condition in which anonymity cannot be guaranteed, or offered to participants (for example if the research includes use of focus groups).

2.8.1 Researchers have a responsibility to keep all data received from research participants in a confidential manner. Where the human participant data / information that is to be collected, or accessed, is of a personal or sensitive nature, the Board may require the researcher to demonstrate significant confidentiality safeguards. The researcher should clearly describe the kinds of information that will be collected. This is particularly important where secondary use of data collected previously is being conducted; for example, by accessing patient files, or personal employment records.

2.8.2 The researcher should describe the means by which data is collected (e.g., note-taking, audiorecording, videorecording, experimental testing, tissue sampling etc.). If there are codes to be used that link the data from various sessions or sources, or to information that could identify participants (names, addresses etc.), how this will be done should be described. If there is to be remote transmission (e.g., by email) from one location to another, this should be described as well as any security arrangements that pertain to this transmission. Where (and in what format) the data will be stored should be described, along with who will have access to it. How data will be reported (e.g., as aggregate statistics, personal narratives) and what the implications of this are with respect to participant anonymity and data confidentiality should be described. If a transcriptionist has access to the data, he/she should be required to sign a simple confidentiality agreement, and a copy of this should be included in the ethics submission.

2.8.3 If focus groups are used, the researcher should have each member sign confidentiality agreements. In such cases, the researcher can not guarantee confidentiality will be preserved. The researcher should state how long the data will be retained. The University Policy on Scholarly Integrity requires that for published work, data must be held securely for 5 years, post publication. Plans for longer retention should be described along with the rationale for this. Also, the researcher should state how or when the data will be

destroyed.

- 2.8.4 Researchers should discuss what steps have been taken to safeguard the anonymity of participants. Anonymous participation in research is only possible when there is no way that an individual can be identified as a participant in a research study. This is not possible where there is face-to-face interaction with the researcher (i.e., interviews) or with others (i.e., focus groups). In some situations or types of research, there can be risk to reputation or risk of reprisals for individuals who are identified as participants. The researcher should consider whether or not these risks could occur in their research, and describe how they will mitigate them. If there is no way to effectively do so, the researcher must demonstrate that he/she has taken all necessary steps to disclose these risks to potential participants in advance of their taking part in the research.
- 2.8.5 Where there are limits to confidentiality that are imposed on researchers due to their legal obligations (i.e., duty to disclose suspected child abuse or neglect, or the abuse or neglect of an adult in need of protection) this must be stated. A simple description of what the researcher will do in such a situation should be provided. This is advisable for research that may, inadvertently, cause such disclosures to be made, and it is imperative for research that specifically deals with issues of sexual or child abuse, domestic violence or elder abuse.
- 2.8.6 If the researcher plans to offer, or seek, a waiver of confidentiality to participants, the reasons for this should be described, along with the way in which it will be done.

## 2.9 **Compensation**

- 2.9.1 Compensation for research participation is generally considered to be an honorarium or gesture of appreciation for the effort or inconvenience experienced by the participant or compensation for travel costs or babysitter costs, etc. It is not intended to represent a payment in the sense of employment. Compensation should not represent an undue influence that would induce a participant to accept significant risks that they otherwise would not. When participants are given monetary compensation, the researcher should get a

signed receipt. This may pose an unreasonable risk of breach of confidentiality where the research deals with a particularly sensitive or even stigmatizing subject area. In these cases, when the researcher wishes to process these payments through their research grant / contract, Financial Services requires that the researcher issue each participant with an ID # that is then used in reporting the number of payments made to each participant. The researcher is then responsible for maintaining a confidential record that links the code number to the research participant names, along with holding the signed receipts. (See also FAQ # 13, page 33)

## 2.10 **Debriefing**

2.10.1 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 question they may have.

