Fraser Health Research Ethics Board
Department of Evaluation and Research Services , FHA
400 – 13450 102 Avenue, Surrey, BC V3T 0H1
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GUIDANCE NOTES ON LEVEL OF REVIEW FOR INITIAL SUBMISSIONS

INTRODUCTION

This guidance note is intended to provide general guidance on how the level of review for initial submissions is determined for research involving humans at Fraser Health.

GUIDANCE NOTE #1: PROPORTIONATE REVIEW

In accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), the level of review assigned to submissions to the Fraser Health Research Ethics Board is determined by the level of risk presented by the research. The level or risk is determined by an assessment of the magnitude and probability of harms presented by the research.

Minimal risk research, defined by the TCPS 2 as "research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research." Research that qualifies as "minimal risk" shall generally receive delegated review. Exceptions to this are detailed in Guidance Note #3.

Studies that are above minimal risk will receive full board review.

The level of review is determined by the FHREB Chair. Any study may be referred to full board review by the Chair for any reason.

GUIDANCE NOTE #2: DELEGATED REVIEW

The research ethics review of studies presenting minimal risk may be delegated to an individual or individuals from among the REB membership. Delegated review occurs on a rolling basis as submissions are received. As such, there is no submission deadline for delegated reviews. Turnaround times for review are variable, depending on the amount of submissions and availability of reviews.

Types of activities/data collection generally qualifying for delegated review include the following:

1. Secondary data collection from medical records, administrative databases, or previously collected diagnostic samples, etc.

2. Interviews or focus groups that do not involve participants made vulnerable in the context of research and/or sensitive subject areas

3. Anonymous surveys

4. Observational (non-interventional/non-experimental) clinical research

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5. Collection of hair, nail clippings, deciduous teeth, excreta, salivary secretions, additional swabs or other external secretions that have been collected in a non-invasive manner and/or collected as part of routine clinical care

6. Collection of placenta or amniotic fluid as a consequence of normal labour and delivery, or fetal tissue collected as a consequence of therapeutic abortion or miscarriage

7. Data recorded using non-invasive procedures routinely employed in clinical practice (e.g., EEG, EKG, ultrasound)

8. Blood samples less than two tablespoons collected by venipuncture or a central line

9. Exercise interventions that align with standard of care recommendations

GUIDANCE NOTE #3: FULL BOARD REVIEW

Full board review is the "default" mode for research submitted to the FHREB. Full board meetings occur on the second Wednesday of every month (with the exception of August). Submissions for full board review are due three weeks prior to the meeting date. Submissions for full board review are added to the meeting agenda on a first come/first served basis. The FHREB reserves the right to limit the number of studies reviewed at one meeting.

Types of activities/data collection generally requiring full board review include the following:

1. Research that has corporate/for-profit sponsorship, or in which a corporate/for-profit entity will have access to raw data

2. Research involving participants incapable of full consent (unless for retrospective chart review or observational data collection only)

3. Research that deviates from standard clinical practices or from normal procurement of tissue/blood

4. Research that involves populations made vulnerable in the context of the research and/or sensitive subject areas (e.g., abuse, suicide, etc.)

5. Research that involves linkage of personal information non-Fraser Health databases/registries (except for linkages to PopDataBC)

6. Research collecting data from MRIs or X-Rays that are not standard of care

7. Research involving a waiver or alteration of normal consent requirements

8. Research whose purpose is to collect tissue/DNA for the purpose of creating or adding to a tissue/DNA bank for genetic research

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9. Research whose purpose is the derivation of stem cell lines from human somatic tissue, umbilical cord or placenta, or research involving the grafting of stem cell lines into humans

10. Research in which the investigators are in a position of power over the participants (e.g., residents and supervisors, students and teachers, etc.)