Guidelines – Informed Consent Form or Information Letter

Introduction to these guidelines
An informed consent form/information letter has two purposes:
1) to enable potential research participants to make an informed choice as to their participation in a study, and 2) to document their decision to participate.

In order to make an informed choice, potential participants must understand the study, how they are involved in the study, and what sort of risks it poses to them. The words and language used to describe these factors must be understandable to potential participants. Evidence of informed consent by the participant or an authorized third party should often be obtained in writing. However, there are instances in which written consent is culturally unacceptable, or where there are good reasons for not needing to or wanting to record informed consent in writing. In such cases, the procedures to seek free and informed consent should be documented. In cases of mailed or telephone interviews, the participants may be sent an information letter prior to participation and willingness to participate in the interview or to complete the questionnaire will often constitute evidence of consent. In many projects, potential participants will read your consent form/information letter prior to deciding whether or not to participate, but in some cases you may read your consent form/information letter to potential participants and they will decide whether or not to participate after listening to your reading.

A template of an informed consent form/information letter is provided at the end of these guidelines. Following the template will help to ensure that the necessary items for approval are included. Checking off an item as it is written into the informed consent form/information letter will assist you in assuring that each element has been addressed in the document. The particulars and context of any specific project will determine what elements need to be included in any specific informed consent form/information letter. Assistance in the preparation of the informed consent form or information letter is available through the Community Research Ethics Office.

Depending on the research method used in the project, each participant must be given a copy of the informed consent form/information letter to read prior to participation in the study. In some projects, the information in the consent form/information letter may be given to participants orally. An information letter may replace a signed informed consent form for survey research in which the return of the survey is considered implicit form.

Items 1-12 are required elements of most informed consent forms/information letters, while items 13-17 may need to be included depending on the nature of your project. Some projects may even require additional items that are not included here.
Identification
1. If your project is associated with a formal organization, institution, body, etc., indicate
the name of that organization, institution, or body in the first paragraph of the informed
consent form/information letter. This identifies your project's affiliation with that
organization, institution, body, etc., to potential participants.

2. List the title of the project and state the researcher(s)'s relationship to any
organizations, institutions, bodies, etc. that are associated with your project. Be sure to list
the names and affiliations of all the project's researchers in the informed consent
form/information letter. If the project is being done for a client or sponsor, include the
name of that client or sponsor in the informed consent form/information letter.

Description of Your Project
3. Invite the participants to participate and describe the following:
   a. Purpose of your research project
   b. Description of the participants: a brief and general description of the participants
   c. Selection of participants: for some projects, it may be appropriate to tell participants
   why and how they were selected
   d. Procedures: what will the participants be asked to do? If a survey, questionnaire, focus
group, or interview is used, mention briefly the topics that will be covered
   e. Expected duration of participation: this includes the time required for each aspect of
   participation and, in projects where participation extends through time, the participant’s
total time commitment
   f. Reasonably foreseeable risks, discomforts, or costs to participants from participating
   g. Reasonably foreseeable risks, discomforts or costs to any communities from
   participants’ participation
   h. Safeguards to be used to minimize those risks, discomforts, or costs to either
   participants or communities
   i. Any benefits to the participants, to communities, or to others.

Confidentiality
4. It is necessary in the informed consent form/information letter to tell participants the
extent to which the information that they provide will be kept confidential and/or
anonymous. Describe the extent, if any, to which confidentiality and/or anonymity of
records identifying the participant will be maintained. Describe how confidentiality and
anonymity will be maintained.
Tell participants how the information will be stored in order to maintain confidentiality and/or anonymity, and what will happen to the raw data when your project is complete or the information has been entered into a secure database. In some situations, such as oral history, you will need to explain when and how confidentiality or anonymity will be broken. Indicate if only aggregate data will be reported, or if individual’s data will be reported.

If participants are identified in reports or presentations, signed consent is usually required. Since participants have the right to know who will have access to the information that they provide, indicate as specifically as possible who will have that access. If research is conducted over the Internet, you must tell participants that you cannot guarantee confidentiality while their data are on the Internet.