## 2.11 **Conflict of Interest**

2.11.1 The researcher should describe whether or not any member of the research team has a relationship with the sponsor of the study that would place them in a conflict of interest. One example of such a conflict would be a researcher's having financial interest in a company sponsoring the research, or in the outcome of the research itself. The applicant should describe how any such conflicts will be managed, and how the researcher intends to comply with UPEI's policy on Conflict of Interest

2.11.2 Conflicts of interest may also arise in the form of relationships between researchers and participants, for example, when a researcher/teacher wishes to recruit students from his/her own class into a research project, or a physician wishes to recruit his/her own patients. A recruitment strategy that involves physicians being paid, per individual, to recruit their own patients (either into their own

research, or that of another researcher) is an example of an unacceptable conflict of interest. In this case the physician faces a conflict between his/her own financial interests and his/her fiduciary responsibility towards patients. The researcher should describe how these conflicts will be managed, and indicate how (s)he intends to comply with UPEI's policy on Conflict of Interest.

2.11.3 Append any agreements to the proposal and give details.

## **2.15 Human Genetics Research**

### **Section 3. CONSENT FORM**

#### **3.1 Consent Form Checklist**

The Checklist is provided to help researchers ensure that all the required elements are present in their Consent Forms. The Checklist should be completed and submitted with the application.

#### **3.2 General notes on creating a Consent Form**

1. Where it is clear that research participants have the capacity (i.e., decision making capability) to provide informed consent, the researcher must ensure that the information provided to research participants is presented in such a manner as to be easily and comprehensively understood. The language and terminology used in describing the research must clearly convey the objectives and methodology of the research project, and the risks and benefits to the research participant. It is recommended that consent forms be written for a **Grade 8 level of reading comprehension**. See Sample Form attached (Appendix L)
2. Consent forms should be drafted such that the research participant is referred to in the second person (i.e., "You are invited..." "You will be asked to ..."). This should be used throughout, with the exception of a signature statement which is in the first person (i.e., "I have read this form..."), is italicized in quotation marks, and which is intended to state the in clear terms what the participant is attesting to in signing the form.
3. When more than one group of participants will be involved, researchers should prepare a separate consent form that describes specifically the kind of involvement of each group.

4. With complex studies and/or lengthy consent forms, or where the study poses significant risks to participants, it is often advisable to provide a copy of the form to participants in advance of the actual time where consent will be obtained, in order that they may consider it carefully, and perhaps have an opportunity to discuss it with family members.

### 3.3 Consent Form Template

The following format should be used for a standard written Consent Form that could be used with individuals capable of giving consent for their own participation in research. Suggested headings for each section in the Consent Form are shown in underlined text, followed by a description of the appropriate content for that section.

#### **Consent Form**

The first page should display:

- the study title in lay language.
- Local contact information for researcher and, if a student thesis project, the student's supervisor. This should identify who the appropriate contact person is for participants should they need additional information or have questions
- the words 'Consent Form' must appear at the top of the page.

#### **Plain Language Guide**

Use Active voice

- Passive: All questions are to be filled in numerological order.
- Active: You should fill all questions in order.

Engage the Reader.

- Non-engagement: Participants must use their proper codes when submitting their surveys.
- Engagement: Please use your proper code when you submit your survey.

Use positive language.

- Negative: Do not fail to notify the researcher if you can't make your interview.
- Positive: Please notify me if you can't make the interview.

Use plain words

- Jargon: We are currently in the process of examining the long term effects of smoking cessation products to ensure

- that the products are effective.
- Plain: We are looking to see if some products work better than others in helping you quit smoking.

Keep words and sentences short.

- Long: The procedures for complying with the experimental parameters are included in the initial information letter that you received in the mail.
- Short: We sent an information letter to you. In that letter, you will find a description of what you need to do.

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The preceding rules and illustrations are based on the PEI Literacy Alliance document, "*How to cut the gobbledegook: An introduction to plain language writing and clear design.*" ([www.pei.literacy.ca](http://www.pei.literacy.ca))

## **Introduction**

Sample Participant Information Letter:

"We invite you to participate in a research project on your health and literacy needs. John Smith will conduct the research supervised by Jane Smith in the Department of Psychology at UPEI. We are conducting this study to fulfill the requirements of Psych 432, Judgment/Decision Making.

