**Consent Form Guidelines**

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| OverviewConsent 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. When applicable, you must submit a copy of the Consent Form to the 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. 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 event in ROMEO to modify your study.  |

A. Style Requirements

* Unless there is compelling reason to do otherwise, the REB requires that the *Consent Form Template* be used
* Faculty researchers: use the appropriate letterhead (e.g., departmental or institutional)
* 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
* 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.

B. Required Elements

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| 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. **Project Title:**

Title of the study (should be consistent with the title of the project in the REB application).

1. **Researcher(s):**

Name(s), title(s), department(s), institutional affiliation(s), telephone number(s), and email address(es) of researchers. This should include the research supervisor, co-investigators, student researchers(s), and research assistant(s).

1. **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.

1. **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.

1. **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.

1. **Potential Risks:**

All foreseeable risks, side effects and discomforts must be stated. Choose from the list below and elaborate on the risk where appropriate:

1. Risk of physical harm (e.g., falling, muscle pain)
2. Physical discomfort (e.g., tiredness, weakness, nausea, physical discomfort related to any application of equipment)
3. Risk of psychological or emotional discomfort (e.g., anxiety, stress, feelings of embarrassment, loss of confidence, regret for disclosing personal information)
4. Legal repercussions (e.g., possibility of being sued, charged with criminal activity)
5. Social repercussions (e.g., possibility of marginalization, being negatively judged by peers or employer, possible loss of status/reputation)
6. Economic inconveniences (e.g., expenses incurred for participation, loss of income during time of participation)
7. Other inconveniences (e.g., long travel to research site, time consumed, disruption of family routines)
8. Other risks (please identify)
9. No risks or inconveniences

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.

1. **Potential Benefits:**

The possible benefits of the study, both to the participant(s) and to others/society, stressing that these benefits are not guaranteed. If there are no benefits, this section may be omitted.

1. **Compensation:**

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. Remuneration or compensation should not be dependent on completion of the project, but may be prorated for those that withdraw before completion.

1. **Confidentiality/Anonymity:**

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

1. A description of how confidentiality or anonymity (if applicable) will be achieved and/or maintained.
2. 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).
3. 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)
4. 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.
5. If applicable, if the records may be scrutinized by the sponsoring company or funder, this must be stated.
6. 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.
7. 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 exit.
8. 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.”
9. 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.
10. When appropriate, include a statement regarding the archiving of data at the completion of a research project, depositing data in a shared/open repository or when sharing datasets in the context of journal publications for purposes of reproducibility/transparency, verification or error detection.
Note that there is a distinction to be made between the storage of data (e.g., archiving) following the completion of a research project and the storage of data for future unspecified use, and this should be clearly specified in both the consent process and in the materials that are submitted to the REB for ethics review and approval. For example, where a research participant has provided consent to participate in a specific research project, this consent extends to the storage of their data for a period of time following the completion of the project, as per the terms of the consent form. This could include securely archiving the data in an institutional repository. However, if the same research participant does not consent to the storage of their data for future unspecified use, their data should not be deposited in a research data repository that serves such a purpose.

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|  **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*:**

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| **GENERAL***“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.”* | **FOCUS GROUP RESEARCH**There are limits to which the researcher can guarantee the discussion will be kept confidential*.**“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.”* |
| **SITUATIONS WHERE CONFIDENTIALITY 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.”*  | **OPTIONAL CHECK BOXES**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: *“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 audiotaped: 🞏 Yes 🞏 NoI grant permission to be videotaped: 🞏 Yes 🞏 NoI grant permission to have my organization’s name used: 🞏 Yes 🞏 NoI wish to remain anonymous: 🞏 Yes 🞏 NoI wish to remain anonymous, but you may refer to me by a pseudonym: 🞏 Yes 🞏 NoThe pseudonym I choose for myself is: \_\_\_\_\_\_\_\_You may quote me and use my name:  🞏 Yes 🞏 No  |

1. **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 know until after the grades have been submitted who has decided to participate and who has not, so that you 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.
1. **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.

1. **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).

1. **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 MacEwan University’s Research Ethics Board. For example: “This project was reviewed on ethical grounds by the MacEwan University Research Ethics Board. Any questions regarding your rights as a participant may be addressed to the Research Ethics Officer at 780-497-4280 or REB@macewan.ca.

1. **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.

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| **CIRCUMSTANCES** | ***Obtaining Signed Consent***Where written consent is obtained, the Consent Form must state or include the following:* That the research project and contents of the Consent Form have been read and explained to the participant
* That he/she understands the context of the Consent Form
* That he/she received a copy of the Consent form for his/her own records
* Date
* Signature of Participant
* Signature of Researcher
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| ***Continued or Ongoing Consent***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.  |
| ***Obtaining Implied Consent for Surveys***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.  |
| ***Obtaining Oral Consent***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”. |

1. **Additional Consent Items:**

**Data Storage for Future Use:**

There have been recent changes to the TCPS2 ([Chapter 3E: Broad Consent for the Storage of Data and Human Biological Materials for Future Unspecified Research](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#e)) that describe new consent requirements to be able to store and use data in future research; this includes storing in a public repository for other researchers to use, as well as your own repository for you to share or use in the future.  Unlike blanket consent, which is typically unrestricted, broad consent always includes specific restrictions (e.g., consent may be restricted to a particular field of study, to a specific disease, or may prevent use by private industry).

Broad consent applies to the storage and secondary use of participants' data collected for research purposes. The use of broad consent is in the context of future research using data with no direct contact or intervention with participants at that time. **While blanket consent is not permitted under the TCPS, broad consent is permitted.**

The participant must now be given the separate option to consent to future use of data, in addition to consent to participate in the current study.  The consent can either be an addition to the original consent form, or a separate consent form, and must include the consent elements outlined in TCPS2 [Article 3.13](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#e). Note that this is required for all types of data collected from participants, even if it is anonymous.

**If you are planning on storing/sharing data for future use, please address this in Section 6.9 of the standard research ethics application form, and include the following information either at the end of your consent form, or in a separate stand-alone consent form.**

**It must be clear to participants that they can choose to participate in the current study, but it is optional to consent to the storage and use of their data for future research.**

**Template Language: Consent to Data Storage for Future Research (optional):**

The researchers also seek consent to store the research data gathered for this study in a research data repository, specifically [*indicate name of data repository, if known*]. This repository is [*indicate information about the governance of the repository, if known*].  This means your anonymized data may be used in future research projects related to [*include purpose of current research project*], and could help [*list possible benefits*].  ​It is possible that researchers using your data may not be subject to the same guidelines as our original study, so some projects may not have undergone ethics review before accessing your data; however you will not be identifiable in any of the information made available to future researchers. It is not possible to know all of the risks that may happen in a study, but the researchers have taken all reasonable safeguards to minimize any known risks to study participants [or identify any specific risks, if known].  If you agree to allow your data to be stored for future research, you will not be able to withdraw your consent, as we will not know which data belongs to you.

Consenting to depositing your data is voluntary, and will not impact your participation in our study [*or ability to access a program, resource etc as it relates to the research*].

I consent to my data being stored and used in future research.

**□**Yes / **□**No

1. **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