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| **Guidance Document** | NMREB Letter of Information and Consent  |
| **Effective Review**  | Delegated & Full Board |
| **Version Date** | July 12, 2016 |

Legend

Blue text: Guidance and/or instructions

Black text: Suggested wording and/or example

Red text: Language that should not be included

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

1. Use plain (lay) 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 / Romeo Form.

**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].

1. **Why is this study being done?**
	1. Provide background information on what prompted the need for this study
	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].

1. **How long will you be in this study?**
	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].

1. **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.

 **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]:

* 1. If applicable, list the different types of study visits to take. Include what is required of the participant at each of these visits.
	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.
	3. Location of the study
	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.

1. **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, please include a list of local (local to where the research is taking place) resources.

##### 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].

1. **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 withdrawal of information collected about you. If you wish to have your information removed please let the researcher know.

**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. No new information will be collected without your permission.

1. **How will participants’ information be kept confidential?**

Describe the protection of the participant’s privacy, 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.

* 1. Indicate if people/groups/organizations outside the study team will have access to information collection.

**E.g.,** Representatives of The University of Western Ontario 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.)

* 1. 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.

**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.

* 1. Include a statement that all information collected during this study will be kept confidential and will not be shared with anyone outside the study unless required by law.

**E.g.,** While we do our best to protect your information there is no guarantee that we will be able to do so. If data is collected during the project which may be required to report by law we have a duty to report.

* 1. 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.

* 1. Include how long identifiable information will be kept.

The researcher will keep any personal information about you in a secure and confidential location for a minimum of [##] 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.

* 1. 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.

* + - 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.
	1. 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.
1. **Are participants compensated to be in this study?**

Include whether participants will incur any expenses as a result of their participation in the study. Include any reimbursement (e.g., parking), gifts, draws, etc. to participants and whether and 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.

1. **What are the Rights of Participants?**
	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].

We will give you new information that is learned during the study that might affect your decision to stay in the study.

You do not waive any legal right by signing this consent form

* 1. 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. Elders may have concerns about some genetic procedures.

1. **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, email: ethics@uwo.ca.

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

1. **Consent**

**Implied Consent**

If your study will use implied consent (that is, you are doing a survey) 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 Western Protocol), 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).

**Do you confirm that you have read the Letter of Information [or the Letter of Information has been read to you] and have had all questions answered to your satisfaction?**

**[ ]  YES [ ]  NO**

**Do you agree to participate in this research?**

**[ ]  YES [ ]  NO**

You may also want to ask any of the below, as applicable and outlined in your protocol/LOI:

Do you agree to be audio-recorded?

**[ ]  YES [ ]  NO**

Do you consent to the use of personal, identifiable quotes obtained during the study in the dissemination of this research?

**[ ]  YES [ ]  NO**

Do you consent to the use of unidentified quotes obtained during the study in the dissemination of this research?

**[ ]  YES [ ]  NO**

Do you agree to have your name [or other specified identifying information] used in the dissemination of this research?

**[ ]  YES [ ]  NO**

**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 / 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:

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 Signature *Date (DD-MMM-*

Obtaining Consent *YYYY)*

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 |  | Date *(DD-MMM-YYYY)* |
|  |  |  |  |  |
| 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