

Informed Consent Form Requirements and Documentation



PROCEDURE

25.5.522

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Purpose: To provide Vancouver Island Health Authority (Island Health) a standardized approach to describe the requirements for the informed consent form and the process of waiving or obtaining and documenting initial and ongoing informed consent.

Context: Island Health offers programs and services on the unceded and traditional territories of the Coast Salish, Nuu-chah-nulth, and Kwakwaka'wakw Peoples.

As a signatory to the 2015 Declaration of Commitment to Cultural Safety and Cultural Humility, Island Health is committed to addressing the ongoing impacts of colonialism and Indigenous-specific racism in order to provide a culturally safe, inclusive, healthy and respectful environment.

The organization is committed to strengthening diversity, equity and inclusion to enable excellence in health and care for everyone, everywhere, every time. Through these commitments, Island Health strives to deliver the highest possible standard of care and to promote safe workplaces.

Scope:

- Audience:
 - Research Ethics Office Personnel; All Research Ethics Board (REB) members and Chairs
 - All Researchers including team members
- Environment:
 - Research Environment
- Indications (when this document is to be used): For outlining the requirements for research informed consent forms and related processes. It may also be referred to as guidance for activities related to projects where human participants are engaged.
- Exceptions (when this document is NOT to be used): Outside of the above indications.

Outcomes:

- Describe requirements and processes related to ongoing informed consent for research at Island Health.

1.0 Responsibility

- All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.
- The Researcher is responsible for providing the REB with a detailed description of the rationale for a consent waiver or the consent documents and a description of the consent process. The Researcher also is responsible for providing a description of the recruitment methods and recruitment materials (if applicable).
- When a written informed consent form is used, the Researcher, the research sponsor and the REB are jointly responsible for ensuring that the consent form contains all of the basic elements of consent and the applicable additional elements of consent. The REB is responsible for verifying that the consent form (if applicable) contains the required elements.
- The REB is responsible for determining whether informed consent exemptions or waivers are applicable and appropriate.
- The REB Chair or designee is responsible for reviewing consent forms or changes to consent forms if the changes meet the criteria for delegated review.

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2.0 Procedure

2.1 REB Review of Required Elements of Informed Consent

- a) The REB will review the proposed consent process for appropriateness, and the proposed consent form(s) for general readability, for appropriateness of the language and content and for the inclusion of the applicable elements per Island Health's guidelines and all applicable regulations.
- b) The REB will review the proposed consent form to ensure that it contains adequate information to safeguard the privacy and confidentiality of research participants.
- c) The REB may require a separate consent form for optional procedures or sub-studies (e.g., tissue, blood, genetic testing or specimen banking).
- d) Following the review, the REB may approve the consent form(s) as submitted or require changes.
- e) When changes are required by the REB and are made by the Researcher, the REB or designee will review the consent form(s) to confirm that the required changes have been made and that the version number and date has been updated.
- f) When the changes meet the criteria for delegated review, the revised consent will be provided to the REB Chair or designee for review and approval.
- g) When changes do not meet the criteria for delegated review (SOP 513.1 Research Ethics Board – Delegated Review), the revised consent form will be reviewed at the next Full Board meeting.

2.2 Translation of Informed Consent Documents

- a) The informed consent document should be in language understandable to the research participant (or acceptable representative).
- b) When a research participant is non-English speaking, documentation of informed consent can be by one of two methods:
 - **Written consent:** The REB approved English version of the informed consent document is translated into the research participant's native language. The REB may require that translated informed consents be accompanied by an attestation from a translator certifying that the translated informed consent accurately reflects the REB approved English informed consent. This method is preferred if it is anticipated that a significant percentage of a prospective research population is non-English speaking. A translated informed consent document does not replace the need for an interpreter to be present during the consent process and throughout the research. The research participant will sign the translated version of the informed consent form document.
 - **Oral consent:** If applicable/acceptable, a qualified interpreter fluent in both English and the research participant's native language orally interprets the REB approved English consent form to the research participant. The interpreter should be an impartial person. When the person obtaining consent is assisted by an interpreter, the interpreter must sign and date the consent form.
- c) If a research participant is unable to read, an impartial witness must be present during the entire informed consent discussion. Verbal consent is obtained from the research participant after the informed consent document and any other written information is read and explained to the research participant. Signatures

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will be obtained from the research participant (if capable) and the impartial witness on the informed consent document, where applicable. The signature of the impartial witness attests that the information was accurately explained to, and apparently understood by, the research participant, and that informed consent was freely given by the research participant.