If you choose to take part in this project it will take thirty minutes of your time, and no harm will come to you. Whether or not you take part is completely up to you. You may stop participating in the project at any time, without any consequences. We will keep all information that we collect during this project confidential and anonymous. We will ensure that you will not be identified from any of your responses. We will destroy the audio-recording of your responses as soon as we have transcribed it. We will identify you only by a number or a code name in the final transcript.

John Smith and Jane Smith are the only people who will have access to the data resulting from this research project. We will retain all the data for five years after the end of the project, and then we will destroy it.

If you participate in this project we will give you:

- A payment of \$20.00 or
- A course credit of 1 mark towards the laboratory component of your grade in Psych 432.

If you do not participate in this research project, there will be more opportunities for you to take part in the projects to make up this laboratory

grade. If you decide to withdraw from the research project at any time, you may keep the course credit or the \$20 we gave you.

If you have any questions or concerns about this research project, please contact Jane Smith at 123-4567 or [jsmith@upei.ca](mailto:jsmith@upei.ca).

For access to the full results of the research project once they are available, please contact John Smith or Jane Smith at 123-4567 or [jsmith@upei.ca](mailto:jsmith@upei.ca).

The Research Ethics Board of UPEI has approved this research project. If you have any difficulties with, or wish to voice concern about, any aspect of your participation in this study, or the ethical conduct of this study, you may contact the UPEI Research Ethics Board, for assistance at (902)620-5104, [Imacphee@upei.ca](mailto:Imacphee@upei.ca)

### **Purpose of the Study**

This section briefly explains the rationale for the study, and what the researcher hopes to achieve. It should provide enough information so that the intent of the study is clear, without biasing the participation of the participant. Researchers should avoid the use of coercive language (such as stating that the success of the researcher's project relies on the participation of the participant).

### **Study Design**

This section describes the kind of study that the research represents. If it is necessary to use words like "randomization" or "multi-centre" these should be described in lay language. If a placebo is to be used it must be described (e.g., an inactive medication) and research participants must be informed that they may receive a treatment that has no medication effect (e.g., "you will have a 50% chance of receiving a placebo"). If there is to be deception or incomplete disclosure of the purpose of the study for any reason, participants should be told that there will be given additional information about the study after their participation is complete (i.e., a debriefing).

### **Who can Participate in the Study**

This section should explain what characteristics the participant must have to be eligible for participation in the stud. The language used should be simple and direct... "You may participate in this study if you are...". Any conditions that exclude a participant from participation must also be listed here. If any screening activities are planned, these should be described.

## **Who will be Conducting the Research**

This section should identify the names and roles of the various people who will be involved in the research. This would include the Principal Investigator, and any technical or administrative staff that the research participant may be dealing with.

## **What you will be asked to do**

All the study procedures must be stated clearly and in sufficient detail that the participant can understand what will be expected of them. The location, frequency/number and length of visits, types of procedures (perception tests, interviews) and the duration of the study must be included here. This description should only include the activities that the participant will experience. Where several groups of individuals will take part in different components of the research, separate consent forms should be developed for each group to keep the description simple and specific.

## **Possible Risks and Discomforts**

This should include all possible adverse events or side effects, along with estimated probability of occurrence (if known) of any of the procedures used in the study. This refers both to discomfort associated with physical procedures (e.g., stress tests) as well as the possibility of emotional or psychological distress caused by interviews or survey contributions. Where there is a possibility of economic repercussions, damage to relationships, or loss of anonymity, these should be described. The steps that will be taken by the researcher to minimize these risks should be stated. In some instances, risks may exist for communities associated with the study (stigmatization, community discord). These should also be discussed. Researchers should not categorically state that there is 'no risk' associated with a study. This suggests a guarantee that is not possible given the inherent uncertainty involved in research. Where the harms or discomforts are no greater than those that are related to common experiences of everyday life, they may be described as 'minimal'.

## **Possible Benefits**

Describe any potential benefits that the participant may derive from their participation in the study. Where there are no anticipated direct personal benefits to participants, this should be explicitly stated. More altruistic benefits (e.g., contribution to knowledge) should be realistically assessed (i.e., not overstated); the text should not imply that these benefits are guaranteed.