If you would like to use quotations in any write-ups or presentations, participants must be told in the information letter/informed consent form (or orally as the case may be) that quotations may be so used. Participants must also be told whether or not any quotations could allow them to be identified. You might consider in some cases informing participants that they will be able to approve any quotations before they are used in write-ups or presentations, and that they may participate without being quoted.

One issue that comes up in focus groups is the fact that confidentiality cannot be guaranteed because all those present at the focus group hear what everyone else says. Tell participants in the informed consent form/information letter how this will be handled in the focus group.

**Compensation**

5. State the terms of any compensation for participating. If participants will receive compensation for participating, indicate how and when they will receive that compensation (e.g., compensation of cash, donation, toys, books, gift cards). Indicate the value of the compensation where appropriate.

Explain if there will be any partial payment if the participant withdraws prior to completion of your study. If compensation is given to parties other than the participants, this needs to be indicated in the informed consent form/information letter.

If class credit will be given, indicate the amount of credit to be earned by participating and the conditions for earning credit toward the final grade. Mention any alternative ways to earn the same amount of credit.

If participants are compensated through a draw or lottery, provide the details of the draw in the informed consent form/information letter: for example, who is eligible, the odds of winning.
winning, the method for determining the winner(s), the prize(s) to be won, when and how
the winner(s) will be notified.

Questions and Approval
6. Include an invitation for participants to ask any questions about the study, its
procedures, or their rights as participants; include a means to contact the researcher(s)
(usually a telephone number and/or e-mail address). Also, if applicable, include a
statement that if the participants experience adverse effects, the researcher and the
REB/Community Research Ethics Office must be contacted immediately.

7. Participants may want to contact someone about their participation who is unrelated to
your project. Since the REB/Community Research Ethics Board has reviewed and approved
your project, you may include a statement in the informed consent form/information
letter:

The REB/Community Research Ethics Board at the Institution/Community Research
Ethics Office has reviewed and approved this project. If you feel you have not been
treated according to the descriptions in this informed consent form/information
letter, or your rights as a participant in research have been violated during the
course of this project, you may contact the Name/Position, REB/Community
Research Ethics Board, Institution/Community Research Ethics Office, (xxx) xxx-
xxxx.

Voluntary Participation
8. Tell participants that participation is voluntary. Further state that refusal to participate
or discontinuation of participation will involve no consequences or loss of benefits to which
the participant is otherwise entitled. Tell participants what will happen to their data if they
withdraw from your project. Also, participants must be told that they have the right to
refuse to answer any question or participate in any activity.

Findings and Feedback
9. Provide a statement about the ways in which the research results will be written up or
presented (for example, a thesis, course project report, publication, presentation,
community report). In addition, if the project is being conducted on behalf of an
organization, institution, agency, company, client, etc. indicate who will receive a report
upon completion of your project.

Tell participants how and when they will be informed of the results of your project. This
could be replaced by a question asking the participants whether they would like a written
or oral summary of the results at the conclusion of your project. If applicable, indicate how
and when the appropriate community will be informed of the results of your project.
Indicate to participants in the informed consent form/information letter how long the information that they provide will be kept and how that information will be disposed of, if that will occur. You may keep the data indefinitely.

**Consent to Participate**

10. Include a statement that says the participant has read and understands the informed consent form, acknowledges receiving a copy of the form, and agrees to participate in the study. If applicable, provide lines for signature of the participant and the researcher, and the date. In some cases the participant’s parent(s)/guardian(s)/legal representative(s) will also sign the informed consent form. Provide two copies of the informed consent form, one to be retained by the participant and one to be signed by the participant and, if applicable, the participant’s parent(s)/guardian(s)/legal representative(s) and returned to you.

In projects where signed consent is not being used, indicate how consent will be obtained and documented.