- d) The REB requires that the translated informed consent materials be submitted for review and approval prior to use in enrolling non-English-speaking participants. The REB may require that the Researcher include a certificate or statement signed by the translator indicating that the translated materials are a true and accurate translation of the REB approved English informed consent materials.
- e) The REB may follow delegated review procedures to review and approve translated informed consent materials if the English language materials have already been approved particularly if a signed translation certificate or statement is on file).
- f) An interpreter should be available to the research participant throughout the research.
- g) The interpreter must sign and date the consent form attesting that the research was accurately explained to, and appeared to be understood by, the research participant.

2.3 Consent Update for Ongoing and Completed Research Participants

- a) The Researcher must inform research participants of any new information that might affect their willingness to continue their participation in the research or that may affect their long-term health even if they have completed their participation in the research.
- b) The Researcher must obtain the currently enrolled participant's consent to continue to participate if there is a significant change to the research or risk.
- c) If required, written documentation of ongoing consent for currently enrolled participants may be obtained by having the research participant sign an REB approved consent document containing the updated information.
- d) If applicable, ongoing consent may be obtained orally by contacting the research participant by phone, providing the updated information, and documenting their agreement to continue.
- e) The nature of the provision of the new information to currently enrolled participants and the documentation required will be determined by the REB.
- f) The Researcher must inform former research participants of any new information that may be relevant to their long-term health by contacting them via phone or mail or in person or electronic means (e.g. email), as applicable.

2.4 Recruitment Methods

- a) **Researcher's Patients:** If the patient is under the care of the Researcher, the Researcher may approach the patient directly for recruitment in a study, but in such a manner, that the patient does not feel pressured or obligated in any way. In this instance, the patient's consent should be obtained by an individual other than the Researcher. Any exceptions to this procedure must be appropriately justified and submitted to the REB for review.

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- b) **In circumstances where the Researchers will obtain consent:** The Researcher must ensure that the consent has been obtained without undue coercion or influence and that there is no likelihood of therapeutic misconception, if applicable.
- c) **Referrals:** The Researcher may send a letter to colleagues asking for referrals of potential patients. The Researcher may provide colleagues with an REB approved consent form or research recruitment information sheet to give to their patients. The patient will then be asked to contact the Researcher directly, or, with documented permission from the patient, the Researcher may initiate the call.
- d) **Health Records Department:** The Researcher may ask the Health Records Department to identify patients who appear to meet the research's eligibility criteria. The Researcher should supply Health Records with a standard letter describing the research to give the patient's physician, and asking whether the physician would be willing to approach their patients about participation. It is NOT acceptable for the Researcher or their staff to contact patients identified through hospital records, clinic charts or other databases independently by phone, unless the patient has previously agreed, or is already under the medical care of the Researcher, or permission has been granted via the role of the Researcher or their staff in the context of research.
- e) **Registries:** If the REB has previously approved a patient research registry and the patient has provided permission to be contacted for potential research, the Researcher or their research team may contact these patients directly. The person contacting the patient should identify themselves as associated with the patient's clinical caregiver, and remind the patient that they have agreed to be contacted. The patient must be offered the option of having his/her name removed from the database.
- f) **Advertising:** The REB must first review and approve the text and the use of any advertisements, notices, or media messages.

2.5 Recruitment Materials

- a) The REB reviews the recruitment materials (e.g., advertisements, letters, notices) for evidence of coercion or undue influence and consistency with the REB approved research and informed consent document.
- b) Advertisements should be reviewed by the REB, as applicable, and according to REB requirements.
- c) All recruitment materials must be approved by the REB and by each organization where the recruitment material will be displayed, as per local practice prior to their use.

