GUIDANCE NOTES ON SUBMISSION REQUIREMENTS FOR INITIAL ETHICAL REVIEW

INTRODUCTION

This guidance note is intended to provide general guidance on the submission requirements and process for initial ethical review for research involving humans at Fraser Health.

GUIDANCE NOTE #1: WHERE TO SUBMIT

All new applications for clinical, behavioural, and other research involving human participants must be submitted using the applicable application form on the ROMEO Research Platform. Complete submissions, along with all supporting documentation must be sent on the appropriate platform.

For clinical research, including clinical trials, clinical observational studies, clinical research registries, studies involving the review of medical records and/or any invasive procedures, submit the Initial Ethical Review Application for Clinical Studies form.

For research that are socio-behavioural in nature or involve humanities research, including status that involve the administration of surveys or semi-structured interviews, submit the Initial Ethical Review Application for Socio-Behavioural Studies form. Note that socio-behavioural research may involve the study of patients or healthcare providers.

1.1 Multi-Jurisdictional Studies

The FHREB is a partner organization in Research Ethics BC (REBC), which aims to streamline the review process for multi-jurisdictional human health research in BC. Researchers applying for ethics review by the FHREB for multi-jurisdictional studies with other REBC partner organizations must submit their ethics application via the Provincial Research Ethics Platform (PREP) on the UBC RISe system.

GUIDANCE NOTE #2: NECESSARY DOCUMENTS FOR REVIEW

All submissions for initial ethical review must include the following documents submitted as application attachments:

- PI's CV,
- PI Administrative Supervisor's Signature,
- TCPS 2 Core Tutorial completion certificates for all study team members,
- Study protocol/proposal,
- All data collection materials: case report forms, interview guides, questionnaires, tests, patient diaries, etc.,
- All consent/assent forms (as applicable),

- All recruitment materials (as applicable): letters of initial contact, brochures, posters, advertisements, recruitment scripts, etc.,
- Notification of Award Letters for Fraser Health PIs awarded grants to conduct the study,
- Any other documents that have an impact on the safety or ethical conduct of the study should be submitted for review, such as patient instruction pamphlets, etc.

Documents that do not have bearing on the safety or ethical conduct of the study and are not related to the collection of data and/or participant-facing, such as SOPs for case report form completion and master tracking logs, should not be submitted. Such documents will not be reviewed by the REB or listed on the approval certificate.

2.1 Additional Documents for Regulated Clinical Trials

- Health Canada No Objection Letter/Letter of Authorization/Notice of Authorization
- Investigator's Brochure/Product Monograph (as applicable)
- Wallet Cards (as applicable)

Generic trial advertisements for industry sponsored trials that are not used for recruitment at the Fraser Health site should not be submitted, unless accompanied by an explanation of how they will be used for recruitment at the Fraser Health site.

2.2 Qualitative and/or Studies with Emergent Design

Researchers should submit the draft interview/focus group guides and data collection tools for review, along with specification of the plan for finalization/amendment over the course of the study. If the data collection tools alter substantially over the course of the study, the amended tools should be submitted to the REB for amendment approval.

For studies with emergent design, each proposed phase of the study should be described to the extent possible in the protocol, including the data collection methods. If draft data collection tools are not available, specify that they will be submitted for amendment once available.

GUIDANCE NOTE #3: DOCUMENT IDENTIFICATION REQUIREMENTS

All documents submitted to the REB for review should be clearly labelled with the date and version number. E.g., "YYYY-MM-DD Document Title Version #". The document footers should also include the corresponding version number and date.