

## INFORMED CONSENT FORM (ICF) GUIDANCE / CHECKLIST



Island Health's HREB (Health Research Ethics Board) and Information Stewardship, Access and Privacy Office have compiled the following list of requirements when studies include an informed consent form (ICF). If you have not included the following or justification as to why not in your research ethics application form, the approval process could be delayed.

The Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS2 (2014)) requires:

- Information that the individual is being invited to participate in a research project;
- A statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;
- A plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;
- An assurance that prospective participants:
  - ✓ Are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;
  - ✓ Will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and
  - ✓ Will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;
- Information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;
- The measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;
- The identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
- 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;
- 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 (see 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;
- Information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;
- 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

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- In clinical trials, information on stopping rules and when researchers may remove participants from trial.

The Freedom of Information and Protection of Privacy Act (FoIPPA) provides guidance on how to ensure that the participant is fully informed regarding the use of their personal information during a study. The ICFs must include:

- a. The personal information for which the individual is providing consent (i.e. the type)
- b. The organization for which they are authorizing to share their personal information (i.e. Island Health)
- c. The date on which the consent is effective, and if applicable, the date on which it expires
- d. Who the information is being shared with and/or collected by
- e. The purposes for the collection of the personal information
- f. Who may store or have access to the personal information
- g. The jurisdiction in which they personal information may be stored / accessed (Canada or other\*)
- h. The purposes for the storage or and access to the personal information
- i. The uses of the personal information
- j. To whom the personal information will be further disclosed
- k. The purpose of the disclosure of the personal information
- l. Who the individual may contact with questions or requests concerning their personal information in the study

*\* Information being sent to, accessed from or stored outside of Canada*

If participant information is being sent to, accessed from, or stored outside of Canada (e.g. If you find that the videoconferencing technology does have a server(s) in the United States), you must provide notice of this to participants. To be FoIPPA compliant, please notify participants by including the following:

- Describe whom the participant is authorizing to use or disclose their personal information (e.g. Island Health, Providence, UVic, UofM);
- Describe who may have access to the personal information after it is disclosed;
- Describe the safeguards in place to protect the information while it is being accessed, sent, or stored;
- Describe which country it is being sent to, accessed from, or stored in;
- The name(s) of the organization(s) it is being sent to, accessed from, or stored at;
- The purpose for which it is being sent to, accessed from or stored outside of Canada;
- The safeguards in place to protect the information while it is being sent to, accessed from, or stored outside of Canada;
- A statement that once information is sent to, accessed from, or stored outside of Canada, it is subject to the laws of that country which may be different from the laws in British

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Columbia/Canada that govern how information may be collected, accessed, used or shared/disclosed.

Additional considerations for ICFs include:

- The informed consent process must include adequate time and opportunity for prospective participants to assimilate the information provided, pose any questions they may have, and discuss and consider whether they will participate. The time required for this initial phase of the consent process will depend on such factors as the magnitude and probability of harms, the complexity of the information conveyed, and the setting where the information is given.
- The key to informed consent is that prospective participants understand the information being conveyed to them by researchers. Researchers and REBs should consider how best to convey that information to facilitate understanding. For example, written documentation may be supplemented with audio and/or visual aids, or accompanied by video presentations.
- When language barriers necessitate the assistance of an intermediary for communication between the research team and participants, the researcher should select an intermediary who has the necessary language skills to ensure effective communication. The involvement of such intermediaries may raise confidentiality issues.

Guidance regarding the form(s) must also include:

- Island Health logo (cut and paste from below left)
- Page numbering and a version number and version date included in the footer
- Island Health Research Ethics Board contact information. "If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, or if you wish to verify the ethical approval of this study, you may email [researchethics@viha.ca](mailto:researchethics@viha.ca) or call 250 370-8620."