2.6 Documentation of Informed Consent

- a) The REB typically requires documentation of informed consent by the use of a written informed consent form approved by the REB and signed and dated by the research participant or the research participant's legally acceptable representative, and by the person obtaining consent.
- b) As required by the Research Sponsor or if required by organizational policies, the Researcher must also sign and date the informed consent form for clinical trials.
- c) For research funded or supported by the U.S. Federal Government, in accordance with applicable regulations, the REB may waive the requirement for the Researcher to obtain a signed informed consent

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form if it finds either that (a) the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality or (b) the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

- d) A copy of the signed consent form shall be provided to the research participant.
- e) The Researcher or designee should document details of the consent process in the research participant's medical record, according to the organization's guidelines.
- f) The Researcher should inform the research participant's primary physician or health care provider, about the research participant's involvement in the research if the research participant agrees to the primary physician being informed.
- g) The REB may approve a written assent document in cases where the research participant may lack the capacity to consent. The assent form contains all required elements of informed consent. The assent document is signed by the research participant. The substitute decision maker signs the informed consent form on behalf of the research participant. The person obtaining consent must sign a copy of the informed consent form.
- h) The REB may approve a process that allows the informed consent document to be delivered by regular mail, email, or facsimile to the potential participant, and to conduct a consent interview by telephone or other electronic communication when necessary, when the participant can read the consent document as it is discussed. All other applicable conditions for documentation of informed consent must also be met when using this procedure.
- i) In some types of research, and for some groups or individuals where written signed consent may be felt by the participants as mistrust on the part of the Researcher, the REB may approve the process of oral consent, a verbal agreement, or a handshake.
- j) Where consent is not documented in a signed consent form, Researchers may use a range of consent procedures (e.g., oral consent, field notes, implied consent through the return of a completed survey/questionnaire). The procedures used to seek consent must be documented by the Researcher and approved by the REB.
- k) For research that is funded or supported by the U.S. federal government, an REB may only waive the requirement for a signed consent form for some or all participants in accordance with applicable U.S. federal regulations.
- l) Whenever possible, the research participant should have written documentation of participation in a research project unless it may compromise their safety or confidentiality.

2.7 Consent Monitoring

- a) In considering the adequacy of informed consent procedures, the REB may require monitoring of the consent process by an impartial observer.
- b) Such monitoring may be particularly warranted when the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided.

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- c) Monitoring may also be appropriate as a corrective action when the REB has identified problems associated with a particular Researcher or a research project.

2.8 Waiver or Alteration of Informed Consent

- a) The REB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent, provided that the REB finds and documents that:
- The regulatory and ethics guidance framework supports the waiver;
 - The research involves no more than minimal risk to the participants;
 - The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;
 - The research could not practicably be carried out without the waiver or alteration;
 - The precise nature and extent of any proposed alteration is defined;
 - The information is used in a matter that will ensure its confidentiality;
 - Whenever appropriate, the participants will be provided with additional pertinent information after participation.
- b) If the research study is funded by or supported by the U.S. federal government, waiver of informed consent or some or all of the required elements of informed consent may only be permitted in accordance with applicable regulations, including a consideration of whether the study would qualify as exempt research under the applicable U.S. regulation(s).
For U.S. FDA regulated research, the REB may not waive informed consent except under the specific provisions in the applicable regulations governing emergency research.
- c) Debriefing should be a part of all research involving an alteration to consent requirements whenever it is possible, practicable, and appropriate.
- d) Participants should have the opportunity to refuse consent and request the withdrawal of their data and/or specimens whenever possible, practicable, and appropriate.
- e) These findings and their justifications shall be clearly documented in the REB minutes when the REB exercises this waiver provision.
- f) Researchers are not required to seek participant consent for secondary use of non-identifiable information or non-identifiable biological specimens.

2.9 Consent For Research Involving Individuals who Lack Capacity

- a) For research involving individuals who lack capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB must ensure that at a minimum the following conditions are met:
- The Researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;

