

### 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 legally authorized representative (LAR) or parent/guardian (for those under the age of 19). Both the researcher and the participant retain signed copies.
  - If a parent, guardian, or LAR provides consent on behalf of a participant, the researcher also obtains assent from the participant.
- b) A consent script read by the researcher to the participant, who then provides verbal consent. The researcher must document receipt of verbal consent.
- c) For anonymous<sup>1</sup> surveys, the researcher obtains implied consent. For example, construct online surveys in such a way that the participant must first read a preamble containing all the elements of informed consent; and the participant cannot access the survey before clicking on a clear statement that continuing to the survey is taken as implied consent.

In any of these situations, the researcher must include all applicable elements of informed consent as described below. This checklist helps researchers ensure consent documents meet requirements.

For clinical trials only, the study team may wish to use the BC Common Clinical Consent template, available online from Michael Smith Health Research BC.

**Checklist: does the consent form contain...**

**Yes No N/A**

Checklist: does the consent form contain...	Yes	No	N/A
A statement that the study involves research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Identification of IH site's principal or qualified investigator (PI or QI) including a contact telephone number and e-mail address.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A clear explanation of why you are inviting them to participate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
An explanation of who is funding the study. If Interior Health is providing an in-kind contribution of human or physical resources, acknowledge them as a funder.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A brief but complete lay language description of the purpose of the project.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A description of all research-related procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<sup>1</sup> The information has no identifiers and never had any identifiers associated with it.

<b>Checklist: does the consent form contain...</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>
A description of what information you will collect about participants, for what purposes, and who will have access to their identifiable information.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A description of the participant's responsibilities, including the total amount of time participants will contribute.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A description of foreseeable risks to the participant and how the researchers will mitigate these risks.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A description of benefits the participant may expect to receive from the study. If there are no anticipated direct benefits to participants, say so.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A description of compensation for participant's time and/or reimbursement of expenses associated with participation. If you will not compensate participants for their time or reimburse reasonable expenses, say so.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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 entitled.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
An assurance that participants have the right to request the withdrawal of their data or specimens, including any limitations to that withdrawal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A statement regarding how the researchers will share results (a) directly with participants, and (b) with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A clear statement if the researcher is considering secondary use of the data, including that such secondary use is subject to prior review and approval by a Research Ethics Board.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
An offer to answer questions about the study and identification of an appropriate contact person for this information.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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> . If UBC is the Board of Record, refer participants to the UBC research participant complaint line.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A description of how researchers will protect the privacy of participants throughout the life cycle of the study.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A statement that the researcher will give a copy of the signed consent form to the person signing the form (participant, legal representative, or parent/guardian). If using remote consent, the researcher advises the participant to keep a copy of the written consent form they received from the investigators for their records.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lay language. For the public, the reading level of the Consent Form is no higher than grade <b>eight</b> .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Consistent use of second-person pronouns (you/your) when referring to participants.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Version number and date of the consent form, as well as page numbering (formatted as page 1 of 5, page 2 of 5...) in the footer on each page.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The IH logo on participant-facing documents and recruitment information posted at IH sites or distributed via IH channels.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**As applicable:**
**Yes No N/A**

If the research involves Laboratory, Diagnostic Imaging, or other clinical tests performed at an IH facility, the researcher informs the participant that results will become a part of their medical record.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If participants are under the age of majority (19 in British Columbia), parental consent forms 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"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information about the possible commercialization of research findings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information about the presence of any possible or perceived conflicts of interest on behalf of researchers, their institutions, or sponsors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A statement indicating if a student researcher is completing the project to fulfill academic requirements.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A statement that the researcher will grant study monitors, auditors, IH Research Ethics Board, and applicable regulatory authorities (name them) direct access to the participant's medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A description of foreseeable risks to an embryo, fetus, or nursing infant.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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"/>	<input type="checkbox"/>	<input type="checkbox"/>
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"/>	<input type="checkbox"/>	<input type="checkbox"/>
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"/>	<input type="checkbox"/>	<input type="checkbox"/>
Assurance that if a research-related illness or injury occurs, participants will receive appropriate treatment at no cost to themselves. If the participant has no health insurance, study funds must cover the cost.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A statement that the researcher will inform participants promptly if information becomes available that may be relevant to the participant's willingness to continue in the study.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anticipated circumstances under which the investigator or sponsor may terminate participation without regard to the participant's consent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>