## **Compensation**

If participants are to be compensated for their participation the full extent of this compensation, and how it will be provided should be described. If participants are to be compensated for expenses incurred in relation to their participation (e.g., parking, transportation costs) this should be stated. Research participants

should also be informed that there is no cost to them for being in the study. If participants are **not** being compensated this should be stated also.

### **Confidentiality & Anonymity**

It is the responsibility of the researcher to safeguard the anonymity of participants and the confidentiality of the information that they provided.

**Anonymity:** Researchers should indicate the way in which the anonymity of participants will be achieved. Where it is not possible to protect a participant's anonymity (e.g., where they are part of a focus group) this limitation should be described. Participants should be told that they will not be identified in any reports or publications. Your not identifying participants does not mean others might not identify them, however. Your role, therefore, is to try to de-identify as much as possible, and inform participants of the risk of anonymity breaches.

**Confidentiality:** Research participants should be told how the data that they will be providing will be treated (e.g., aggregated, coded) and stored (e.g., locked file cabinet, password protected on a computer), and who will have access to it. This should be described clearly and in terms that are easily understood. In addition, the limitations of these safeguards should be stated clearly. For example, government agencies or drug companies may need access to the data to ensure accuracy. If it is necessary that a participant's health records must be accessed as part of the study, at the beginning or in the future, this must be stated, and permission sought.

Where there are limits to confidentiality that are imposed on researchers due to their legal obligations (i.e., duty to disclose suspected child abuse or neglect, or the abuse or neglect of an adult in need of protection) this must be stated. A simple description of what the researcher will do in such a situation should be stated. This is advisable for research that may, inadvertently, cause such disclosures to be made, and it is imperative for research that specifically deals with issues of sexual or child abuse, domestic violence or elder abuse.

University of PEI Policy on Research Integrity requires that data be securely maintained by the institution for 5 years, post publication and then disposed. Researchers should indicate this and briefly state how this will be accomplished.

### **Questions**

Participants must be provided with a means of having their questions about the study addressed. A local telephone contact and email should be available. In addition, participants should be assured that they will be provided with any new information that might affect their decision to participate in the study.

### **Summary (optional)**

If the protocol is a complicated one, a simple summary might be helpful. Participants should also be told that they will receive a copy of the consent form

for their records and information at the outset of the study, and that they will be informed at the completion of the study what medication they received during the research (if any).

### **Problems or Concerns**

The following statement **must** be included at the end of every consent form: **“If you have any difficulties with, or wish to voice concern about, any aspect of your participation in this study, or the ethical conduct of this study, you may contact the UPEI Research Ethics Board, for assistance at (902)620-5104, lmacphee@upei.ca”**

### **Signature Page**

This page should be formatted as a separate page and the title of the study must appear at the top. The Consent Form should be signed and dated by the research participant or by the person authorized to sign on behalf of the research participant (e.g., a parent or care giver). In the latter instance, the participant's name must also be clearly indicated. The following statement can be used: “I have read the explanation about this study. I have been given the opportunity to discuss it and my questions have been answered to my satisfaction. I hereby consent to take part in this study. However I realize that my participation is voluntary and that I am free to withdraw from the study at any time.” It should be clear, from the format of the page that “I” refers to the research participant.

Explicit consent must be sought from participants for the following, where applicable:

- audiorecording or videorecording
- recontacting for future phases of research or other studies
- use of substantial quotations
- waiver of confidentiality

Consent for each of these should be indicated with a separate signature line or tick box. It should be clear in the protocol why each of these permissions is being sought.

A signature and date line should also be provided for the person who is obtaining consent (usually, but not always the researcher). This should be completed at the time when the consent form is signed by the participant. A witness signature is not generally required.

With respect to permission for the use of quotations, the best practice is to **confirm** explicit permission for this after the interview / focus group is completed so that individuals will have a clearer understanding of what might be contained in quotations.

Researchers who may wish to take personal data outside of Canada or to share it with colleagues outside of the University of Prince Edward Island must seek Consent for this from participants. This is required for the research to be in compliance with privacy legislation.