

<b>Guidance Document</b>	Preparing a Letter of Information and Consent Document
<b>Effective Review</b>	Non-Medical REB (Delegated & Full Board)
<b>Version Date</b>	March 6, 2024

Legend
Blue text: Guidance and/or instructions
Black text: Suggested wording and/or example
Red text: Language that should not be included

**This guidance document is not intended to be used as the template for the Letter of Information and Consent (LOI/C). It is here to help provide guidance on what should be included in the LOI/C. The template is a separate document and can be found on our website and the WREM Help section.**

When writing the letter of information and consent, please remember:

1. Use plain (lay, Grade 8) language that is easy for someone not trained in your field of work to understand.
2. Remove unnecessary repetition throughout the form; if technical words are used a simple definition in lay terms should be included beside the terminology in brackets.
3. Use the “second person” voice – e.g., “You will be asked to...”
4. Use a size and font of text that is consistent and easy to read (size 11 or larger is recommended).
5. Define all acronyms and abbreviations when they first appear.
6. The participant must be provided with a copy of the letter of information and consent form and this should be stated.
  - E.g., “This letter is for you to keep” OR “You will be given a copy of this Letter of Information once it has been signed.”
7. The only identifiers that should be on the consent form are the participant’s name and initials (initials are not required). If there are legitimate reasons for collecting other identifiers on the consent form, this needs to be explained in the REB application.
8. Use the term “participant” instead of “subject” in all instances to emphasize the voluntary nature of participation.
9. All letters of information and consent forms should be printed on institutional letterhead.  
[http://communications.uwo.ca/comms/western\\_brand/vis\\_toolkit/templates.html](http://communications.uwo.ca/comms/western_brand/vis_toolkit/templates.html)
10. **PROOFREAD** before submitting to the REB.
11. Include a simple and short footer on each page: the version date (dd/mm/yyyy) and pagination (“Page x of y”).
12. Do not state “This study has been approved by the research ethics board...” as this may appear to offer a guarantee of safety.

13. The LOI/C document is only ONE component on the consent process. Consent must be informed, ongoing, and voluntary. Researchers are responsible for communicating this information as appropriate to participants throughout the study.

## Project Title

Enter the complete title of study exactly as it appears in WREM.

Note: If there are methodological reasons for including a vague study title on participant-facing documents, you may add the 6-digit REB/Project ID # after the title (e.g., “Study Title 123456”). Do not reference the REB, include the number only; this allows the REB to locate the study file if contacted by a participant.

## Document Title

Add particular study subgroups to the document title, as applicable. This enables everyone to differentiate between consent forms and groups within a study (e.g., student group, teacher, parent).

**E.g.,** Letter of Information and Consent – Student

## Principal Investigator + Contact

Enter the Principal Investigator’s name, with title and contact information.

**E.g.,** **Principal Investigator**  
Dr. John Doe, PhD, Psychology  
Western University, X80000  
Email.address@emailaddress.com

## Student Researcher + Contact

When a student is conducting this research for their academic requirements (thesis/dissertation), include the student’s name, affiliation and contact information.

## Additional Research Staff + Contact (optional)

You may choose to enter names and titles of Additional Research Staff, but this is not required. Please note: if you do enter names and titles, it will be necessary to submit an amendment with a revised Letter of Information and Consent Form for review and approval if that personnel information changes.

**E.g.,** **Additional Research Staff**  
Dr. Mary Jones, PhD, Anthropology  
Dr. James Wright, MA, Ivey

## 1. Sponsor/Funder Information (if applicable)

Enter the full name of all sponsor(s) as documented on the protocol/contract, including funding source's and intervention suppliers. Please also include in-kind contributions (even when there is no cash funding). The nature of the in-kind contributions informs the process for bringing in the in-kind.

