Fraser Health Research Ethics Board
Department of Evaluation and Research Services , FHA
400 – 13450 102 Avenue, Surrey, BC V3T 0H1
Phone: (604) 587-4436 Fax: (604) 930-5425

GUIDANCE NOTES ON STUDIES INVOLVING HUMAN BIOLOGICAL MATERIALS

INTRODUCTION

This guidance note is intended to provide guidance on submission requirements and ethical standards for studies involving human biological materials, whether collected expressly for a specific research purpose or collected incidentally to medical or diagnostic procedures.

GUIDANCE NOTE #1: DEFINITIONS

Human biological materials: materials obtained from participants, including tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva and other bodily floods.

Identifiable human biological materials: Human biological materials that may reasonably be expected to identify an individual, alone or in combination with other available information, are considered identifiable biological materials.

Biobank: A collection of human biological materials. It may also include associated information about individuals from whom biological materials were collected (also referred to as a tissue bank).

GUIDANCE NOTE #2: SUBMISSION REQUIREMENTS

Researchers conducting studies using human biological materials must specify the following information in the study protocol and participant consent form, as applicable:

1. The type and amount of biological materials to be taken;
2. The manner in which biological materials will be taken, and the safety and invasiveness of the procedures for acquisition;
3. The intended uses of the biological materials, including any commercial use;
4. The measures employed to protect the privacy of and minimize risks to participants;
5. The length of time the biological materials will be kept, how they will be preserved, the location of storage (e.g., in Canada, outside Canada), and the process for disposal, if applicable;
6. Any anticipated linkage of biological materials with information about the participant; and
7. The researchers' plan for handling results and findings, including clinically relevant information and incidental findings.

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Where human biological materials are being donated for future, unspecified uses, the conditions for this donation must be made explicit in the consent form. The consent form must also indicate this donation is optional and specify whether the investigator plans to seek the participant's consent for future projects involving these materials.

GUIDANCE NOTE #3: BIOBANKING STUDIES

Biobanks provide an opportunity to create an ongoing resource for research that avoids duplication of sample collection. However, biobanks may also present privacy and others risks to participants as well their biological relatives and others with shared genetic characteristics.

In accordance with Article 12.5 of the Tri-Council Policy Statement: Ethical Conduct For Research Involving Humans (TCPS 2), researchers intending to establish a biobank must ensure they have appropriate facilities, equipment, policies and procedures to store human biological materials safety, and in accordance with applicable standards. Researchers shall also establish appropriate physical, administrative and technical safeguards to prevent unauthorized handling of the materials and any other information.

3.1 Obtaining Biological Materials from Deceased Persons

In cases where biological materials are obtained from a deceased donors, consent must either be obtained in a prior directive or from an authorized third party

3.2 Mandatory Biobanking

Mandatory biobanking is only permitted if the biological materials are being banked for purposes **directly related** to the study at hand (i.e. the banking must be integral to the study, such that there would be no study if the participant did not contribute the tissue).

It is unethical to *require* that participants agree to allow their tissue to be banked for future use or experimentation that is unspecified or unrelated to the study at hand as a condition for entry into a therapeutic trial, as this could be perceived as a coercive method of obtaining tissue samples through offering a perceived therapeutic opportunity.

GUIDANCE NOTE #4: USE OF PREVIOUSLY COLLECTED BIOLOGICAL MATERIALS AND/OR DATA OBTAINED FROM BIO AND DATA BANKS

Use of biological materials or data that have been previously collected must receive authorization from the custodian of that bank or registry for its use, regardless of whether the materials/data are anonymized or de-identified. Evidence of this authorization must be submitted with the application to the FHREB.

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If the biological materials/data are not anonymized, evidence that consent was obtained at the time of collection for use of these materials/data must also be submitted (or a waiver of consent from the institution's REB). This may include the original signed consent form or an assurance from the investigator that appropriate protections were undertaken to ensure confidentiality and privacy.

GUIDANCE NOTE #5: OPTIONAL SUB-STUDIES

Optional sub-studies involving human biological materials may be submitted to the FHREB with the main study application, or at a later time through an amendment. The details of the sub-study must be provided, either in a sub-section or appendix to the main study protocol.

Optional sub-studies should only be embedded within the main study consent form if the risks and procedures are not substantively different from those in the main study. Otherwise, a separate consent form for optional consents should be used. Examples of optional sub-studies that are appropriate for inclusion in a main consent include additional questionnaires for optional cost-effectiveness studies, or additional collection of blood for purposes other than genetic testing or tissue banking when blood samples are already being taken for the main study.

Separate consent forms should be used for sub-studies that include genetic and DNA testing, tissue and blood banking studies, pharmacokinetic studies, use of individual data, records, or personally identifying information in another study, and analysis of secondary data from linked databases.

The consent form must clearly indicate which procedures are optional and that participation in the main study is not contingent on participation in the optional studies. The section on withdrawal should also explain what will happen to the data collected in optional studies.

5.1 Genetic optional sub-studies

Where sub-studies include testing of genetic materials, such as RNA or DNA, the submission must include details of the plan for addressing reasonably foreseeable material incidental findings that may arise from such testing. Material incidental findings are defined by the TCPS Guidance on How to Address Material Incidental Findings as findings that have:

- Analytical Validity: the researchers have verified the accuracy and precision of the finding
- Potential Significance for the Participant: Findings may significantly affect the participant's welfare, health or otherwise. Such findings may be immediate or in the future.
- Actionability: Sharing findings in a timely manner may allow the participant to initiate an action to remove or help manage the risk their welfare.

The possibility of such reasonably foreseeable incidental findings arising must be detailed in the consent process, and genetic counselling should be made available to participants in such circumstances.