

CONSENT FORM GUIDELINES

Overview

Consent forms are used to communicate to participants the essential elements of the research so that they are able to give free and informed consent to participate.

You must submit a copy of the Consent Form to the Research Ethics Board (REB) along with the ethics application. Please ensure that the information provided in the Consent Form is consistent with the information provided in the Ethics Application. These should be on institutional letterhead

Please note that the REB will need to see the exact version that will be given to participants. If you wish to make changes to your Consent Form after it has been approved, you will need to submit an *REB Modification Form*.

A. Style Requirements

- Unless there is compelling reason to do otherwise, the REB requires that the *Consent Form Template* be used
- Use Institutional letterhead (YukonU template is available on research ethics templates page)
- Font size should be no smaller than the type of this page (12 point)
- MUST be written in lay terms (i.e., non-technical).
- Attention must be paid to the participants' level of education and/or fluency in English or other language in which the consent is written. Appropriate language or reading level and format needs to be used when considering populations (e.g., children, the elderly, populations with compromised literacy, populations with unique cultural considerations, etc.).
- Do not obscure the important information in a lot of detail
- Write out all acronyms the first time they appear in the consent form.
- Use non-pejorative language throughout
- Use the active voice whenever possible
- Use the first or second person where possible (e.g., *I* or *you* rather than *the subject* or *participants*)
- First person pronouns must be used in the final statement of consent.
- Consider using a date footer in the document to be clear which version of the Consent Form has been submitted and approved for use by the REB.
- Explain the whole research process in a way that participants can understand. Put yourself in the place of the participant when composing your information sheet.

B. Required Elements

Please see the *REB Reviewer Consent Form Checklist* for a list of required elements, and the *Consent Form Template* for how to apply the required elements.

1. **Statement that this is an invitation** to take part in your study, stating that it is research and that it is voluntary. (*You are invited to participate in a research study...*)
2. **Project Title:**
Title of the study (should be consistent with the title of the project in the REB application).
3. **Principal Investigator and Study Team (Researchers):**
Principal Investigator Name, title, department(s), institutional affiliation(s), telephone number(s), and email addresses.
If the study includes a Co-Investigator, Research Supervisor, Student Researcher or Research Coordinator/Assistant that will be involved with participants or their data, include their names, titles (for example Research Assistant, Research Coordinator), institutional affiliations and contact numbers.
For student research the instructor / supervisor contact details must be included on the form as a team member.
List the names and affiliations of other members of the study team as well (for example Data Managers). Phone numbers are not necessary for other study team members.
4. **Purpose(s) of the Research:**
Include a brief but complete description of the purpose of the study in LAY TERMS. Indicate if data is being collected for a graduate thesis, course credit, etc.
5. **Procedure(s):**
Include all procedure(s) to be followed, including details of any interviews, questionnaires, and other data gathering instruments including a description of any recording devices, as well as an estimate of time commitment of the participant. You should also include a statement indicating where the research will take place and how many potential participants will be included or are anticipated.
6. **Funded by:**
If you or any of the other investigator(s) 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(s) of interest on the part of the researchers or sponsors.
7. **Potential Risks:**
All foreseeable risks, side effects and discomforts must be stated. 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.

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(s) of your legal obligations.

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

8. **Potential Benefits:**

Describe any potential/possible benefits of the study, both to the participant(s) and to others/society, stressing that these benefits are not guaranteed. Where there are no anticipated direct personal benefits to participants, this should be explicitly stated.

*“You may not receive any direct benefit from your participation in this study. However, your participation **may allow** researchers to better understand [add brief description of study goal]”*

More altruistic benefits (e.g., contribution to knowledge) should be realistically assessed, not overstated. **The text should not imply that these benefits are guaranteed.** If there are no benefits, this section may be omitted.

9. **Compensation (Payment or Remuneration):**

Clearly describe any compensation that will be offered to participants for taking part in the study. The amount and kind of payment should be included. If a course credit is available to University students, explain the process. Remuneration or compensation should not be dependent on completion of the project, but may be prorated for those that withdraw before completion. This section should also include a clear statement regarding what will happen to the compensation if the participant withdraws from the study early.

10. **Privacy/Confidentiality/Anonymity:**

This section can be fairly complex, depending on the nature of your research. Please include:

- a) A description of how confidentiality or anonymity (if applicable) will be achieved and/or maintained.
- b) Information on who will have access to the research data and where it will be kept (i.e., a locked cabinet in a locked room, and/or on a password protected computer, with the file encrypted).
- c) If applicable, a statement of how the data collected will be used (e.g., presented at academic conferences, published in academic journals, report to an agency, or thesis/dissertation)
- d) Information about whether participants will (i.e., using direct quotes) or will not be identified in any future presentations or publications OR if total anonymity cannot be achieved (i.e., small sample size), make this clear.

- e) If applicable, if the records may be scrutinized by the sponsoring company or funder, this must be stated.
- f) A statement related to how long the study data (with or without identifiers) will be kept before it is destroyed (i.e., “Study data, including personal information about you will be stored by the faculty member/researcher at the University for X years after the study is over, at which time it will be destroyed.”). This statement may be omitted if the data is anonymous.
- g) Where appropriate, for data collected using an on-line survey company (e.g., Survey Monkey), participants must be informed of the location where the data is stored and about any limits to confidentiality that may exist.
- h) Where appropriate, the procedures 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”.
- i) Where appropriate, if the Consent Form and/or data are returned to you in a way that potentially identifies the participant (i.e., questionnaires are returned by fax or email), participants must be informed about this loss of anonymity, and you must describe the procedures that will be implemented in order to minimize this loss.

