# RS0200 – SECONDARY USE OF IDENTIFIABLE HUMAN BIOLOGICAL MATERIALS

Interior Health would like to recognize and acknowledge the traditional, ancestral, and unceded territories of the Dãkelh Dené, Ktunaxa, Nlaka'pamux, Secwépemc, St'át'imc, Syilx, and Tŝilhqot'in Nations, where we live, learn, collaborate and work together.

Interior Health recognizes that diversity in the workplace shapes values, attitudes, expectations, perception of self and others and in turn impacts behaviors in the workplace. The dimensions of a diverse workplace includes the protected characteristics under the human rights code of: race, color, ancestry, place of origin, political belief, religion, marital status, family status, physical disability, mental disability, sex, sexual orientation, gender identity or expression, age, criminal or summary conviction unrelated to employment.

## 1.0 PURPOSE

To describe processes for the secondary use of identifiable Human Biological Materials from Interior Health (IH) for the purpose of research, and the ethical review by the Research Ethics Board.

## 2.0 DEFINITIONS

| TERM | DEFINITION |
|---|---|
| *Anonymized:* | *Information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.* |
| *Authorized Third Party:* | *Any person with the necessary legal authority to make decisions on behalf of a prospective participant who lacks the Capacity to Consent to participate, or to continue to participate, in a particular research project. An individual who is recognized by the institutional policy as acceptable for providing Consent in the non-research context to the procedures involved in the research will be considered an Authorized Third Party for the purposes of the research.* |
| *Capacity:* | *The ability of prospective or actual participants to understand relevant information presented (e.g. purpose of the research, foreseeable risks, and potential benefits), and to appreciate the potential consequences of any decision they make based upon this information.* |

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|---|---|
| *Consent:* | *An indication of agreement by an individual to become a participant in a research project. The term "Consent" implies free (also referred to as voluntary), informed and ongoing Consent.* |
| *Human Biological Materials* | *Tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials. The term may include materials derived from living or deceased persons.* |
| *Impracticable* | *As defined by the Tri-Council Policy Statement, incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience.* |

## 3.0 POLICY

3.1 Secondary use of Identifiable Human Biological Materials

3.1.1 Secondary use refers to the use in research of information originally collected for a purpose other than the current research purpose.

3.1.2 Privacy concerns and questions about the need to seek Consent arise when Human Biological Materials provided for secondary use in research can be linked to individuals, and when the possibility exists that individuals can be identified in published reports, or through data linkage. Privacy legislation recognizes these concerns and permits secondary use of identifiable materials under certain circumstances.

3.1.3 Researchers who have not obtained Consent from participants for secondary use of identifiable Human Biological Materials will only use such materials for these purposes if the REB is satisfied that:

3.1.3.1 Identifiable Biological Materials are essential to the research;

3.1.3.2 The use of identifiable Biological Materials without the participant's Consent is unlikely to adversely affect the welfare of individuals to whom the material relates;

3.1.3.3 The researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable Biological Materials;

3.1.3.4 The researchers will comply with any known preferences previously expressed by individuals about any use of their Biological Materials;

3.1.3.5 It is impossible or Impracticable to seek Consent from individuals from whom the Biological Materials were collected; and

3.1.3.6 The researchers have obtained any other necessary permissions for secondary use of Biological Materials for research purposes.

3.1.4 If a researcher satisfies all the conditions in 3.13, the REB may approve the research without requiring Consent from the individuals to whom the Biological Material relates.

3.1.5 In cases where the secondary use of identifiable Biological Materials without the requirement to seek Consent has been approved by the REB, if the researcher proposes to contact the individuals for additional information and/or Materials, REB approval must be obtained prior to contact.

3.2 Collection and Use of Identifiable Human Biological Materials with Consent

3.2.1 Human Biological Materials may be obtained in different ways:

3.2.1.1 They may be collected expressly for a specific research purpose;

3.2.1.2 They may be collected incidentally to medical or diagnostic procedures with no initial intent to be used in research; or

3.2.1.3 They may be collected for research or medical or diagnostic purposes with some expectation that they may, or will, also be used in future research, although the precise research project(s) may not be known at the time.

The first category above refers to the initial collection of Human Biological Materials for research. The latter two categories are relevant to subsequent, secondary uses of Human Biological Materials for research that may not have been conceived at the time the tissue was taken.

3.3 Research involving collection and use of Human Biological Materials requires REB review and:

3.3.1 Consent of the participant who will donate Biological Materials; or

3.3.2 Consent of of an Authorized Third Party on behalf of a participant who lacks Capacity, taking into account any research directive that applies to the participant; and assent of the participant, as described in policy RR0700 Obtaining Consent for Research; or

3.3.3 Consent of a deceased participant through a donation decision made prior to death, or by an Authorized Third Party.

3.4 To seek Consent for use of Human Biological Materials in research, researchers shall provide to prospective participants or Authorized Third Parties, applicable information as set out in TCPS2 Article 3.2 as well as the following details:

3.4.1 The type and amount of Biological Materials to be taken;

3.4.2 The manner in which Biological Materials will be taken, and the safety and invasiveness of the procedures for acquisition;

3.4.3 The intended uses of the Biological Materials, including any commercial use;

3.4.4 The measures employed to protect the privacy of and minimize risks to participants;

3.4.5 The length of time the Biological Materials will be kept, how they will be preserved, location of storage (e.g., in Canada, outside Canada), and process for disposal, if applicable;

3.4.6 Any anticipated linkage of Biological Materials with information about the participant; and

3.4.7 The researchers' plan for handling results and findings, including clinically relevant information and incidental findings.

3.5 Use of Identifiable Human Biological Materials Without Consent

3.5.1 Researchers who have not obtained Consent from participants for secondary use of identifiable Human Biological Materials shall only use such material for these purposes if the REB is satisfied that:

3.5.1.1 Identifiable Human Biological Materials are essential to the research;

3.5.1.2 The use of identifiable Human Biological Materials without the participant's Consent is unlikely to adversely affect the welfare of individuals from whom the Materials were collected;

3.5.1.3 The researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable Human Biological Materials;

3.5.1.4 The researchers will comply with any known preferences previously expressed by individuals about any use of their Biological Materials;

3.5.1.5 It is impossible or Impracticable to seek Consent from individuals from whom the Materials were collected; and

3.5.1.6 The researchers have obtained any other necessary permission for secondary use of Human Biological Materials for research purposes.

3.5.2 If a researcher satisfies all the conditions in 3.5.1.1 to 3.5.1.6, the REB may approve the research without requiring Consent from the individuals from whom the Biological Materials were collected.

## 4.0 PROCEDURES

4.1 The REB will follow procedures for the ethical review of any research involving participants as identified in this policy per research ethics policies RR0100 Activities Requiring Research Ethics Review, RR0300 Initial Review of Research and RR0700 Obtaining Consent for Research.

## 5.0 REFERENCES

1. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 701.003: *Informed Consent Form Requirements and Documentation.*

2. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2022.

3. Interior Health (2022). Research Policy Manual: RR0100 Activities Requiring Research Ethics Review.

4. Interior Health. (2021). Research Policy Manual: RR0300 Initial Review of Research.

5. Interior Health. (2022). Research Policy Manual: RR0700 Obtaining Consent for Research.

6. UBC Office of Research Ethics. (2018). Standard Operating Procedure 502: *Special Categories of Research*.

7. US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).