



<b>TITLE</b>	<b>502: Special Categories of Research</b>
<b>SCOPE</b>	All research submitted to the University of British Columbia’s Research Ethics Boards
<b>RESPONSIBILITIES</b>	The Vice-President, Research & Innovation, delegated to the Director, Office of Research Ethics, all Research Ethics Board (REB) Chairs and members and all REB Office Personnel
<b>APPROVAL AUTHORITY</b>	The Vice-President, Research & Innovation
<b>EFFECTIVE DATE</b>	May 2018
<b>Supersedes documents dated</b>	May 2011, April 2009, July 2003

**1.0 PURPOSE**

The purpose of this standard operating procedure (SOP) is to describe review of specific types of research, some of which may require additional considerations by the REB.

**2.0 DEFINITIONS**

See the Glossary of Terms.

**3.0 PROCEDURE**

Certain categories of research involve either methodologies that might require additional considerations, or for which there are federally mandated determinations that REBs are required to make and document.

**3.1 Research in Emergency Health Situations**

Research in emergency health situations must have REB approval prior to implementation. This may be provided by the REB Chair or his/her designate. This may be provided in situations which meet the criteria outlined below. Prior to approving such research, the REB Chair, or his/her designate, must ascertain that a formal research protocol exists, that a serious threat to the prospective participant requires immediate intervention, that the Researcher is qualified to provide the experimental treatment, that all standard known efficacious treatment has been administered, and that the patient or third party has provided informed consent. Consent may be waived if adequate attempts have been made to locate an authorized third party and have failed.

- 3.1.1** Subject to all applicable legal and regulatory requirements<sup>1</sup>, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the REB;
- 3.1.2** The REB may allow research that involves medical emergencies to be carried out without the consent of participants, or of their authorized third party, if all of the following apply:
  - a) A serious threat to the prospective participant requires immediate intervention; and
  - b) Either no standard efficacious care exists or the research offers a realistic possibility of direct benefit to the participant in comparison with standard care; and
  - c) Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the prospect for direct benefits to the participant; and
  - d) The prospective participant is unconscious or lacks capacity to understand risks; methods and purposes of the research project, and
  - e) Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
  - f) No relevant prior directive by the participant is known to exist;
- 3.1.3** When a previously incapacitated participant regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the research project;
- 3.1.4** The REB Chair or his/her designate should also inform the Researcher of his/her responsibility to inform the REB of the outcome of the treatment together with any serious adverse events associated with it in a formal report to be submitted at the point the patient is discharged from the unit in question;
- 3.1.5** If a research study is subject to the U.S. Food & Drug Administration regulations and involves an exception to informed consent for emergency research, the REB shall review and comply with the applicable FDA regulations<sup>2</sup>.

## **3.2 Secondary Use of Identifiable Information for Research Purposes, including Health Records and Medical Chart Review**

Secondary use refers to the use in research of information originally collected for a purpose other than the current research purpose. Common examples are social science or health survey datasets that are collected for specific research or statistical purposes, but then re-used to answer other research questions. Information initially collected for program evaluation may be useful for subsequent research. Other examples include health care records, school records, biological specimens, vital statistics registries or unemployment records, all of which are originally created or collected for therapeutic, educational or administrative purposes, but which may be sought later for use in research.

Privacy concerns and questions about the need to seek consent arise, however, when information 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 information under certain circumstances.

**3.2.1** Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that<sup>3</sup>:

- a) identifiable information is essential to the research,
- b) the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates,
- c) the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information,
- d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information,
- e) it is impossible or impracticable to seek consent from individuals to whom the information relates, and
- f) the researchers have obtained any other necessary permission for secondary use of information for research purposes;

**3.2.2** If a Researcher satisfies all the conditions in (a) to (f) of section 3.2.1, the REB may approve the research without requiring consent from the individuals to whom the information relates.

## **3.3 Collection of Human Biological Materials**

Human biological materials may be obtained in different ways:

1. They may be collected expressly for a specific research purpose,

2. They may be collected incidentally to medical or diagnostic procedures with no initial intent to be used in research, or
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.

**3.3.1** Research involving collection and use of human biological materials requires REB review and<sup>4</sup>:

- a) consent of the participant who will donate biological materials; or
- b) consent of an authorized third party on behalf of a participant who lacks capacity, taking into account any research directive that applies to the participant; or
- c) consent of a deceased participant through a donation decision made prior to death, or by an authorized third party;

**3.3.2** 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<sup>5</sup> as well as the following details<sup>6</sup>:

- a) the type and amount of biological materials to be taken;
- b) the manner in which biological materials will be taken, and the safety and invasiveness of the procedures for acquisition;
- c) the intended uses of the biological materials, including any commercial use;
- d) the measures employed to protect the privacy of and minimize risks to participants;
- e) 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;
- f) any anticipated linkage of biological materials with information about the participant; and
- g) the researchers' plan for handling results and findings, including clinically relevant information and incidental findings.

## **3.4 Consent and Secondary Use of Identifiable Human Biological Materials for Research Purposes**

**3.4.1** 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<sup>7</sup>:

- a) identifiable human biological materials are essential to the research;
- b) 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;
- c) the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable human biological materials;
- d) the researchers will comply with any known preferences previously expressed by individuals about any use of their biological materials;
- e) it is impossible or impracticable to seek consent from individuals from whom the materials were collected; and
- f) the researchers have obtained any other necessary permission for secondary use of human biological materials for research purposes;

**3.4.2** If a Researcher satisfies all the conditions in (a) to (f) above, the REB may approve the research without requiring consent from the individuals from whom the biological materials were collected.

## **3.5 Use of Tissue and/or Data Obtained from Tissue and Data Banks**

**3.5.1** Institutions and researchers that maintain biobanks<sup>8</sup>:

- a) shall ensure that they have or use appropriate facilities, equipment, policies and procedures to store human biological materials safely, and in accordance with applicable standards, and
- b) shall establish appropriate physical, administrative and technical safeguards to protect human biological materials and any information about participants from unauthorized handling;

**3.5.2** Use of tissue or data that has been previously collected must receive authorization from the custodian of that bank or registry for its use, regardless of whether the tissue/data is anonymized;

**3.5.3** Evidence of this authorization must be attached to the RISE application form when submitting to the appropriate REB;

**3.5.4** If the tissue/data is not anonymized, evidence that consent was obtained at the time of collection for use of the tissue/data must also be attached to the RISE application form. This may include the original consent form or assurance from the Researcher that appropriate protections were undertaken to ensure confidentiality and privacy.

## **4.0 REFERENCES**

1. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 3.8:  
[http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3\\_en\\_a3.8](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.8)

2. *U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 50 (21 CFR 50.24):*  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=50.24>
3. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 5.5:*  
[http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#ch5\\_en\\_a5.5a](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#ch5_en_a5.5a)
4. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 12.1:*  
[http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/#ch12\\_en\\_a12.1](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/#ch12_en_a12.1)
5. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 3.2:*  
[http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3\\_en\\_a3.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.2)
6. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 12.2:*  
[http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/#ch12\\_en\\_a12.1](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/#ch12_en_a12.1)
7. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 12.3:*  
[http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/#ch12\\_en\\_a12.3a](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/#ch12_en_a12.3a)
8. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 12.5:*  
<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/#toc12-1d>