**Behavioural Research Ethics Board**

**Consent Form Overview and Guidelines**

**Overview**

The goal is to communicate the essential elements of free and informed consent without obscuring the important information in a lot of detail; the greater the cognitive capacity of the participant, the greater the amount of information that could and should be communicated. The choice of whether to present the information orally or in writing will depend on a number of considerations including but not limited to, the literacy level of the target population, cultural expectations, and age.

A copy of the consent form must be submitted to the Research Ethics Board along with the ethics application.

Guidelines

The Consent Form and any information provided to participants must be written in language that is non-technical and can be understood by a layperson. Attention must be paid to the participants’ level of education and fluency in English or other language in which the consent is written. Appropriate language and format needs to be used when considering specific populations (such as children, the elderly, populations with compromised literacy, populations with unique cultural considerations, etc.) The Consent Form must be in a minimum of 12-point font for clarity and ease of reading. Please ensure that the information provided in the Consent Form is congruent with the information provided in the Ethics Application.

A description of the required elements of the Consent Form appears below. A Consent Form Template is appended to these guidelines. Unless there is compelling reason to do otherwise, the committee requires that this template be used. The Consent Form should include:

1. The title of the study, which must correspond with the title of the REB application title.

2. Name(s), institutional affiliation(s) and telephone number(s) of researchers. This should include the research supervisor, co-investigators, student researcher(s), and research assistant(s).

3. The purpose and objective(s) of the study.

4. The procedure(s) to be followed, including details of any interviews, questionnaires, and other data gathering instruments, as well as an estimate of the time commitment of the participant. It can include a statement indicating where the research will take place and indicate how many potential participants will be included or are anticipated.

5. If the investigators have received a grant or contract to conduct this study, include the name of the industry sponsor or granting agency. Also, if applicable, include a statement of any actual or potential conflict of interest on the part of the researchers or sponsors.

6. All foreseeable risks, side effects and discomforts must be stated. Risks may include social harms such as breach of confidentiality, social stigmatization, threats to reputation, economic repercussions, damage to relationships and/or psychological harms (e.g. anxiety, regret or guilt feelings). Describe the strategies to be used to minimize or manage the risks for participants. If potential risks or discomforts are anticipated or the research project is of a sensitive nature, information on the arrangements/availability of counselling or other such services must be outlined on the Consent Form.

 Participants should be encouraged to only answer those questions that they are comfortable with. A statement to this effect should be included in the Consent Form.

 If the research has the potential to reveal information that is required by law to be communicated to a law enforcement or other agency (e.g. child abuse), inform your participant of your legal obligations.

 If appropriate, describe the circumstances under which someone’s participation in the study may be terminated.

7. The possible benefits of the study, both to the participant and to others, stressing that these benefits are not guaranteed**.** In cases where the objectives of the research project are purely scientific, such that immediate application of the research findings is not anticipated, this statement may be omitted.

8. Describe any compensation that will be offered to participants. The amount and kind of payment should be included. If a course credit is available to University students, explain the process. The payment should not be such that the participant will base their decision to participate on the potential material rewards. Remuneration or compensation should not be dependent on completion of the project, however may be prorated for those that withdraw before completion. For example: In order to defray the costs of inconvenience/transportation/etc, each participant will be reimbursed or will receive an honorarium in the amount of $XX. (*Research Participants Funding Requisition Guidelines and Procedures - University of Saskatchewan*).

9. A description of the degree of confidentiality that will be maintained. A statement that participation is voluntary, that the participant is free to withdraw from the research project, and, if applicable, that this withdrawal will not affect the participants’ academic status, and/or access to, or continuation of, services provided by public agencies such as the University, hospitals, social services, schools, etc. It should also be stated that when a participant withdraws, his/her data will be deleted from the research project and destroyed, if desired (Detailed further in section 10 – Right to Withdraw). Note that this is only relevant when the data for individual participants can be identified; if the data have been collected anonymously, then the statement regarding withdrawal of data should be omitted**.**

Please ensure that identifying information (i.e. consent forms and master list) is stored separately from the data collected. Also, please ensure that the master list is destroyed when data collection is complete and it is no longer required. A brief description of this process should be included in the Consent Form.

Anonymity and Confidentiality:

Confidentiality and anonymity are related but distinct concepts. Confidentiality is defined as “spoken or written in confidence; charged with secrets”, while anonymity is defined as, “of unknown name, or unknown authorship”. In regards to research, to assure a participant of confidentiality means that the researcher will ensure that they do not disclose identifiable information about the participant in the reporting or dissemination of the research findings. To assure a participant of anonymity means that the research participant’s identity will not be known to anyone, including the researcher. There are times when the ability to protect anonymity and confidentiality are congruent, and times when clearly there are separate measures needed to deal with each.