## 2. Conflict of Interest (if applicable)

*Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators, study staff or member of their immediate family. A conflict of interest exists if there is a potential benefit to the investigator(s), study staff or member of their immediate family beyond the professional benefit from academic achievement or presentation of the results. Examples include, but are not limited to, speaker's fees, travel assistance, consultant fees, honoraria, gifts, and intellectual property rights such as patents. A declaration of conflict of interest should include the identity of the person with the conflict of interest, the type of incentive or inducement, and its source. See examples below.*

The identify individual, e.g., study investigator, insert name, is receiving personal financial payment from identify source of funds e.g., the study Sponsor for include reason for payment e.g., providing advice on the design of the study. You may request any details about this payment.

OR

The insert recipient of funding e.g., Western University is receiving financial payment from [insert Sponsor/Funder] to help offset the costs of conducting this research.

## 3. Invitation to Participate

Introduce the research, invite the potential participant to participate, indicate why the participant is being approached, and why this research is being done.

**E.g., Introduction**

You are being invited to participate in this research study about [explain what the study is about] because you [explain WHY the individual is being approached and asked to participate (e.g., general inclusion criteria)].

## 4. Why is this study being done?

4.1. Provide background information on what prompted the need for this study.

4.2. Explain the purpose of the study in lay terminology.

**E.g.,** The purpose of this study is to [indicate why the study is being done and your objectives].

## 5. How long will you be in this study?

5.1. Include the anticipated length of the study the number of study visits and how long each study visit will take.

**E.g.,** It is expected that you will be in the study for [length of study - [# days/weeks/months/years], there will be [#] study visits during your participation in this study and each visit will take approximately [# of hours].

## 6. What will happen during this study?

### 6.1. Assignment to a group

If there is more than one study group, describe how participants are placed into study group(s). See suggestion below. If this suggestion is not applicable, provide a lay description appropriate to the specific protocol.

Example for Randomized study:

If you decide to participate then you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have *explain probability of randomization e.g., e.g., equal; 50/50; 1 in 3 chance of being placed in either/any group.* Neither you nor the researchers can choose what group you will be in.

Explain whether participants or others (e.g., researchers) will know which group the participant will be in.

### 6.2. Include inclusion/exclusion criteria.

### 6.3. The number of people to participate (optional)

In some instances, providing the anticipated number of participants will impact informed consent (e.g., odds to be assigned to a particular condition, or odds to win a draw). However, the NMREB does not require sample size to be disclosed in the LOI/C as it is understood that this number may change. Note: If you include this information in the LOI/C, and this number increases, then an amendment will need to be submitted to the REB for approval.

## 7. What are the study procedures?

The Procedures section should outline what is expected of the participant. This section should be exceptionally clear so that participants are clearly informed of what they will

experience as they take part in this study, including any applicable responsibilities they may have.

Consider inserting a table of study procedures/time commitments to assist participants in understanding what they are agreeing to.

**E.g.,** If you agree to participate you will be asked to [the following items are things to consider when writing this section of the LOI/C]:

- 7.1. If applicable, list the different types of study sessions/activities to take place. Include what is required of the participant at each stage of the project.
- 7.2. If applicable, information on audio-/video-recording is needed. If audio-/video-recording is being used the participant must know if they can still participate if they do not agree to be recorded. If there is an option, a check box must be added to the Consent Form to accompany this section.
- 7.3. Location of the study activity (e.g., physical location? Online? Telephone? Teleconference? Etc.)
- 7.4. Nature of measures

Some description of the type of measures may also be needed. If the measures involve potentially sensitive or personal questions that may affect a participant's willingness to participate (e.g., sexual practices, IQ measures, illegal activities, etc.). There is recognition that in some cases full disclosure about the nature of the measures might compromise the integrity of the data. If the researcher believes this to be the case, he/she should explain the use of deception in the REB application along with any plan/details for debriefing.

## 8. What are the risks and harms of participating in this study?

Outline possible risks and harms as per your REB application. If none are expected, indicate this.

**E.g.,** The possible risks and harms to you include [insert possible risks and harms here].

OR

**E.g.,** There are no known or anticipated risks or discomforts associated with participating in this study.

If there is a risk of emotional upset or distress and/or non-emotional risks/harms, please include a list of local (local to where the research is taking place) resources.

If you are collecting personal identifiers, please note the risk of privacy breach.

