

GUIDE FOR INFORMED CONSENT

Consent to participate in a research study should be understood as a *process* rather than an event. Researchers should plan for and articulate the steps by which consent is initially obtained and the steps by which it is reviewed throughout the study. In order for participants to give meaningful consent, they should be able to understand the intent of the research, be clear about what they are being asked to do and if any risks are involved, and know how their information will be used.

Consent may be documented in many ways. Oral or implied consent are as legitimate as written consent, and in some contexts may even be more appropriate. For example, oral consent may be more appropriate than written consent if literacy, criminality or cultural appropriateness is an issue. The key idea is to go over the information verbally and document the process of gaining consent in field notes so as to leave a written trail. It is still reasonable to leave written material with the participant (e.g., an information letter). Regardless of the way in which consent is sought or documented, the primary focus of ethical concern should be on the *quality* of the consent. Consent should always be in language that is understandable and not legalistic or too scientific, and the consent process should make room for questions, as appropriate to the research context.

In the majority of cases, where a written-and-signed approach to consent is used, the information letter and consent form are best presented as one document. The information letter should begin with an invitation to potential participants and should explain why they have been asked to participate. The *body* should provide a brief (i.e., a paragraph or two), plain-language description of the proposed research project including a description of the project and the nature of participation. An explanation of how key ethics issues—such as consent and confidentiality—will be handled, along with a discussion of risks and benefits, and compensation if any, should follow. The information letter should be written as if it was being sent from the researcher to the participant, that is, in the 2nd person. It should include an introduction of the researchers and their affiliations.

The consent portion of the Information and Consent Form should include a brief summary of what will happen from the participant's perspective—without redundancy. It should note that the study has been explained to the participant, and the participant has had a chance to have his or her questions answered. The basic elements of consent, bulleted below, are typically relevant regardless of process – whether written in hard copy, via e-mail, on the web, or presented verbally in person or over the phone. However, not all items are appropriate for all protocols, and some additional items may be requested by an REB on a case-by-case basis.

General points

- Letters are presented on letterhead of the department/organization undertaking the research
- The language level is appropriate to the age and reading level of the participant population

- Affiliation and contact information for the investigators and (where appropriate) research coordinator is included
- Any co-existing roles that might be understood as creating conflict of interest and how these will be managed are explained
- A sentence explains that participants can contact the Research Oversight and Compliance Office - Human Research Ethics Program at ethics.review@utoronto.ca or 416-946-3273, if they have questions about their rights as participants
- Participants are given a copy of the information letter to keep for their own reference (this may be implicit)

Introductory information

- An invitation to participate should be worded in a professional and respectful manner
- The purpose of the research should be consistent with that described in the ethics application form
- The sponsor of the research may be relevant, particularly if this might affect consent (e.g., industry funded, military funding)
- The time commitment and the location of where the study will be conducted should be clarified
- The reason why the potential participant is being approached should be explained, and a list of relevant inclusion and exclusion criteria, should be provided
- If relevant, the number of participants who will be involved should be mentioned (e.g., if this could affect confidentiality - see below)

Conditions for participating

- There must be an explicit statement that the individual's participation is voluntary, and that he/she may refuse to participate, may withdraw at any time, and may decline to answer any question or participate in any parts of the procedures/tasks – all without negative consequences
- Any conditions on withdrawal of data if the participant chooses to withdraw from the study should be clarified (e.g., if data are anonymized or de-linked, they cannot be withdrawn; similarly, it is almost impossible to withdraw data from a focus group discussion)
- Information regarding use of audio and video recordings (including potential use for teaching or presentation purposes) should be broken out as separate options, to which participants can consent (or not)

Risks/Benefits

- Reasonably foreseeable risks, harms or inconveniences and how they will be managed should be clearly explained in lay terms
- Mechanisms for reporting significant risk-related issues that are identified during the study and for providing referrals in response to these issues should be described where

appropriate—e.g., in the discovery of unusual test results and occurrence of emotional distress resulting from this discovery or from any other aspect of participation

- Potential benefits—including information that there is no direct benefit—should be mentioned, as appropriate
- Information about any payment or compensation for participation or expense reimbursement should be mentioned (but not over-emphasized)

Access to information, confidentiality, and publication of results

- Information regarding who will have access to the data should be clarified
- Information regarding partnership agreements with communities who may want/have access to or possibly ownership of the data should be discussed
- Information regarding retention and disposition of the data during and after completion of research may also be relevant. Note: destruction of data is not the only acceptable method of disposition. Methods will depend on the identifiability, sensitivity, and richness of the data, and the standards of the researcher's discipline.
- If relevant, different degrees of confidentiality should be presented as options
- Procedures for maintaining confidentiality, should be described, if relevant—e.g., use of study-specific ID numbers, pseudonyms, generic descriptors, composites, or aggregates
- Any foreseeable limits to confidentiality—e.g., for participation in focus groups or research involving key informants or duty to report—should be mentioned
- The researcher's intent to publish or make public presentations based on the research should be made explicit
- A summary of the research results, and a mechanism to provide the summary, should be offered

A brief notification should be added to the consent document/process to inform the participants that a UofT representative may review their research files for quality assurance. An example of the notification that must be provided to all participants could be: "The research study you are participating in may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Human Research Ethics Program (HREP) may access study-related data and/or consent materials as part of the review. All information accessed by the HREP will be upheld to the same level of confidentiality that has been stated by the research team."