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- The Researcher seeks and maintains consent from authorized third parties;
 - The authorized third party is not the Researcher or any other member of the research team;
 - The Researcher demonstrates that the research is being carried out for the participant's direct benefit or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant, the Researcher shall demonstrate how the research will expose the participant to only a minimal risk and how the participant's welfare will be protected during participation in the research.
- b) If an authorized third party has consented on behalf of a person who lacks legal capacity but that person has some ability to understand the significance of the research, the Researcher ascertains the wishes of that individual with respect to participation.
- c) Assent from a participant is not sufficient to permit them to participate in a research project in the absence of consent by an authorized third party; however, their -expression of dissent must be paramount.
- d) Prospective participants who may be capable of verbally or physically assenting to, or dissenting from, participation in research include:
- Those whose capacity is in the process of development, such as children whose capacity for judgment and self-direction is maturing;
 - Those who were once capable for making an autonomous decision regarding consent but whose capacity is diminishing or fluctuating; and
 - Those whose capacity remains only partially developed, such as those living with permanent cognitive impairment.
- e) If assent for research is required, the Researcher must submit to the REB the proposed procedures for obtaining consent from the capable substitute decision maker and assent from the research participant. The Researcher must submit an assent form or summary of the assent process to the REB for approval as per the organization's guidelines.
- f) When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the research, the Researcher will seek the participant's consent as a condition of continuing participation.
- g) If an individual signed a research directive indicating their preference for ongoing and/or future participation in research, in the event that the individual loses capacity or upon their death, an authorized third party may be guided by these directives during the consent process.

2.10 Inappropriate Inclusion and Exclusion of Participants

- a) The REB will determine appropriate protections for individuals and groups who might be inappropriately excluded from research on the basis of attributes such as culture, language, sex, race, ethnicity, age and disability, and who require additional protections. For these individuals and groups the REB will take into account the risks and benefits of the research, and will consider protections afforded by organizational policies, and provincial and federal law.

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- b) In addition, when the REB regularly reviews research involving individuals, groups, or populations who may be vulnerable in the context of research, consideration shall be given to the inclusion of one or more individuals who are knowledgeable and experienced in working with these participants.

Specific populations that may require representation may include, but are not limited to:

- Children;
 - The elderly;
 - Individuals with mental illness;
 - Pregnant women;
 - Individuals with limited language skills;
 - Indigenous individuals and communities;
 - Prisoners.
- c) If research involves prisoners, children, pregnant women, fetuses and/or neonates, and is funded or supported by the US Federal Government, the REB shall apply the requirements of [45 CFR 46](#), including as appropriate, Sub-Parts, [B](#), [C](#) and [D](#).

2.11 Consent for Research in Health Emergencies

- a) The REB establishes the criteria for the conduct of research involving medical emergencies prior to approval of the research, as outlined in Island Health Research Ethics SOP 518. The Researcher must justify to the REB the reasons why an exception to obtaining informed consent from participants is required;
- b) The REB allows research that involves health emergencies to be carried out without the free and informed consent of the participant or of their authorized third party if ALL of the following apply:
- A serious threat to the prospective participant requires immediate intervention;
 - Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care;
 - Either the risk of harm is not greater than that involved in standard therapeutic care, or it is clearly justified by the potential for direct benefit to the participant;
 - The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research project;
 - Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so, and;
 - No relevant prior directive by the participant is known to exist.
- c) When a previously incapacitated participant regains capacity, or when an authorized third party is found, free and informed consent is sought for continuation in the project and for subsequent research-related procedures.

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2.12 Consent and Secondary Use of Identifiable Information and/or Human Biological Materials for Research Purposes

- a) The REB allows the secondary use of identifiable information and/or human biological materials for research purposes without obtaining consent from research participants if the Researcher is able to satisfy the following conditions:
- Identifiable information/materials is essential to the research;
 - The use of identifiable information/materials without the participant's consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
 - The Researchers will take appropriate measure to protect the privacy of individuals, and to safeguard the identifiable information/materials;
 - The Researchers will comply with any known preferences previously expressed by individuals about any use of their information/materials;
 - It is impossible or impracticable to seek consent from individuals to whom the information relates/materials were collected, and;
 - The Researchers have obtained any other necessary permission for secondary use of information/materials for research purposes.
- b) In cases where the secondary use of identifiable information/materials without the requirement to seek consent has been approved by the REB, if the Researcher proposes to contact individuals for additional information and/or materials, REB approval must be obtained prior to contact.

2.13 Incidental Findings

- a) Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research. The Researcher's plan to identify and to disclose incidental findings must be submitted to the REB and approved prior to implementation.

3.0 Training

- 3.1 Review of the SOP 522 Informed Consent Form Requirement and Documentation.