**E.g.,** Please note that because we are collecting personal identifiers, there is always the risk of a privacy breach.

## 9. What are the benefits?

Outline possible benefits to the participants and to society as per your REB application. You may indicate there are no benefits to the participant but there should always be societal benefits. Monetary compensation is **NOT** a benefit.

**E.g.,** The possible benefits to you may be [insert benefits here]. The possible benefits to society may be [insert societal benefits here].

OR

**E.g.,** You may not directly benefit from participating in this study but information gathered may provide benefits to society as a whole which include [insert societal benefits here].

## 10. Can participants choose to leave the study?

Insert information on the participant's right to request the withdrawal of data including any limitations on the feasibility of that withdrawal.

**If withdrawal of data is possible when the participant withdraws from the study, insert the following:**

**E.g.,** If you decide to withdraw from the study, you have the right to request (e.g., by phone, in writing, etc.) withdrawal of information collected about you. If you wish to have your information removed, please let the researcher know and your information will be destroyed from our records. Once the study has been published, we will not be able to withdraw your information.

**If you are collecting identifiable information, identifiable consent, or retaining a master list, please include the following:**

It is important to note that a record of your participation must remain with the study, and as such, the researchers may not be able to destroy your signed letter of information and consent, or your name on the master list. However, any data may be withdrawn upon your request.

Note: Data destruction procedures must comply with institutional policies.

**If withdrawal of data is not feasible (e.g., data collected anonymously, or when personal information has been removed from the data and all data are**

**anonymized) and the PI will continue to use the participants' data after they have withdrawn from the study, insert the following:**

**E.g.,** If you decide to withdraw from the study, the information that was collected prior to you leaving the study will still be used as the researchers will be unable to identify an individual participant's responses. No new information will be collected without your permission.

OR

**E.g.,** If you decide to withdraw from the study, you may do so at any time by [e.g., exiting the survey window]. Due to the anonymous nature of your data, once your [survey] responses have been submitted, the researchers will be unable to withdraw your data.

OR

**E.g.,** You have the right to withdraw from the study at any time. However, in the event you choose to withdraw from the focus group during or after the session, we cannot guarantee that comments made in the focus group session will be removed from researchers' notes as it is an active discussion and we will be unable to reliably track who said each comment.

## 11. How will participants' information be kept confidential?

**Describe the protection of the participant's privacy, indicate what identifiable information will be collected, the method of storing research data, where the data will be stored, how long it will be stored, who will have access to the information collected for the study, and how it will eventually be destroyed. Ensure that it is clear who has access to what type of information.**

**NOTE:** This information must be consistent with the data security and confidentiality information included in the REB application.

- 11.1. Indicate if people/groups/organizations outside the study team will have access to information collection (e.g., including institutional representatives, transcription company, community partners, non-Western-affiliated academic collaborators (and their REBs), etc.).

Note: This statement is always required and must be included in the LOI:

Delegated institutional representatives of Western University and its Non-Medical Research Ethics Board [insert other entities as appropriate] may require access to your study-related records to monitor the conduct of the research in accordance with regulatory requirements.



**E.g.** If using a third party for data collection, storage, or transfer (for example Qualtrics, REDCap, NVIVO etc.) please include the following information (at a minimum), as applicable:

- Use of 3rd party
- Name of 3rd party
- Link to 3rd party's privacy policy
- Country where data is stored using 3rd party (do not need to include Western storage location once exported from 3rd party platform)
- Identify risks (i.e. nothing over the internet is ever 100% safe)

11.2. If identifiable information must be collected (e.g., contact information, date of birth, etc.) OR the research is being conducted in small populations where triangulation may occur, it must be made very clear that the participant may be identified by others:

- a) what identifiable information (direct or indirect) is being collected, why, and who will have access?
- b) what, if any, identifiable information (direct or indirect) is going to be disclosed in dissemination?
- c) what options are available for the way in which these identifiers are used in dissemination (e.g., consent to use name, consent to use direct quotes, consent to use position/title, consent to use photos, etc.)?

