Informed Consent Letter Guidance

This guide provides:

- Suggestions for headings and lead-ins for each section of your consent form;
- Bullet points that indicate required elements of consent (unless rationale for exclusion outlined in the ethics application is approved by BUREC).
- Additional guidance to assist with drafting a complete and effective consent form.

- The Informed Consent Letter/Form and other correspondence to participants should be on BU Letterhead. Digital and pre-printed letterhead templates can be found at: https://www.brandonu.ca/communications/visual-identity/templates/

Title of the Study: *(Insert Title here)*

Principal Investigator and Research Team:

(Provide full name of the PI, CI, and Faculty Supervisor, as applicable. Include affiliations(s), such as Faculty of XXX (Department XXX), Brandon University, telephone number and email address for the PI and Faculty Supervisor, and member of research team responsible for collecting and documenting consent.)

(Suggested Introductory Text):

"To help you make an informed decision regarding your participation, this consent form will outline what the study is about, the possible risks and benefits, and your rights as a research participant. If any information provided is unclear, please ask a member of the research team for clarification prior to consenting to participate. You will be provided with a copy of this form for future reference, if you choose to participate in this study."

Purpose of this Study:

"You are invited to participate in a research study about…"

- Outline the purpose and objective(s) of this study in a clear statement, using language that the participant population will understand.
- Include a rationale for this study or a statement about why this research is being conducted.
- For student research, include a statement about the purpose of this study related to your coursework, for example, for a course project/thesis/pilot study, etc.
- If this research is funded, identify the funder or sponsor.

Additional Guidance:

- *Be sure to use plain and lay-person language when explaining the purpose, rationale, and objectives of the study, and throughout the form. The language used in this form should be appropriate to the participant population.*
- *If you are recruiting from the general public or general student population, avoid discipline-specific terms and jargon, so a non-specialist can understand.*
- *For some participant populations, for example people with low vision, the font size used in the form should be considered.*

Participant Responsibilities:

What does participation involve?

"Participation in this study will consist of… in which you will be asked to…"

- Outline the number of sessions and the estimated length of time for each session (for example, interview, survey, focus group, etc.) Identify when the sessions will be scheduled, including the location and time for each session.
- Describe the tasks/procedures that the participant will be asked to do during the study, in the order the participant will experience them.
- A statement about what information will be collected from/about participants and for what purpose. If the study involves a questionnaire(s), focus group(s), interview(s), etc., indicate what kind of questions will be asked of participants.
- If the study is being conducted using online data collection methods, for example, Zoom, Survey Monkey, etc., this needs to be stated. In addition, details about data maintenance and security must be outlined.
- If the study involves a group format, the limits to confidentiality must be explained. The following statement may be included to address this: "Given the group format of this session, we will ask you to keep in confidence information that identifies or could potentially identify a participant and/or their comments."

Additional Guidance:

- *If participation involves multiple sessions or procedures, consider using a numbers list or bullet points for clarity.*
- *If the study procedures/groupings and schedule are complex, consider including a flow-chart for clarity.*

BRANDON UNIVERSITY

Who may participate in this study?

"This study will involve up to… and in order to participate in this study you must be…"

- This section should include all relevant inclusion and exclusion criteria and clearly define any academic terms in lay person language.

Participant Rights:

Is participation in this study voluntary?

"You are under no obligation to participate. You participation is voluntary and you may decline to answer any question (or you may choose to end the interview at any time). You may withdraw from the study at any time, up to [DATE] when it will no longer be possible due to [anonymization of the raw data or submission of report for publication]…"

Additional Guidance:

- *Details about the right to, and how to, withdraw from the study must be provided, including any limitations on withdrawal. For example, participants may withdraw from the study until the point in which data is anonymized or the report is published. Limitations for withdrawing should be communicated in concrete terms, such as a date.*
- *Depending on the type of data being collected (i.e. anonymous, electronic, audio, etc.), different language may be necessary to clearly outline how and when a participant can withdraw their data.*

Will I receive anything for participating in this study?

"There is no payment for your participation in this study…", or "In appreciation of your time, you will receive…", or "To thank you for your time, you will receive a total of …", and/or "You will be reimbursed for [e.g. parking, travel, child care expenses…]"

- Indicate if any expenses will be incurred and what compensation will be offered. If an incentive is offered, indicate what will given for participation. Also outline specifically that if a participant withdraws their consent, all payments due prior to the point of withdrawal will be received. If the study is using a lump-sum incentive for participation, the participant is entitled the entire amount. If a payment schedule is used, participants shall be paid in proportion to their participation.

What are the possible benefits of the study?

"Participation in this study may benefit you in the following way(s)…", or "Participation in this study may not provide any personal benefit to you…", or "The study will benefit the community/society in the following way(s)…".

- A scientific and/or social benefit should be provided.

