Informed consent-General Guidelines

Free and Informed Consent is required of all human participants participating in a research project according to the Tri-Council Policy Statement (2022). Please see Chapter 3 for a full discussion of the Consent Process (https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html

Review Chapter 3, section B for permitted changes to the general principles of consent.

Nothing in the subsequent information should be interpreted as contravening the TCPS-II directions. Information and lists should not be considered exclusive, all researchers are responsible for ensuring their research meets all relevant TCPS-II guidelines, including consent.

Informed consent considers many factors:

- How will prospective participants be contacted?
- When and how will the details of the research be explained to the participants?
- How will consent be obtained, and how/when may it be withdrawn?
- How is consent documented? Is documentation possible or necessary?
- If the participant is not competent or eligible to give consent, how will consent be obtained and from whom?
- For participants not competent or eligible to provide consent, is assent being sought?

There is no, single template for this expectation; processes vary according to the project, and are developed by the researcher/research team.

Regardless of the process being used, the general Informed Consent information must still be presented to the potential participant.

The TCPS-II provides a list for 'information generally required for informed consent (some wording reduced or summarized for clarity and space; see the full list and wording in Article 3.2);

a. information that the individual is being invited to participate in a research project;
b. a statement of the research purpose in plain language, the identity of the researcher, the identity of the funder/sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;
c. a plain language description of all reasonably foreseeable risks and potential benefits, that may arise from research participation;
d. an assurance that prospective participants:
    - are under no obligation to participate and are free to withdraw at any time;

- will be given ongoing information that is relevant to their decision to continue or withdraw from participation; and
- will be given information on their right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;

e. information concerning the possibility of commercialization of research findings, and the presence of any conflicts of interest on the part of the researchers, their institutions or the research sponsors;
f. the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;
g. the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
h. the identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;
i. an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants; a description of how confidentiality will be protected (Article 5.2); a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;
j. information about any payments, including incentives, reimbursement and compensations;
k. a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and
l. in clinical trials, information on stopping rules and when researchers may remove participants from trial.

If you require advice or assistance in developing an Informed Consent Form, please contact Steve Crema, Chair of REB, at screma@fanshawec.ca.

Consent - given by individuals to participate (typically of legal age (18 years old))

Assent - the agreement of someone not able to give legal consent to participate (typically from a parent, caregiver, guardian, Power of Attorney etc.)