**E.g.,** While we do our best to protect your information there is no guarantee that we will be able to do so. The inclusion of your [e.g., professional role and organization] in dissemination of the results may allow someone to link the data and identify you.

11.3. If identifiable information will be shared with others outside the study team, please clarify what information will be disclosed and with whom it will be shared.

Note: If there is planned disclosure of personal identifiers, or if they are used on any research-related information/documents, or if they are part of the unique identifier, this must be justified in the REB application and approved.

11.4. Include how long identifiable information will be kept.  
The researcher will keep all personal information about you in a secure and confidential location for [##] years (Western's Faculty Collective Agreement stipulates a research data retention policy of 7 years). A list linking your study



number/pseudonym with your name [and other identifiers if applicable, such as contact information] will be kept by the researcher in a secure place, separate from your study file.

- 11.5. If applicable, include a statement that participants will not be named in any reports, publications, or presentations that may come from this study.

**E.g.,** If the results of the study are published, your name will not be used

- 11.6. For studies which include focus groups or other group-based data collection activities, please include a statement regarding the limitations to confidentiality:

**E.g.,** Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of insert as appropriate (e.g., focus groups) prevents the researchers from guaranteeing confidentiality. The researchers would like to remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others.

- 11.7. If the data is to be professionally archived, a description of where it will be archived and who may have access to the archive is needed.

- 11.8. If the researcher wishes to use personal quotes, titles, names or other identifying information within the publication, this must be made clear. There must also be a check box on the Consent Form to accompany this section. A check box is required for the use of directly identifiable quotes and even for quotes which are not directly attributable to an individual.

- 11.9. If applicable, include a statement that all identifiable information collected during this study will be kept confidential and will not be shared with anyone outside the study unless required by law.

- 11.10. **Re: open access data:**

If you anticipate data may be made available to journals and/or other researchers (e.g., for replication studies) then participants must be informed of this in the Letter of Information and Consent (LOI/C), as well as what type of information will be shared. NOTE: Indicating that all information will be kept confidential to the researchers will restrict you from sharing this information (even if anonymized) outside of the research team in the future.

**E.g.,**

All identifiable information will be deleted from the dataset collected so that individual participant's anonymity will be protected. The de-identified data will be accessible by the study investigators as well as the broader scientific community. More specifically, the data [will/may be posted on specific database

OR made available to other researchers upon publication] so that data may be inspected and analyzed by other researchers. The data that will be shared on [insert database/publication] will not contain any information that can identify you.

See Open Access Guidance Document for more information.

#### 11.11. Re: Future use of data:

The future use of data for secondary purposes (for a new purpose beyond the specific objectives of the original project) requires:

- a) separate REB oversight or exemption at the time of the future research and
- b) broad consent.

This is distinct from open-access data sharing. Broad consent is defined as consent for future unspecified research. 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 and/or human biological materials collected for research purposes. The use of broad consent is in the context of future research being conducted using data and/or human biological materials with no direct contact, consent, or intervention with the participants who provided the data and/or biological materials at that time. While blanket consent is not permitted under the TCPS, broad consent is permitted. **Broad consent MUST be optional and contain all applicable information outlined in TCPS2 Article 3.13** (see interpretation - [https://ethics.gc.ca/eng/policy-politique\\_interpretations\\_consent-consentement.html](https://ethics.gc.ca/eng/policy-politique_interpretations_consent-consentement.html)).

#### Optional Broad Consent for Future Secondary Use of Data

##### Example:

Researchers will need to customize the text in [brackets] to their consent.

We wish to use your [*de-identified, identifiable, anonymous, anonymized*] data [*and/or biological specimens*] for future research related to [*scope*]. While such research is not planned at this time, it is possible that we may use [*and/or share your data with other researchers {at this institution/in Canada/around the world}*] in the future. Once data is shared, it cannot be withdrawn [*or if it can be, then include the mechanism to do so*]. [*If data will be entered into a formal repository, please describe oversight and governance*]. It is unknown at this time what the risks of any future research are [*if there are known risks such as to genetic research, please state the risks. Any risk of re-identification or incidental findings and how they will be managed need to be disclosed*]. You may not personally benefit but the future research will contribute to knowledge about [*scope*]. Participation is optional and it will not impact your participation in the current study. A location to indicate your decision is provided on the last page of this document. You

[will/will not/may choose to be] be contacted about this future research [matching option for future contact should be provided on signature page of LOI].