 A statement is required detailing the precautions that will be taken to protect the confidentiality and/or anonymity of the participant, including, where applicable, the storage of audiotapes, videotapes, and transcripts. When the anonymity of participants is compromised (i.e., they have provided personal, identifying information or when they have provided direct words that would make them identifiable), the Consent Form must indicate that the research project results and associated material will be safeguarded and securely stored by the faculty member/researcher at the University for a minimum of five years post publication . When the data is no longer required, it will then be appropriately destroyed. For non-University researchers, the data will be stored at their institution (where, by whom and for how long the data will be securely stored needs to be transparent).

 Please note: If the data are anonymous, the statement describing the need for ensuring that the data be securely stored may be omitted.

 Confidentiality Examples:

a. “Although the data from this research project will be published and presented at conferences, the data will be reported in aggregate form, so that it will not be possible to identify individuals. Moreover, the Consent Forms will be stored separately from the (materials used), so that it will not be possible to associate a name with any given set of responses. Please do not put your name or other identifying information on the (materials used).”

“The data from this research project will be published and presented at conferences; however, your identity will be kept confidential. Although we will report direct quotations from the interview, you will be given a pseudonym, and all identifying information (list relevant possibilities such as the name of the institution, the participant’s position etc.) will be removed from our report.”

 b. When conducting focus group research, there are limits to which you, as the researcher, can guarantee the discussion will be kept confidential. A disclosure such as the following is therefore appropriate under these circumstances: “The researcher will undertake to safeguard the confidentiality of the discussion, but cannot guarantee that other members of the group will do so. Please respect the confidentiality of the other members of the group by not disclosing the contents of this discussion outside the group, and be aware that others may not respect your confidentiality.”

 c. There are several contexts in which the confidentiality of respondents may be compromised.

When participants are selected from a small, closed group, they may be identifiable to each other, and to others who are familiar with this group of people on the basis of what they have said. This situation is especially problematic when the researcher plans to report direct quotations in the write-up of the study. In this case, a warning such as the following is appropriate: “Because the participants for this research project have been selected from a small group of people, all of whom are known to each other, it is possible that you may be identifiable to other people on the basis of what you have said.”

Where appropriate, specify the procedures that will be in place to allow participants to review their transcripts and/or to review the quotations that will appear in the final report. For example, “After your interview, and prior to the data being included in the final report, you will be given the opportunity to review the transcript of your interview, and to add, alter, or delete information from the transcripts as you see fit.”

 When the Consent Form and data are returned to the researcher in a way that potentially identifies the participant (i.e., questionnaires are returned by fax or e-mail), participants must be warned about this loss of anonymity, and the researcher must describe the procedures that will be implemented in order to minimize this loss. A description of any recording devices to be used such as videotape or audiotape should be included. Also, a statement that acknowledges that participants may request that the recording device be turned off any time should be included.

 Information must be provided on how the data collected will be used, e.g., a thesis, articles, report to an agency, etc. Include a statement describing how the data will be reported. For example, if direct quotations will be reported, or if personally identifying information will be included in the report, this needs to be clearly stated; if the data will be reported anonymously in an aggregated or summarized form**,** this should also be stated.

If applicable to the research, describe options available to the participant. To do so, it may be useful to create “check boxes” to help enumerate a participant’s choices. For example, you might instruct the participant:

“There are several options for you to consider if you decide to take part in this research. You can choose all, some or none of them. Please put a check mark on the corresponding line(s) that grants me your permission to:”

I grant permission to be audio taped: Yes: \_\_\_ No: \_\_\_

I grant permission to be videotaped: Yes: \_\_\_ No: \_\_\_

I grant permission to have my organization’s name used: Yes: \_\_\_ No: \_\_\_

I wish to remain anonymous: Yes: \_\_\_ No: \_\_\_

I wish to remain anonymous, but you may refer to me by a pseudonym: Yes: \_\_\_ No: \_\_\_

The pseudonym I choose for myself is:

You may quote me and use my name: Yes: \_\_\_ No: \_\_

***10. Right to Withdraw****:*

 a. For surveys and interviews, state that the participant may refuse to answer individual questions. In cases where direct quotations from the participants will be reported and participants will not be asked to review the transcripts of the interview, they should be informed of the procedures that will be in place for withdrawing their responses from the research project after the interview is complete, as well as the time limit, if any, for doing so.

 b. In the case where the participants constitute a captive or dependent population, or where the researcher has, or has had, a relationship of power over the participants, or where participation is solicited as part of a person’s employment or educational role, the researcher must describe in detail the steps that will be taken to ensure that a person’s decision to withdraw will not jeopardize their standing within the institution or their relationship with the researcher. For example, when participants are solicited from a classroom for which the teacher is acting in the role of researcher, a clause such as the following may be included: “The teacher will not know until after the grades have been submitted who has decided to participate and who has not, so that your decision to participate or withdraw cannot have any impact on your standing in the class or on your final grade.”

c. The right to withdraw statement should explain the point at which data withdraw may no longer be possible. A statement similar to the following would be appropriate, “Your right to withdraw data from the study will apply until \_\_\_\_ (results have been disseminated, data has been pooled, etc.). After this it is possible that some form of research dissemination will have already occurred and it may not be possible to withdraw your data”.

d***.*** Researcher’s Relationship with Participants: (*if applicable)* The researcher may have a relationship to you as [State the relationship, e.g., teacher/student; therapist/client; supervisor/employee]. To help prevent this relationship from influencing a participant’s decision to participate, describe the steps to prevent coercion have been taken [Explain how coercion will be prevented].

