GUIDANCE NOTES ON PRINCIPAL INVESTIGATOR RESPONSIBILITIES

INTRODUCTION

This guidance note is intended to provide general guidance on who can conduct research at or under the auspices of Fraser Health in the capacity a Principal Investigator (PI), and what are the responsibilities of the PI. The guidance notes are not intended to be a substitute for the original source documents referenced within. Researchers should refer to the original documents for complete information.

GUIDANCE NOTE #1: DEFINITION OF A PRINCIPAL INVESTIGATOR

The Principal Investigator, as defined by the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS 2, 2018), is the person who has overall responsibility for the conduct of the study. This includes the actions of any member of the team, and the development, conduct, analysis, and reporting of the study. The Principal Investigator bears direct responsibility for ensuring the protection of the research participants.

In submitting the Application Form for Initial Ethical Review, the PI attests that the information submitted to the FHREB is complete and accurate and that the research will be conducted in accordance with the Fraser Health Policy on the Ethical Conduct of Research Involving Human Participants, as well as all other applicable laws, regulations, and guidelines.

GUIDANCE NOTE #2: WHO CAN BE A PRINCIPAL INVESTIGATOR AT FRASER HEALTH?

In accordance with the Fraser Health Research Policy, any research conducted in Fraser Health must be have a PI who is directly affiliated with Fraser Health. This includes:

1. Fraser Health employees
2. Physicians with privileges at Fraser Health
3. Non-Fraser Health researchers with academic appointments at their home institution who have signed onto a research affiliation/collaboration agreement with Fraser Health

Students, residents, and non-Fraser Health employees/privileged physicians who do not have an appointment at academic institution are not permitted to serve as Principal Investigator. Such individuals may participate on research teams as co-investigators, collaborators, or study staff.

2.1 Research collaboration agreements for external researchers

Non-Fraser Health researchers who hold academic appointments at an external research institution may apply for research privileges with Fraser Health by submitting their CV, TCPS 2 Core Tutorial Certificate, and brief description of the study to the Research Contracts Coordinator. External researchers who have been granted research

privileges at Fraser Health must also have a Co-Investigator who is a Fraser Health employee/privileged physician on their study team.

2.2 Fraser Health employees/privileged physicians conducting research as students in an academic program

Fraser Health employees/privileged physicians who wish to conduct research as part of an academic program outside of their Fraser Health responsibilities may serve as Principal Investigators if their direct administrative supervisor at Fraser Health signs off on the application to allow the student to conduct the research as part of their duties at Fraser Health, and their academic institution allows them to serve as PI on their academic REB's application.

If permission is not granted to the student to serve as PI, the academic supervisor must sign onto a Research Collaboration Agreement with Fraser Health. The student may serve as the Fraser Health Co-Investigator in this circumstance.

2.3 Fraser Health employees/privileged physicians with secondary clinical or academic appointments

Fraser Health employees/privileged physicians with clinical or academic appointments at other institutions are responsible for determining whether they require ethical approval from the REBs of those institutions. Investigators with secondary clinical or academic appointments should not list those affiliations on the application form or study documents if they do not have REB approval and are not conducting the study under the auspices of those institutions.

2.4 Principal Investigators for clinical trials

In accordance with Health Canada Regulations, the Principal Investigator of a regulated clinical trial must be a physician in good standing of a professional medical association with privileges at the site where the trial will take place. For unregulated clinical trials involving inpatients at Fraser Health, a physician directly involved in the care of the participants must be on the study team.

GUIDANCE NOTE #3: FRASER HEALTH ADMINISTRATIVE SUPERVISOR SIGN-OFF FOR RESEARCH CONDUCTED BY FRASER HEALTH EMPLOYEES OR PRIVILEGED PHYSICIANS

The Principal Investigator's direct Administrative Supervisor at Fraser Health must sign the attestation form located in the Attachments tab of the ROMEO application to attest that the Principal Investigator has the appropriate qualifications, experience, and resources to carry out the research. If the Administrative Supervisor is a member of the study team, then the next Administrative Supervisor must sign the form.

GUIDANCE NOTE #4: PRINCIPAL INVESTIGATOR RESPONSIBILITIES

The Principal Investigator is responsible for the overall ethical conduct of the study, including (but not limited) to the following:

- Ensuring the research adheres to all applicable Fraser Health policies, regulations, standards, and guidelines
- Ensuring that all research team members have the appropriate training and qualifications to carry out the research, including completion of the TCPS 2 Core Tutorial
- Ensuring that all research-related procedures are conducted in compliance with the approved protocol
- Notifying the REB of any proposed changes to the research and/or supporting documents and obtaining REB approval prior to implementation, with the exception of changes necessary to eliminate immediate hazards to participants
- Notifying the REB of any changes to the study funding, research team, and regulatory approvals
- Ensuring the informed consent process, as approved by the REB, is followed, and that consent is voluntarily given by the potential participants, and ensuring ongoing consent throughout the research process
- Ensuring the accuracy, completeness, and legitimacy of all data collected, and the maintenance of appropriate study records
- Ensuring continuing REB review of the study by submitting renewal requests or study-closeout requests prior to the expiry date of the REB approval
- Reporting any unanticipated problems, protocol deviations, serious adverse events, and privacy breaches to the REB in a timely manner
- Notify the REB of any new information that could impact the study or alter the REB's approval of the study

GUIDANCE NOTE #5: CHANGE OF PRINCIPAL INVESTIGATOR

In order to change the Principal Investigator, an amendment requesting a change in Principal Investigator along with other documents that require amending (e.g., consent form, recruitment materials, etc.) must be submitted for FHREB review on the ROMEO Research Platform.

The Change in Principal Investigator Form must list all changes to the study and study documents.

The new Principal Investigator (PI) must complete the event form on ROMEO and obtain the **new PI's Administrative Supervisor's signoff.** This form is required to provide the appropriate contact information for the new Principal Investigator, document the new Principal Investigator's attestation to abide by the TCPS 2, and declare any conflict of interest that may arise from assuming this role.