For example:

We wish to use your de-identified data for future research related to stress and heart development in children. While this research is not planned at this time, it is possible that we may share your data with researchers around the world. Once data is shared, it cannot be withdrawn. It is unknown at this time what the risks of any future research are, and your data may be combined with other data that may re-identify you to other researchers. You will not personally benefit but the research will contribute to knowledge about heart development. Participation is optional and it will not impact your participation in the current study. A location to indicate your decision is provided on the last page of this document. You will not be contacted about this future research.

**12. Are participants compensated to be in this study?**

NMREB Definitions:

Reimbursement = to cover accrued expenses

Compensation = base amount given to all participants

Incentives = performance-based on top of compensation

Include whether participants will incur any expenses as a result of their participation in the study. If applicable, indicate how reimbursement will be pro-rated if participants withdraw early from study.

If compensation will be a draw, review Appendix A for guidance on what is required.

Include any details of compensation AND how participants will receive their compensation. **E.g.,** You will be compensated [insert what the compensation is, if applicable] for your participation in this study. If you do not complete the entire study you will still be compensated at a pro-rated amount of [indicate the pro-rated amount and how it will be offered]. You will receive your compensation [insert details of how/when participants will be compensated].

OR

**E.g.,** You will be entered into a draw to win [insert prize]. It is expected that there will be [insert number of participants]. If you win the draw, you will be notified by [insert communication method] and will be given your prize by [insert method of providing participants their prize].

OR

**E.g.,** You will not be compensated for your participation in this research.

Include any details of incentives.

**E.g.,** You will have an opportunity to accumulate [insert incentive details] based on your responses on the tasks. The average bonus amount is [insert], ranging from [insert lowest possible bonus] to [the highest possible bonus].

## 13. What are the Rights of Participants?

### 13.1. You must include the following statements:

Your participation in this study is voluntary. You may decide not to be in this study. Even if you consent to participate you have the right to not answer individual questions or to withdraw from the study at any time. If you choose not to participate or to leave the study at any time it will have no effect on you/your [care/employment status/academic standing - choose only those that are applicable].

You do not waive any legal right by consenting to this study.

### 13.2. If applicable, please include the following:

We will give you any new information that may affect your decision to stay in the study.

## 14. Commercialization (if applicable)

[Sponsor name] and/or others intend to claim sole ownership of any research results consistent with this consent. By signing this consent, you agree that [Sponsor name] can apply for patents and you will not receive any financial benefit that might come from the research.

## 15. Whom do participants contact for questions?

Instructions on whom (name and phone number) to contact regarding any questions or concerns that may be raised by participating in the study or questions that may be raised by being a research participant. Note: the Principal Investigator must be listed as the primary contact, the research assistant or student researcher may also be listed in addition to the PI.

**E.g.,** If you have questions about this research study please contact [Principal Investigator: Name, Phone Number, Email Address].

You must also include:

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Human Research Ethics (519) 661-3036, 1-844-720-9816, email: [ethics@uwo.ca](mailto:ethics@uwo.ca). This office oversees the ethical conduct of research studies and is not part of the study team. Everything that you discuss will be kept confidential.

**This letter is yours to keep for future reference.**

## 16. Consent

### General Guidance on Consent:

Consent must be documented, and there are generally three methods for collecting consent:

- Written
- Verbal
- Implied

The default is written consent, which is signed and dated by both the participant and the researcher. Both the participant and the researcher should retain copies of this signed consent form. See the suggested layout for a consent form below.