In the case of survey research where a signed informed consent form is not used, completion and return of the survey is considered an alternative to signed consent. In such cases, the participants should retain a copy of the information letter. Mention in the information letter that returning a completed survey will be taken as consent to include the participant’s information in your data set.

In research involving participants who are not competent to give free and informed consent on their own behalf, free and informed consent must be sought from their authorized representative(s). In such situations where third-party consent has been obtained, but participants understand the nature and consequence of the research, their assent must be obtained; a potential participant’s dissent will preclude his or her participation.

**Withdrawal of Participation**

11. The consequences of a participant’s decision to withdraw from the research and the procedures for orderly termination of participation by the participant need to be described in the informed consent form/information letter. (Explain what will happen to data if a participant withdraws.)

**Number of Participants**

12. Since some people relate confidentiality and anonymity to the total number of participants, the approximate number of participants involved in your study should be indicated. If participants might be identifiable in reports because individual responses will be described, a statement to this effect must be included in the informed consent form/information letter.
When appropriate, one or more of the following additional elements of information (13-17) should also be provided to each participant in the informed consent form/information letter.

**Taping**
13. If you plan to use audio tape, videotape, or film the participants, request permission to do so and indicate how you will be using this material. The details include: will there be audio taping, videotaping, or both? research purposes only?, research and instruction?, who will have access to or view the tapes?, will participants be allowed to preview the tapes?, what will happen to the tapes and transcripts at the end of the study?, what will happen to the tapes if the participant withdraws?

All possible uses of the tapes/films/photos (current and future) should be described if known. Indicate how tapes will be transcribed and who has access to the transcripts; if the transcriber is someone other than the researcher, indicate whether the transcriber will keep all information on the tapes confidential. If the researcher keeps the tapes beyond the end of the study and/or they are archived, then the following statement must be included: "The tapes/films/photos will not be used for any additional purposes without your additional permission."

**Deception or Concealment**
14. If deception or concealment is used, include a statement to the effect that your research cannot be fully described at this time, but at the conclusion of participation, an explanation will be provided. Provide a copy of the debriefing statement/script with your package for the REB/Community Research Ethics Board to review. This statement/script must be prepared in order to remove any misconceptions about the project that participants may have and to re-establish trust which might have been lost. Be sure to explain why the deception or concealment was necessary. The participant must be assured that the deception or concealment was neither arbitrary nor capricious.

In the interest of the right to withdraw at any time, participants would be allowed to remove their information from your research once the deception or concealment has been explained to them.

**Unforeseen Risks or Harms or Costs**
15. In some situations, a statement should be included in the informed consent form/information letter that the particular treatment or procedure may involve currently unforeseeable risks to the participant.

**Termination of Participation**
16. There may be anticipated circumstances under which the investigator may terminate the participant’s participation without regard to the participant’s consent. Those circumstances would be mentioned in the informed consent form/information letter.
Children
17. Do the proposed participants include persons under the age of 16? A separate informed consent form or, in the case of very young children, oral assent must be obtained both from them and from their parent(s)/guardian(s), and, if applicable, from a school authority, agency director, etc. Normally, persons age 16 and over may give free and informed consent on their own behalf.

For younger children prepare a script of what will be said to them to verbally recruit their participation, using age-appropriate language. Despite the informed consent of parent(s)/guardian(s), children must be able to refuse to participate in research or to withdraw their participation at any time.

ADDITIONAL NOTES FOR RESEARCHERS

- It is suggested that researchers use the wording in the provided template, as it applies to their project, and follow the suggested list format of the template. The form should be written in second person ("You are invited..."). Use of first person ("I") can be interpreted as suggestive and coercive.

- Information letters for mail surveys may take the format of a letter but their contents should be the same as in an Informed Consent Form.

- If the Informed Consent Form/Information Letter is to be in a foreign language, submit the foreign language version and an English translation.

- The template format for item 10, the signature section, is highly recommended for all informed consent forms.

- Be sure to include any of items 13 - 17 on the guidelines and template that are appropriate to your research project.

- It is suggested that researchers should not provide their home address or personal phone number.