

Guidance Document	Guidance for Non-Clinical Research - Letter of Information and Consent
Effective Review	Delegated & Full Board
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<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.

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 accepted on the consent form are the participant’s name and initials (initials are not required).
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. Keep the footer simple and short; it should only include the version date (dd/mm/yyyy) and pagination (“Page x of y”) on every page.
12. Do not state “This study has been approved by the research ethics board...” as this may appear to offer a guarantee of safety.

Project Title

Enter the full title of study exactly as it appears on the Western Protocol

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 telephone number.

E.g., **Principal Investigator**
Dr. John Doe, PhD, Psychology
Western University, X80000

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 a revised Consent Form and Western Protocol for review and approval any time personnel changes.

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

1. 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].

2. Why is this study being done?

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

2.2. 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].

3. How long will you be in this study?

- 3.1. 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].

4. What are the study procedures?

The Procedures section should outline what is expected of the participant. This section should be exceptionally clear so that the participant is clearly informed of his/her responsibilities.

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 Consent document]:

- 4.1. If applicable, list the different types of study visits to take. Include what is required of the participant at each of these visits.
- 4.2. If applicable, information on Audio / Video-recording. 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.
- 4.3. Location of the study
- 4.4. Nature of measures

Some description of the type of measures may also be needed. If the measures involve potentially sensitive or personal questions (e.g., sexual practices, IQ measures, illegal activities, etc.---these are just a few examples and the researcher should consider whether they feel the participant's willingness to participate might be affected by the nature of the questions). 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 address it in the protocol.

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

Outline possible risks and harms here as per your protocol submission, or if there are none, indicate that here.

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 disclose that there is always the risk of a privacy breach.

6. What are the benefits?

Outline possible benefits to the participants and to society as per your protocol submission. You may indicate there are no benefits to the participant but there should always be societal benefits.

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].

7. 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., written, calling, etc.) withdrawal of information collected about you. If you wish to have your information removed please let the researcher know. It is important to note that a record of your participation must remain with the study 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 and/or samples may be withdrawn. .

NOTE: once the study has been published we will not be able to withdraw your information.

If withdrawal of data is not feasible (e.g., when personal information has been anonymized and added to a data pool) 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.

8. How will participants' information be kept confidential?

Describe the protection of the participant's privacy, indicate what identifiable information will be collected, 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 ethics application.

- 8.1. Indicate if people/groups/organizations outside the study team will have access to information collection (e.g., including transcription company, community partners, etc.).

E.g., Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held to check that the information collected for the study is correct and follows proper laws and guidelines. They may also be given remote access to these records through the internet via secure video conference or through redacted (personal identifiers blacked out) copies

Examples include:

- Representatives of Lawson Quality Assurance Education Program
- Representatives of the Western University and its Health Sciences Research Ethics Board that oversees the ethical conduct of this study. (Note: This statement is always required and must be included in LOI.)

- 8.2. If identifiable information must be collected (e.g., date of birth and initials) it must be made very clear that in doing this the participant may be identified, this is also true for research in small populations where triangulation may occur.

It should be clear:

- 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 (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., initials and date of birth] may allow someone to link the data and identify you.

8.3. If using tele/video conferencing include wording regarding potential risk of these platforms. For example: like online shopping, teleconferencing/videoconferencing technology has some privacy and security risks. It is possible that information could be intercepted by unauthorized people (hacked) or otherwise shared by accident. This risk can't be completely eliminated. We want to make you aware of this.

8.4. 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.

8.5. Include how long identifiable information will be kept.
The researcher will keep any personal information about you in a secure and confidential location for [##] years (Western's Faculty Collective Agreement research data retention policy is 7 years). A list linking your study number with your name will be kept by the researcher in a secure place, separate from your study file.

8.6. 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

8.7. For studies which include focus groups 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 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.”

- 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.

8.8. 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.

8.9. **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.

Example:

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.

8.9 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)

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

Include whether participants will incur any expenses as a result of their participation in the study.

Compensation = base amount given to all participants

Reimbursement = to cover accrued expenses

Incentives = performance-based on top of compensation

Include how reimbursement will be pro-rated if participants withdraw early from study.

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].

OR

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

10. What are the Rights of Participants?

10.1. 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.

11. 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, Contact Information].

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. The REB is a group of people who oversee the ethical conduct of research studies. The HSREB is not part of the study team. Everything that you discuss will be kept confidential.

Or

If this is a study that requires Lawson oversight:

The Letter of Information should include the following language for St. Joseph's Health Care London as a contact outside of the research team:

If you have any questions/concerns about your rights as a research participant or the conduct of this study, please contact: St. Joseph's Health Care London Patient Relations Consultant at 519-646-6100 ext. 64727

The Letter of Information should include the following language London Health Science Centre as a contact outside of the research team:

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036.

This letter is yours to keep for future reference.

12. Consent

Implied Consent

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

E.g., Completion of 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 recruitment script that you will read to the participant to obtain their consent (see example below).

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

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.

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 Written 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 personal quotes or names in your publication, insert the following into the Written Consent template:

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

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 name used in the dissemination of this research

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	<i>Date (DD-MMM- YYYY)</i>

IF APPLICABLE INCLUDE THE FOLLOWING:

If the study involves children, you may also need to obtain Assent from the child. Please see the Assent Letter Guidance Document.

Child's Name: _____

Parent / Legal Guardian / Substitute Decision Maker (Print): _____

Parent / Legal Guardian / Substitute Decision Maker (Sign): _____

Parent / Legal Guardian / Substitute Decision Maker (Date): _____

IF APPLICABLE INCLUDE THE FOLLOWING:

If you are including people with communication difficulties, insert the following into the Written 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 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	<i>Date (DD-MMM-YYYY)</i>

Language		

IF APPLICABLE INCLUDE THE FOLLOWING:

If you are including illiterate people (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