Interior Health

Research Ethics Board
3rd Floor, 505 Doyle Avenue
Kelowna, BC V1Y 0C5
Phone: 250-870-4602
Email: researchethics@interiorhealth.ca

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 (as applicable) or parent/guardian for those under the age of **19**. Signed copies are retained by both the researcher and the participant.
b) A consent script to be read by the researcher to the participant, who then provides verbal consent. Receipt of verbal consent must be documented by the researcher.
c) For anonymous surveys in hard copy format, 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 containing all elements of informed consent described below. The preamble is presented in such a way that the potential participant will read it 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 Canadian REBs use to evaluate consent documents submitted for review. Researchers are encouraged to use this checklist to check consent documents prior to submission.

Checklist

Does the consent form contain…	**Yes**	**No**	**N/A**
A statement that the study involves research.	☐	☐	☐
A clear explanation of why the potential participant has been invited to participate in the study.	☐	☐	☐
Identification of researchers including a contact telephone number and e-mail address for the principal investigator or the lead local investigator.	☐	☐	☐
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.	☐	☐	☐
A statement indicating if the research is being done in order to complete academic requirements (e.g. graduate thesis, residency or internship) if applicable.	☐	☐	☐
Consistent use of second-person pronouns (you/your) when referring to participants.	☐	☐	☐
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.	☐	☐	☐
Brief but complete description in lay language of the purpose of the project.	☐	☐	☐
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.	☐	☐	☐

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Does the consent form contain…	**Yes**	**No**	**N/A**
If Laboratory, Diagnostic Imaging or other clinical tests will be performed at an IH facility, the participant is informed that results will be recorded in their medical record.			
Identification of the participant's responsibilities, including statement of the total amount of time that will be required of the participant.	☐	☐	☐
The approximate number of participants expected to be enrolled in the study in Interior Health sites (and at non-IH sites as applicable).	☐	☐	☐
A statement of all known or anticipated risks, discomforts and inconveniences (e.g. physical, psychological or employment risk; risk to privacy), and a description of how risks will be minimized.	☐	☐	☐
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.	☐	☐	☐
Details of monetary or other compensation to be offered to participants; if there is no reimbursement of expenses that participants are likely to incur as a result of research participation (e.g. transportation costs), this is stated.	☐	☐	☐
A description of what information will be collected about participants and for what purposes, including who will have access to information about participant identity.	☐	☐	☐
Assurance that the identifiable data collected will be kept confidential and an explanation of how this will be done.	☐	☐	☐
An offer to answer any inquiries concerning the study and identification of an appropriate contact persons to obtain additional information about the study.	☐	☐	☐
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 researchethics@interiorhealth.ca. *If the study involves UBC, please use the UBC language, available from their website.	☐	☐	☐
A statement regarding how results will be shared (a) directly with participants, and (b) with others. If the researcher is considering secondary use of the data, this is clearly stated, including that such secondary use is subject to prior review and approval by a Research Ethics Board.	☐	☐	☐
An assurance that participants have the right to request the withdrawal of their data or specimens, including any limitations to that withdrawal.	☐	☐	☐
A statement that a copy of the consent form will be given to the person signing the form (participant, legal representative, or parent/guardian). If consent is obtained remotely, the participant is advised to keep a copy of the written consent form they received from the investigators for their records.	☐	☐	☐
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").	☐	☐	☐
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**.	☐	☐	☐
Version number and date of the consent form is given in the footer on each page.	☐	☐	☐
Pages are numbered (page 1 of 3, page 2 of 3, etc.)	☐	☐	☐

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Does the consent form contain…	Yes	No	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.	☐	☐	☐
Information about the possible commercialization of research findings, including the presence of any possible or perceived conflicts of interest on behalf of researchers, their institutions, or sponsors.	☐	☐	☐
IH logo is present on participant-facing documents.	☐	☐	☐

Specific considerations for above-minimal risk consent forms and clinical trial consent forms

A clear statement that study Monitors, Auditors, IH Research Ethics Board, and regulatory authorities (as applicable) 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.	☐	☐	☐
A description of any reasonably foreseeable risks to an embryo, fetus or nursing infant, when applicable.	☐	☐	☐
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.	☐	☐	☐
A statement that an alternate course of treatment that may be available to the participant and a description of the potential benefits and risks.	☐	☐	☐
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.	☐	☐	☐
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. For clinical trials, include a statement that information collected will not be made publicly available to the extent permitted by the applicable laws.	☐	☐	☐
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.	☐	☐	☐
Anticipated circumstances under which participation may be terminated by the investigator and/or the sponsor without regard to the participant's consent.	☐	☐	☐
A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm.			