Additional Guidance:

- *It is important to indicate the absence of direct personal benefit when this is the case.*
- *The opportunity to participate in research or learn about study procedures is generally not considered a personal benefit to participations.*

What are the possible risks associated with the study?

"There is the potential for…", or "There is always the risk of…", or "The (procedure) may cause you to feel…". "We will attempt to minimize this risk by…".

- Describe any potential risks associated with participation in the study (e.g. emotional, psychological, physical, social, economic, or other).
- Indicate the safeguards in place to mitigate the risks.
- If there are no anticipated risks, the following statement may be used: "There are no known or anticipated risks associated with participation in this study."

Will my identity be known?

"The research team will know which data is from your participation", or "If you participate in the focus group/workshop, you will not be anonymous to the other participants. However, what is said during the focus group/workshop is confidential and we ask all participants to maintain confidentiality", or "Your participation in this study, and the data collected, is anonymous".

- Indicate if the participant's involvement in the study will be anonymous, anonymized, coded, etc. Anonymous means the data collected will not have any identifiers associated with it and the researchers do not know the identity of those who participated.
- In some studies, the participants may want their identities/contributions to known (e.g. public figure). For studies where this may be the case, this option should be provided in the consent form with a "yes/no" checkbox option specific to this point.

Will my information be kept confidential?

"The information you provide will be safeguarded and kept confidential by…"

- Describe the data management and security plan. How will the data be kept secure? Who will have access to the data? How long the data will be kept? If the data will be kept indefinitely, how will the data be archived?
- Indicate whether the dataset will be provided to publishers or in an open access repositories.

"While the researcher team will take measures to ensure your identity and data is kept confidential, depending on the information shared with, there may be an ethical or legal obligation to disclose information to a third party. For example, there is compelled disclosure on a report of abuse of children or persons in care…"

Additional Guidance:

- *Researchers must advise participants of reasonably foreseeable disclosure requirements.*
- *It is the researcher's responsibility to identify legal disclosure requirements that are foreseeable for the study.*
- *Include a statement about seeking consent from the participant if their personal information may be shared with mandated government departments or agencies (such as local public health authorities), community partners in research, a research sponsor (such as a pharmaceutical company), the Research Ethics Board or other regulatory agency.*

What will be done with the research findings?

"The research team intends to…" or "The research findings will be shared with…"

- Include a statement indicating who or what groups will receive the study report/findings/publication.

Additional Guidance:

- *All forms of planned dissemination must be disclosed as part of the consent procedures. Dissemination shall include, but is not limited to, publication in a peer-reviewed journal, conference or public presentation, addition to a publically available database, and/or posting on a website.*
- *All forms of planned dissemination for undergraduate and graduate theses should also be listed. For example, presentation to a class or thesis committee, public presentation, available in the Library or otherwise publically accessible.*

"There is no intention to commercialize the research findings." or "Commercial objectives for this research include…"

- Include a statement about commercial objectives. Note the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors.

Who should I contact if I have questions regarding my participation in this study?

"If you have questions regarding this study, or would like additional information to assist you in reaching a decision about participation, please contact [insert researcher's name] and [insert researcher's telephone number and email address].

"If you have ethics-related questions or concerns about this study, please contact the Brandon University Research Ethics Committee (BUREC) at (204) 727-9712 or burec@brandonu.ca".

What if the study procedures or topic(s) causes me distress/concern? (Optional Section)

"Should this study, or participation in this study, cause you distress or concern, please contact…"

- A list of appropriate counselling services accessible within the area that the participant resides, should be provided. This can be provided by way of a separate document.

Other Information:

"This study has been reviewed and received Ethics approval by the Brandon University Research Ethics Committee (BUREC)."

"By providing your consent, you are not waiving your rights to legal recourse in the event of research-related harm."

Additional Guidance:

- *For clinical trials, include information on stopping rules and when researcher may remove participants from trial.*

Consent:

"I have read the information presented in this consent document. I have had the opportunity to ask questions related to the study and have received satisfactory answers to my questions and any additional details."

☐ I agree to participate in this research study.

[Additional consent options to use, applicable]:

☐ I agree to my interview being audio-recorded {video-recorded] to ensure accurate transcription and analysis.

☐ I agree to allow audio/video clips, digital images or photographs in which I appear to be used in teaching, scientific presentations and/or publications with the understanding that I will not be identified by name. [If the clip or image includes a participant's face or other identifying feature(s), indicate if this will be blurred/obscured.]

☐ I agree to the use of quotations in any quotations in any thesis or publication that comes from this research. [Indicate whether the quotation will be presented as anonymous, with a pseudonym, or as a direct quotation.]

Additional Guidance:

- If being audio or video-recorded is a condition of participation, this needs to be explicitly stated as part of the "I agree to participate in this research study" statement.
- It is important to note that audio or video-recording in group data collection settings, e.g. focus groups, may have to be a condition of participation.