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MEMO

To: Fraser Health Researchers and Research Personnel

From: Kate Keetch, Director, Department of Evaluation and Research Services

CC: Linda Dempster, Vice President, Patient Experience
Tracy Irwin, Executive Director, Innovation, Research and Transformation
Dr. Greg Haljan, Regional Medical Director Research

Date: March 19, 2020

Re: **Suspension of all non-essential research studies in Fraser Health due to COVID-19**

Effective immediately, Fraser Health is suspending all non-essential research studies in Fraser Health facilities until **April 6, 2020**. During this time, *no Letters of Authorization will be issued and non-essential research procedures must cease.*

Enrollment into clinical trials and clinical research studies that are part of essential clinical care, projects related to the COVID-19 pandemic, or those that have significant cost or time-related implications will be assessed on a case-by-case basis.

We recognize that some ongoing clinical trials and clinical research studies require important safety monitoring and/or on-site visits that are crucial to the participant's clinical care, and therefore encourage investigators to use good judgement and consider the level at which this is appropriate for each ongoing protocol and participant. Investigators conducting clinical trials in Fraser Health facilities should be contacting their sponsors to determine changes to process in light of the COVID-19 pandemic.

Where in-person participant contact cannot be modified, delayed or eliminated, we recommend that study-related personnel call each study participant prior to their visit. Specifically, please ask the participant the following:

- Have they recently travelled outside of Canada?
- Do they have the following symptoms: cough, sneezing, fever, sore throat and difficulty breathing?
- Have they been in close contact with a sick person, especially if they had a fever, cough or difficulty breathing?

If they respond with a "Yes" to any of these questions, please reschedule their study visit.

Fraser Health Authority
Central City

Department of Evaluation and Research Services
Suite400, 13450 102 Avenue
Surrey, BC
V3T 0H1 Canada

Tel (604) 587-4681
Fax (604) 930-5425
www.fraserhealth.ca

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Research Ethics Considerations:

While TCPS 2 typically requires review and approval of modifications prior to implementation, an exception can be made where the change is necessary to eliminate an immediate risk to participant(s) (Article 6.15). Such changes may be implemented but must be reported to the Research Ethics Board (REB) at the earliest opportunity (within 5 business days as a guide). Similarly, studies that must comply with the US federal regulations require that the REB review any revision to the protocol before they are implemented except in cases, "where necessary to eliminate apparent immediate hazards to the human subjects." 21 CFR 56.108(a)(4).

Please contact the Fraser Health REB (FHREB) office for your study whenever possible if you are considering revisions to the approved protocol. The FHREB office will remain open for the foreseeable future. However, should you determine that changes in your procedures are immediately required, you may implement them, without prior notice to or approval from the FHREB. You will need to ensure that you are **not** introducing other risks, and you may need to ask participants to sign revised informed consent forms. The changes should be reported to the FHREB as soon as possible. If a full revised protocol cannot be completed, a document that describes the changes and explains how they will protect participants can be submitted, along with copies of any new or revised participant-facing materials.

Notification to the sponsor of the study where applicable is required. This is the responsibility of the Principal Investigator. Investigators should be mindful of any FDA or Health Canada directives that may be affecting the conduct of specific clinical trials when applicable.

CONTACT INFORMATION

For general questions and concerns:

Kate Keetch,
Director, Department of Evaluation and Research Services
kate.keetch@fraserhealth.ca

For research ethics questions:

Sara O'Shaughnessy,
Research Ethics and Regulatory Specialist
sara.oshaughnessy@fraserhealth.ca

For research contracts questions:

Patrick Altejos
Contracts and Business Development Specialist
patrick.altejos@fraserhealth.ca

For finance and grant administration questions:

Ashley Kwon
Research Development Specialist
ashley.kwon@fraserhealth.ca