However, some study designs or participant needs may require modifications to the standard written consent process. For example, implied consent has been used for survey research to preserve anonymity (e.g., paper survey dropped into confidential dropbox) and also where there may be feasibility concerns (e.g., online research). In other instances, verbal consent might be more appropriate (e.g., telephone interviews, interactions with participants with vision impairments or literacy concerns, etc.). In any case, the consent process needs to be clearly outlined in the REB application and made clear to participants in their Letter of Information and Consent document.

In other cases, it may be appropriate to request a waiver of consent. Alterations to consent requirements are discussed in the current version of the Tri-Council Policy Statement and researchers shall justify to the satisfaction of the REB that the request for a waiver meets the conditions outlined by Tri-Council.

Below are some examples of how to indicate the consent documentation process in the formal letter of information and consent document.

### **Implied Consent**

If your study will use implied consent (as requested and justified in REB application) add one of the following examples to obtain Implied Consent to the end of your letter of information.

**E.g.,** Submitting the survey is indication of your consent to participate.

OR

**E.g.,** You indicate your voluntary agreement to participate by responding to the questionnaire / survey / etc.

### **Verbal Consent**

If your study will use verbal consent (that is, you are not receiving written consent for a justifiable reason as outlined in the REB application), please include a verbal consent script that you will read to the participant to obtain their consent. This must include explicit questions that the participant has read (or had read to them) the Letter of Information, whether they have any questions, and also include any optional consent items (e.g., “Do you agree to be audio-recorded? Do you agree to unidentifiable quotes shared in the dissemination of the results” etc.).

Please note verbal consent must be documented (e.g., on audio-recording, by researcher checking the appropriate boxes on behalf of participant, in field notes, etc.).

## Written Consent

If your study will use written consent (that is, you are carrying out the study procedures face-to-face), include this section with the rest of the LOI document, but on its own page.

Note: If you are not conducting the study face-to-face, please consider logistically how you will obtain the signed consent form, in a way that is both feasible and protects participants’ confidentiality. Ensure this is clear in the REB application and to the participant (e.g., in recruitment and/or LOI/C materials).

### 1. Project Title

### 2. Document Title

### 3. Principal Investigator + Contact

### 4. Additional Research Staff + Contact (optional)

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

#### IF APPLICABLE INCLUDE THE FOLLOWING:

If you wish to ask participants to provide broad consent for future use of data (See Section 11.11), please provide check boxes before the “Participant’s Signature” block for participants to accept or decline to have their data/specimens used in the future. See example below:

#### CONSENT FOR FUTURE USE

Please check the appropriate box below and initial:

I agree to have my data [*and/or specify biospecimen*] used in future research studies

I do NOT agree to to have my data [*and/or specify biospecimen*] used in future research studies



**IF APPLICABLE INCLUDE THE FOLLOWING:**

If you wish to ask participants to consent to future contact for additional studies, please provide check boxes before the “Participant’s Signature” block for participants to accept or decline to be contacted for other studies in the future.

See example below:

**CONTACT FOR FUTURE STUDIES**

Please check the appropriate box below and initial:

I agree to be contacted for future research studies

I do NOT agree to be contacted for future research studies

**IF APPLICABLE INCLUDE THE FOLLOWING:**

If the participant has an option of being audio or video-recorded, insert the following into the Letter of Information/Consent template:

I agree to be audio-recorded in this research.

YES  NO

I agree to be video-recorded in this research.

YES  NO

**IF APPLICABLE INCLUDE THE FOLLOWING:**

If you are including names, personal quotes, or other directly or indirectly identifiable information in your publication, insert the following into the Letter of Information/Consent template:

**NOTE:** These must only be provided as options IF disclosed in the REB application AND described in the confidentiality section of the LOI.

I agree to have my name used in the dissemination of this research.

YES  NO

I consent to the use of personal, identifiable quotes obtained during the study in the dissemination of this research.

YES  NO

I consent to the use of unidentified quotes obtained during the study in the dissemination of this research.

YES  NO

I agree to have my [other directly or indirectly identifiable information; e.g., professional title, organization name, etc.] used in the dissemination of this research.

YES  NO

I consent to the use of my data for future research purposes.