A statement that participation is voluntary, that the participant is free to withdraw from the research project at any time and, if applicable, that this withdrawal will not affect the participants’ academic status, and/or access to, or continuation of, services provided by public agencies such as the University, hospitals, social services, schools, etc. It should also be stated that when a participant withdraws, his/her data will be deleted from the research project and destroyed, if desired. Note that this is only relevant when the data for individual participants can be identified; if the data have been collected anonymously, then the statement regarding withdrawal of data should be omitted**.**

It should also include a specific reference to other researcher(s) or personnel who will see the data. Include the following information: “If you withdraw from the research project at any time, any data that you have contributed will be destroyed at your request*.*” If the research project extends over a significant length of time, include a statement to the effect that the researcher will advise the participant of any new information that could have a bearing on their decision to participate, as well, participants should be informed about the process by which ongoing consent will be sought.

4. If you have not already mentioned the procedure for reviewing transcripts under ‘confidentiality’, and transcript review is part of your procedure, state that “After your interview, and prior to the data being included in the final report, you will be given the opportunity to review the transcript of your interview, and to add, alter, or delete information from the transcripts as you see fit.”

11. A summary of the research results should be offered, and a mechanism to provide the summary. This could be a website location or email address to request a copy of the results, paper, etc.

12. A statement informing the participant that the proposed research project was reviewed and approved on ethical grounds by the University’s Behavioural Research Ethics Board.

U of R: This project has been approved on ethical grounds by the U of R Research Ethics Board. Any questions regarding your rights as a participant may be addressed to the committee at 585-4775 or research.ethics@uregina.ca. Out of town participants may call collect.

U of S: This project was reviewed on ethical grounds by the U of S Behavioural Research Ethics Board. Any questions regarding your rights as a participant may be addressed to the Research Ethics Office toll free at 1-888-966-2975 or ethics.office@usask.ca . Out of town participants may call collect.

13. In cases where the research entails more than minimum risk to the participants, where deception is used, where the participant has revealed culturally sensitive or personally identifying information, or where there is a possibility that participants may become stressed or upset as a result of participation in the study, the Consent Form should describe the debriefing and feedback procedures.

14. Evidence of free and informed consent by the participant needs to be obtained prior to embarking on any research project. This should ordinarily be obtained in writing; however, where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented [Article 2.1(b)].

 If multiple contacts with research participants are planned, the process for obtaining consent at each instance should be outlined. It should outline when and how subsequent contact will be handled – verbal, new form, etc.

 (a) Consent – Obtaining Signed Consent

When participants are asked to disclose information that the researcher may be obliged to report to relevant authorities (e.g., child abuse, intent to do violence, etc.), researchers must disclose the limits to which they are able to safeguard the anonymity and confidentiality of responses.

Where written consent is obtained, the Consent Form must state that the research project and contents of the Consent Form have been read and explained to the participant, that he/she understands the contents of the Consent Form, and that she/he received a copy of the Consent Form for his/her own records. The Consent Form must be dated, and signed by the participant(s), and the researcher(s). If for any reason, the Consent Form is being faxed back, it is important that the fax machine to which the Consent Form is being faxed ensures anonymity.

 (b) Consent – Implied Consent for Surveys

 When a Consent Form is not used, then some other means must be available for participants to indicate their consent. For example, in a research project utilizing survey methodology, participants should be informed that completion and return of the survey will constitute consent to participate and permission for the researcher to use the data gathered in the manner described.

 (c) Consent – Obtaining Oral Consent

 If on the other hand the consent has been obtained orally, the Consent Form must be dated, and signed by the researcher(s) indicating that “I read and explained this Consent Form to the participant before receiving the participant’s consent, and the participant had knowledge of its contents and appeared to understand it.”

 (d) For Visual Data – In cases where photographs or video footage of third parties are being sought, a third party photo release form may need to be used.

 In instances where a participant wishes to have their name known the following disclosure may be appropriate.

 [WAIVING CONFIDENTIALITY] *PLEASE SELECT STATEMENT*

I agree to be identified by name / credited in the results of the study.

I agree to have my responses attributed to me by name in the results.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Participant to provide initials)

15. The following additional information may also be required, depending on the nature of the study:

* + 1. An explanation of the responsibilities of the participant
		2. If appropriate, the researcher may choose to discontinue a participant’s involvement in the study, in which case his/her data will be deleted from the research project and destroyed. The conditions for such a situation should be outlined in the Consent Form.
		3. Information on any costs, payments, or reimbursements for expenses or compensation for injury along with a statement to the effect that withdrawal from the research project will not affect the participant’s entitlements. In the case where participants are paid, this statement should indicate that they will be compensated even if they withdraw, or that they will receive a pro-rated amount.
		4. In the case of randomized trials, the probability of assignment to each option.