4.0 Compliance Monitoring

- 4.1 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for ongoing monitoring of Island Health operations to verify compliance with this SOP.
- 4.2 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for communicating any changes to this SOP to all relevant personnel.
- 4.3 Deviations from this SOP will be addressed through corrective and preventative action implementation.

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5.0 Definitions

- **Informed Consent:** Means a process by which a participant voluntarily confirms their willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate.
- **Informed Consent Form (ICF)** (also called a consent form): Means a written form that provides the study participant with information essential to making an informed decision about participating in a clinical investigation. The signature of the study participant or the participant's legally authorized representative on the ICF indicates the intent of the participant or the participant's legally authorized representative to give informed consent.
- **Impartial Witness:** Means a person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the participant or the participant's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the participant.
- **Delegated review** (also referred to as expedited review): Means the level of Research Ethics Board (REB) review assigned to minimal risk research studies, to minor changes in approved research and to continuing review applications that meet the delegated review criteria. Delegated reviewers are selected from among the REB membership to conduct the review.
- **Recruitment:** Means the processes and activities used to identify patients/participants for clinical trials, from a base population through to enrolment into the study.

6.0 Related Island Health Policy Documents

- [513.1 Research Ethics Board – Delegated Review](#)
- [513.2 Delegated Review - Delegated Responsibility to REB Office Personnel](#)

7.0 References

- [Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. \(2022\). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 \(2022\). \(Chapter 3, Article 3.4\).](#)
- [Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. \(2022\). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 \(2022\). \(Chapter 4, Articles 5.5, 5.6\).](#)
- [Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. \(2022\). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 \(2022\). \(Chapter 3, Article 3.8\).](#)
- [Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. \(2022\). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 \(2022\). \(Chapter 5, Article 5.3\).](#)

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- [Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. \(2022\). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 \(2022\).](#)
- [Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. \(2022\). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 \(2022\). \(Chapter 3, Article 3.11\).](#)
- [Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. \(2022\). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 \(2022\). \(Chapter 3, Article 3.7b\).](#)
- [Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. \(2022\). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 \(2022\). \(Chapter 3, Article 3.9\).](#)
- [Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. \(2022\). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 \(2022\). \(Chapter 3, Article 3.2\).](#)
- [Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. \(2022\). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 \(2022\). \(Chapter3, Article 3.3\).](#)
- [Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. \(2022\). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 \(2022\). \(Chapter 3, 3.12\).](#)
- [Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. \(2022\). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 \(2022\). \(Chapter 3, Article 3.7a\).](#)
- [Documentation of informed consent, 45 C.F.R. § 46.177a. \(2024\).](#)
- [Documentation of informed consent, 45 C.F.R. § 46.177c. \(2024\).](#)
- [Documentation of informed consent, 45 C.F.R. § 46.117\(b\)\(2\). \(2024\).](#)
- [Elements of informed consent, 21 C.F.R. § 50.25 \(2024\).](#)
- [Exception from informed consent requirements for emergency research, 21 C.F.R. § 50.24. \(2024\).](#)
- [General requirements for informed consent, 45 C.F.R. § 46.116d. \(2024\).](#)
- [General requirements for informed consent, 45 C.F.R. § 46.116. \(2024\).](#)
- [General requirements for informed consent, 21 C.F.R. § 50.20. \(2024\).](#)
- [International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6\(R2\).\(2016\). \(4.8.6, 4.8.8, 4.8.11\).](#)
- [Protection of Human Subjects, 45 C.F.R. § 46. \(2024\).](#)
- [University of British Columbia \(2019\). Research Involving Human Participants. The University of British Columbia Board of Governors.](#)

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8.0 Resources

- Glossary of Terms – Research Ethics

9.0 Summary of Changes

Version	Effective Date	Comments
V 1.0	01 JUL 2013	New Procedure
V 2.0	01 MAR 2024	Addition of wording based on revisions to TCPS 2 for consistency, changes in language. Changed Issuing Authority from Research & Capacity Building to Vice President Quality, Research & Chief Nursing & Allied Health Officer

Maintained by:	Research Ethics & Compliance						
Issuing Authority:	Vice President Quality, Research & Chief Nursing & Allied Health Officer						
Version No.:	2.0	Last Revised:	2024-FEB-23	Last Reviewed:	2024-FEB-23	First Issued:	2013-JUL-01
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