Confidentiality and Anonymity Definitions:

Confidentiality and anonymity are related but distinct concepts. Confidentiality is defined as “spoken or written in confidence”, 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.

Sample Confidentiality Statements:

GENERAL	FOCUS GROUP RESEARCH
<i>“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,</i>	There are limits to which the researcher can guarantee the discussion will be kept confidential. <i>“The researcher will undertake to safeguard the confidentiality of the discussion, but cannot guarantee</i>

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."

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."

<p>SITUATIONS WHERE CONFIDENTIALITY MAY BE COMPROMISED</p> <p>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:</p> <p><i>“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.”</i></p>	<p>OPTIONAL CHECK BOXES</p> <p>If applicable, describing the different options available to the participant can be helpful. To do so, it may be useful to create “check boxes” to help outline a participant’s choices. For example, you might instruct the participant:</p> <p><i>“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></p> <p>I give my permission to be audiotaped: <input type="checkbox"/> Yes <input type="checkbox"/> No I give my permission to be videotaped: <input type="checkbox"/> Yes <input type="checkbox"/> No I give my permission to have my organization’s name used: <input type="checkbox"/> Yes <input type="checkbox"/> No I wish to remain anonymous: <input type="checkbox"/> Yes <input type="checkbox"/> No I wish to remain anonymous, but you may refer to me by a pseudonym: <input type="checkbox"/> Yes <input type="checkbox"/> No The pseudonym I choose for myself is: _____ You may quote me and use my name: <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
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11. Right to withdraw:

Participants should be informed that they have the right to withdraw from the study at any time. A statement about whether their data withdrawal is possible should be included. If data withdrawal is not possible at all or after a certain time point, this should be communicated.

Surveys and interviews:

- Include a statement that outlines that participants 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. E.g. “Your right to withdraw data from the study will apply until _____(results have been disseminated, data has been pooled, etc.). After this date, it is possible that some form of research dissemination will have already occurred and it may not be possible to withdraw your data.”

In cases where the participant(s) constitute a captive or dependent population, or where one of the researchers 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, you must describe, in detail:

- A description of 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 where the teacher is acting in the role of researcher, “The teacher will not now 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.”
- How the researcher-participant relationship should not influence a participant’s decision to participate and describe the steps to prevent coercion that have been taken.

12. Future Use of Data

Include a statement about future use of the research data if it is retained and not destroyed at the conclusion of the study. Describe potential future use(s) and that consent will be requested from the participant before any future use of data.

13. Disposal of Data

Your data from this study will be disposed of in the following manner: *{examples included for illustrative purposes only, please fill in information specific to your study}*

Data Source	How Destroyed	When Destroyed
<i>Completed case report forms</i>	<i>Shredded</i>	<i>These will be retained for XX (number) years after study completion. This is required by my funding agency.</i>
<i>Audiotapes</i>	<i>Erased/shredded</i>	<i>Immediately following transcription</i>
<i>Interview notes</i>	<i>Shredded</i>	<i>These will be retained for XX (number) years after study completion. This is required by my funding agency.</i>

14. Sharing of Study Results

A summary of the study results will be provided to you upon request *{remove if not applicable}*... The study results will be published and presented to *{provide details on dissemination of study results. Include possible website address. Remove entire sentence if not applicable}*

15. Follow up:

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.

16. Questions or Concerns:

A statement informing the participant(s) that if they have any questions or concerns, to contact the researchers. Provide reasonable means of contact (e.g., phone number, email, office number, etc).

17. Questions or Concerns about Ethical Conduct:

A separate statement informing the participant(s) that the proposed research was reviewed and approved on ethical grounds by Yukon University's Research Ethics Board. For example: "This project was reviewed on ethical grounds by the Yukon University Research Ethics Board. Any questions regarding your rights as a participant may be addressed to the Research Ethics Chair at ethics@yukonu.ca

18. Documenting Consent:

Evidence for free and informed consent by the participant must 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.

CIRCUMSTANCES	<p><i>Obtaining Signed Consent</i> Where written consent is obtained, the Consent Form must state or include the following:</p> <ul style="list-style-type: none"> • That the research project and contents of the Consent Form have been read and explained to the participant • That they understand the context of the Consent Form • That they understand that their participation is voluntary and can end their participation at any time without penalty • That they have received a copy of the Consent form for his/her own records • That by signing the consent form the participant is not waiving any legal rights • Date • Signature of Participant • Signature of Researcher
	<p><i>Continued or Ongoing Consent</i> If multiple contacts with research participants are planned, you should explain how subsequent contact with participants will be handled and briefly outline the process of obtaining continued consent.</p>
	<p><i>Obtaining Implied Consent for Surveys</i> When implied consent for surveys is sought, other means must be available for participants to indicate their consent. For example, participants should be informed of all relevant aspects related to free and informed consent and 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.</p>
	<p><i>Obtaining Oral Consent</i> If the consent has been obtained orally, the Consent Form should be dated and signed by the researcher(s) indicating that “I have 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”.</p>

15. Other:

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

- An explanation of the responsibilities of the participant
- 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
- Information on any costs, payments, or reimbursements for expenses.

Copy of Information Sheet to Participant.

A copy of the signed consent form must be given to the participant to take home with them. If your study does not require the participant give written consent (i.e. oral consent or consent by overt action) you should still provide a copy of the information sheet to the participant for their records.

In the case of implied consent, ie., survey research, replace the consent statement at the end of the form with the something like the following, **“By submitting the survey your consent to participate is implied”**.