

Guidance Document	Preparing a Letter of Information and Consent Document
Effective Review	Non-Medical REB (Delegated & Full Board)
Version Date	Sept 13, 2018

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

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
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

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.

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.

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 transcription company, community partners, non-Western-affiliated academic collaborators (and their REBs), etc.).

E.g., Representatives of Western University's Non-Medical Research Ethics Board may require access to your study-related records to monitor the conduct of the research. (Note: This statement is always required and must be included in LOI.)

E.g, If using Qualtrics, please include the following information, as applicable:

"Your survey responses will be collected anonymously through a secure online survey platform called Qualtrics. Qualtrics uses encryption technology and restricted access authorizations to protect all data collected. In addition, Western's Qualtrics server is in Ireland, where privacy standards are maintained under the European Union safe harbour framework. The data will then be exported from Qualtrics and securely stored on Western University's server."

OR

"Your personal health information (PHI) will be collected using a secure online survey platform called Qualtrics. Qualtrics uses encryption technology and restricted access authorizations to protect all data collected. In addition, Western's Qualtrics server is in Ireland, where privacy standards are maintained under the European Union safe harbour framework. All identifiable information, such as your **insert as applicable per the REB application:** name, contact information, and medical history will be collected separately from study data and linked only by a unique ID code which will be assigned to you after the study/provided to you by the research team. The master list linking your study ID and your identifiable information will only be available to the researchers. However, representatives of Western University's Health Sciences

Research Ethics Board may require access in order to monitor the ethical conduct of the study. If the results of this study are published, only de-identified information will be made available. Your identity as a research participant in this project will not be released without your prior consent.”

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 add the following statement:

“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. **Future use of data:**
If you anticipate retaining anonymous/anonymized data indefinitely for secondary use, participants should be informed of this.

E.g., All data will be collected anonymously and neither the researchers nor anyone else will be able to identify you as a research participant. The data will be stored on a secure server at Western University and will be retained for a minimum of 7 years. Your data may be retained indefinitely and could be used for future research purposes (e.g., to answer a new research question). By consenting to participate in this study, you are agreeing that your data can be used beyond the purposes of this present study by either the current or other researchers.

OR

Other researchers may request access to the data for future research purposes. If you agree to share your data for future research purposes, it is expected that researchers will analyze this data for X purpose; however, it is impossible to predict all ways this data could be analyzed in the future. Your identifiable information will not be shared with researchers outside of the present study team. Please indicate your consent to this possible future use on the consent form prior to signing. [If optional]

- 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 and/or re-analysis for different research questions) 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.

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.

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 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.

13.3. For studies involving Aboriginal populations, insert if applicable

If you are a First Nations or an indigenous person who has contact with spiritual 'Elders', you may want to talk to them before you make a decision about this research 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 a student 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. 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 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 signature lines on the written consent form. Note: Assent from the participant may also be needed, and the method for obtaining assent must be described in the REB application.

Participant's Name: _____

Substitute Decision Maker (Print): _____

Substitute Decision Maker (Sign): _____

Substitute Decision Maker (Date): _____

IF APPLICABLE INCLUDE THE FOLLOWING:

If you are including people with communication difficulties, insert the following into the Letter of Information/Consent template:

Was the participant assisted during the consent process?

YES NO

If **YES**, please check the relevant box and complete the signature space below:

The person signing below acted as a **insert as applicable: e.g., translator** for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

Print Name of Translator

Signature

Date (DD-MMM-YYYY)

Language

IF APPLICABLE INCLUDE THE FOLLOWING:

If you are including illiterate people (e.g., those who cannot read English), add the following:

The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and has had any questions answered.

Print Name of Witness

Signature

Date (DD-MMM-YYYY)

Relationship to Participant