YES  NO

**IF APPLICABLE INCLUDE THE FOLLOWING:**

If participants are able to provide written consent, insert the following:

\_\_\_\_\_  
Print Name of Participant

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date (DD-*MMM*-*YYYY*)

**REQUIRED FOR WRITTEN CONSENT:**

The person obtaining consent must also sign the consent form. Please insert the following:

My signature means that I have explained the study to the participant named above. I have answered all questions.

\_\_\_\_\_  
Print Name of Person  
Obtaining Consent

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date (DD-*MMM*-*YYYY*)

**IF APPLICABLE INCLUDE THE FOLLOWING:**

If the study involves children, you may need to obtain Parental/Guardian Consent, as well as Assent from the child. Please see the Assent Letter Guidance Document for the assent document. The parent/guardian letter of information and consent requires the following information:

Child's Name: \_\_\_\_\_

Parent / Legal Guardian (Print): \_\_\_\_\_

Parent / Legal Guardian (Sign): \_\_\_\_\_

Parent / Legal Guardian (Date): \_\_\_\_\_

**IF APPLICABLE INCLUDE THE FOLLOWING:**

If the study involves participants with diminished capacity to provide consent, you may also need to obtain consent from a substitute decision maker. Include the following



## Relationship to Participant

### **Appendix A: Guidance on Lotteries, Raffles and, Draws**

General information: There are various federal laws including Criminal Code of Canada, Competition Act, and provincial laws that apply to lotteries. When proposing to offer a research-related draw as a form of compensation, researchers should keep this guidance in mind to minimize the likelihood of triggering legal issues.

#### **Guidance**

- a. Researchers should use the term “draw” rather than “lottery” or “raffle,” since the latter terms imply purchase of tickets by participants.
- b. To further avoid the possibility that a draw would be perceived as a lottery, the researchers should permit all individuals who are contacted concerning the research to enter the draw. This would encompass individuals who are invited to participate but decline, prospective subjects who are ineligible, and subjects who enroll but later withdraw/are withdrawn by the researchers. Additionally, the researchers should permit any individual who asks to be included in the draw to be included in the draw. These steps would be the equivalent to a “no purchase necessary” option seen in most commercial draws and would demonstrate that no consideration was required to participate in the draw. <sup>1</sup>
- c. Both the amounts and number of prizes should not be coercive or exert undue influence on participants. Some universities specify that the prize is not to exceed \$500. Several low value prizes are preferred over one high value prize.

---

<sup>1</sup> Note that it is possible that individuals may abuse the draw or commit fraud. Examples may include the use of bots to enter the draw or participants using multiple identities to obtain multiple draw entries. In such cases, entry into the draw or the award of prizes may be voided. The REB has provided guidance on such scenarios [here](#).

- d. You cannot require participants to pay money or other valuable consideration to participate in the draw.
- e. If personal information is collected solely for the administration of the draw, the researcher should maintain security of this information throughout the duration of the study and should destroy it once the prize is awarded.
- f. The draw should be conducted in a manner that does not otherwise compromise participant anonymity or confidentiality that is protected by other protocol methodology.
- g. All participants who are interested in being considered for a draw should have the same chance of winning the prize(s).
- h. The researcher, any co-researchers or research assistants named in the protocol, their immediate family members and any other person with a direct interest in the research study should be excluded from participation in the draw.
- i. Participants should be afforded the opportunity to not participate in the draw.
- j. Social media companies (e.g. Facebook, Instagram, Twitter, etc.) may have specific requirements related to draws when a researcher uses the social media platform (i) as an active means of entering and participating in the draw; and/or (ii) to promote the draw. Researchers using a social media platform for a draw will have to identify and comply with these requirements. Note that these requirements may change from time to time.
- k. The protocol and consent document(s) should include the following information:
  - Description of the prizes, including estimated value, and the total number of prizes to be awarded.
  - The odds of winning a prize, if known, or explanatory language similar to this: “For any draw, the odds of winning a prize depend on how many people are entered in the draw. As we do not know how many people will participate in this study and related draw, we cannot predict what will be the odds of winning a prize.”

The approximate timing of the draw (e.g., month/year).