

**Interior Health Research Ethics Board  
Guidance Note – Consent for Research**

Researchers must obtain informed consent from participants prior to participation in any research study. The consent process may involve:

- a) A written consent form signed by the participant or his/her legal representative or parent/guardian (as applicable);
- b) A consent script to be read by the researcher to the participant, who then provides verbal consent. This process must be documented by the researcher.
- c) For anonymous surveys, provision of consent information in the form of a written Information Letter containing the consent information described below; for anonymous online surveys, a preamble to the survey that must be read prior to activating the survey link.

In any of these situations, the researcher must include all applicable elements of informed consent as described below. These are the criteria against which the consent documents submitted to the IH REB are evaluated. You may use this checklist to check your consent documents prior to submission.

A statement that the study involves research.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
A clear explanation of why the potential participant has been invited to participate in the study.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Identification of researchers including a contact telephone number and e-mail address for the principal investigator or the lead local investigator.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
An explanation of who is funding the study. If Interior Health is providing an in-kind contribution of human or physical resources, this is acknowledged.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
A statement indicating if the research is being done in order to complete academic requirements (e.g. graduate thesis, residency or internship).	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Consistent use of second-person pronouns (you/your) when referring to participants.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
An unambiguous statement that participation is voluntary, and that refusal to participate or withdrawing from the study at any time will involve no penalty or loss of benefits to which the participant is otherwise entitled. This must also appear in recruitment documents or information letters.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Brief but complete description in lay language of the purpose of the project.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Description of all research-related procedures, with a clear distinction between research procedures and usual care. Include a description of the randomization process if applicable.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Identification of the participant's responsibilities, including statement of the total amount of time that will be required of the participant.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
The approximate number of participants expected to be enrolled in the study in Interior Health sites (and at non-IH sites as applicable).	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Description of the likelihood of any discomforts and/or inconveniences associated with participation.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

A statement of all known risks (e.g. physical, psychological or employment risk; risk to privacy), and a description of how risks will be minimized.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
For research involving greater than minimal risk, an explanation as to what compensation and medical treatments are available if injury occurs, and who to contact in the event of a research-related injury.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Description of any benefits to the participant or others which may reasonably be expected from the study. If there are no anticipated direct benefits to participants, say so.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Details of monetary or other compensation to be offered to participants.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Assurance that the identifiable data collected will be kept confidential, an explanation of how this will be done, and a statement of who will have access to the study information. Include a statement that information collected will not be made publicly available to the extent permitted by the applicable laws.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
An offer to answer any inquiries concerning the procedures and identification of contact persons to obtain additional information about the study (usually the principal investigator).	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
A statement that if the participant has concerns about his/her rights as a research participant or their treatment, he/she may contact the Chair of the IH REB at 250-870-4602 or <a href="mailto:researchethics@interiorhealth.ca">researchethics@interiorhealth.ca</a> .	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
A statement regarding how results will be shared with participants and with others (e.g. via presentations or publications). If the researcher is considering secondary use of the data, this needs to be clearly stated, including that such secondary use is subject to prior review and approval by a Research Ethics Board.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
A statement that the participant will be informed promptly if information becomes available that may be relevant to his/her willingness to continue in the study.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
The consequences of a participant's decision to withdraw from the research (e.g. will his/her data still be used?) and a description of what the participant should do if s/he decides to withdraw.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Anticipated circumstances under which participation may be terminated by the investigator and/or the sponsor without regard to the participant's consent.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
A statement that a copy of the consent form will be given to the person signing the form (participant, legal representative, or parent/guardian).	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
The consent form is written in lay language. For the general public, the reading level of the Consent Form is no higher than grade eight.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Version date of the consent form is given in the footer on each page.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Pages are numbered (page 1 of 3, page 2 of 3, etc.)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
For anonymous surveys, the accompanying Information Letter (or preamble to an online survey) includes a statement that if the survey is completed, it is assumed that consent to participate has been given.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

**Specific considerations for clinical trial consent forms:**

A clear statement that study Monitors, Auditors, IH Research Ethics Board, and regulatory authorities will be granted direct access to the participant's medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant. By signing a written consent form, the participant is authorizing such access.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
A description of any reasonably foreseeable risks to an embryo, fetus or nursing infant, when applicable.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
For written consent, provide space for the printed name and signature of participant (or legal representative), printed name and signature of witness, and date signed.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
If participants are under the age of 19, parental consent forms must contain a statement of choice providing an option for refusal to participate (e.g. "I consent/I do not consent to my child's participation in this study").	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
A statement that an alternate course of treatment that may be available to the participant and a description of the potential benefits and risks.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A