FAQs for the Fraser Health Research Community During the COVID-19 Pandemic | 2020 March 31 [V1.0]

Fraser Health is working in partnership with the BC Ministry of Health and the BC Centre for Disease Control to respond to the COVID-19 pandemic. BC declared a public health emergency on March 17, 2020 and a provincial state of emergency on March 18, 2020. We are actively following new directives that will continue to change as the situation evolves.

*Effective March 31, 2020, Fraser Health has SUSPENDED all non-essential research procedures **until further notice**. Fraser Health is focused on reducing risks for research participants and the public, and on proactively ensuring that Fraser Health and health system resources are prioritized and available to fully respond to the public health emergency as it develops.*

This curtailment will be extended as needed and reflects the following key principles:
1. Safety of our research participants, their families and staff.
2. Limit excessive use of resources within Fraser Health, given the increased risks involved with decreased number of staff and increasing demands on our health care system.
3. Minimize the potential spread of COVID-19.
4. Limit adverse impact on the integrity of ongoing clinical trials.
5. Provide guidance as the situation evolves. We will review and advise on any changes on a regular basis.

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GENERAL OFFICE INFORMATION

Is the Fraser Health Department of Evaluation and Research (DERS) still open?
DERS remains open during the COVID-19 pandemic, however, our operations are running remotely offsite to protect our staff and their families. The best method to contact our team is through email at this time.

Is the Fraser Health Research Ethics Office still open?
The Fraser Health Research Ethics Office will remain open and running remotely offsite for the foreseeable future, however, non-essential research submissions will be processed only on a case-by-case basis at this time. Submissions will be prioritized in accordance with the following criteria:

1. Initial ethics new trials related to COVID-19
2. Continuing ethics review of currently approved clinical trials
3. Renewal submissions for non-essential research
4. Amendments to currently approved protocols necessary to address changes related to COVID-19

The Research Ethics Office can be contacted by email at REB@fraserhealth.ca.

RESEARCH ACTIVITIES AND APPROVALS DURING THE COVID-19 PANDEMIC

What research activities are currently permitted?

- Ongoing participant care and follow-up for clinical trials and clinical research studies that are part of essential clinical care. Where possible, in-person procedures should be minimized, and investigators, in conversation with their sponsors, should consider if their research protocols could be modified or delayed, to limit personal contacts, laboratory visits or trips into clinics and hospitals.
- Enrollment into clinical trials and clinical research studies related to the COVID-19 pandemic.
- Data analysis that can be done remotely offsite.
- Participant follow-up that can be conducted remotely offsite by phone or email that does not impact patient care or clinical operations.

NOTE: Research activities that have significant cost or time-related implications will be assessed on a case-by-case basis by the Fraser Health Research Ethics Office.

What research activities are currently suspended?

- All non-essential research procedures.
- Recruitment for new and ongoing clinical trials/clinical research studies.
- All research, including phone interviews and surveys, requiring Fraser Health leadership, clinicians, healthcare works, and/or support staff as participants.

What research approvals are currently suspended?

- Letters of Authorization to Conduct Research (LOAs) at Fraser Health will not be issued for any new submissions other than COVID-19 related research.
- LOAs for currently approved non-essential research are suspended. Exceptions will be made on a case-by-case basis.

CURRENTLY APPROVED RESEARCH

Do I still need to renew my ethics approval if my study is considered non-essential?
Yes. The FHREB will continue to review study renewals and closeouts, and these should be submitted as per usual.

Can I enroll new participants to my clinical trial?
No, recruitment must be halted on clinical trials ***until further notice***.

Is safety monitoring of active clinical trials permitted?
Important safety monitoring and/or on-site visits that are crucial to the participant's clinical care may be required. Investigators are encouraged 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 contact their sponsors to determine changes to process in light of the COVID-19 pandemic.

What questions should I ask my study sponsor?[i]
When speaking with your study sponsor you may require clarification on the following:

- Does the sponsor foresee accrual being stopped for the study?
- Would it be acceptable to ship oral medications directly to the patients? In the case where a central lab is being used, is it acceptable to use a local lab for safety lab results in cases where a patient cannot/should not come into the site?
- Are there any concerns about shipping central lab kits to the sites? Are delays possible?
- For central labs, can the sponsor confirm that the labs are open to accept samples? Has there been any changes to the lab hours, or any operational considerations our site should be aware of?

What if in-person participant contact is necessary?
Where in-person participant contact cannot be modified, delayed or eliminated, and is absolutely necessary for continued participant clinical care, 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, their study visit must be rescheduled.

What if I need to make changes to my research to eliminate immediate risk to participants?
TCPS Article 6.5 provides an exception to the typical requirement to obtain Research Ethics Board (REB) approval of modifications prior to implementation where the change is necessary to eliminate immediate risk to participants.

FDA regulated studies regulations require that FHREB review of 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).*

Changes may be implemented but must be reported to the REB at the earliest opportunity (within 5 business days as a guide).

What if the risk to participants is not immediate?
Wherever possible, please contact the FHREB office at REB@fraserhealth.ca if you are considering revisions to the FHREB approved protocol prior to implementation when there is not an immediate risk to participants.

What should I consider before implementing modifications to eliminate risk?
You must ensure that modifications do **not** introduce new risks and should consider how to provide and obtain revised participant informed consent, including documentation of consent.

How do I report study changes related to COVID-19 to the FHREB?
Any Post-Approval Activities (PAAs) or e-mails sent to the REB that relate to COVID-19 must be named accordingly so that they can be more easily tracked and actioned. For example, the e-mail subject line should include "COVID-19." In all cases, accurate and detailed documentation of the circumstances surrounding any alterations or amendments is extremely important.

Should I contact the study sponsors to notify them of modifications in response to the COVID-19 pandemic?
Yes. Notification to the sponsor of study modifications 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.

What about protocol deviations in relation to COVID-19?
We expect that there will be an increase in protocol deviations; please ensure they are well documented, to enable appropriate evaluation for the trial. Only protocol deviations that expose participants to increased risk, compromise the integrity of the study, alter participant eligibility, and/or affect the privacy of the participants are required to be reported to the FHREB. Protocol deviations that are repetitive in nature due to COVID-19, but do not meet the above criteria, do not require submission to the FHREB.

Do protocol deviations need to be reported to Health Canada?
Clinical trial sites should have a system in place to identify, document, assess, and report all protocol deviations to the sponsor and REB in accordance with sponsor and REB requirements. These deviations need to be documented, to facilitate future analysis of the study findings. The sponsor should define and identify the protocol deviations to be reported. Unless

the deviations may place participants at risk, sponsors will not be required to report these deviations to Health Canada.[ii]

Should temporary study halts be reported to the FHREB?
The majority of temporary halts will not need to be submitted to the FHREB as a substantial amendment and we will provide further guidance on this.

How should I obtain wet signatures typically required for research procedures?
If your processes require wet-ink signatures, consider alternative methods of demonstrating approvals, such as email confirmation. You may want to consider an SOP deviation to cover this change.

ACADEMIC RESEARCH

Can multi-jurisdictional academic research continue?
At this time Fraser Health is not permitting non-essential research involving Fraser Health sites, patients, staff, and/or resources. If you are working on an academic study where research activities are occurring at other sites, it is important to directly consult the academic institution(s) where research is occurring.

Most institutions have information related to research activities during the COVID-19 pandemic posted on their websites.

For Research Ethics BC (REBC) partner institutions, please check the REBC website for regular updates and resources regarding research during a public health emergency. Up-to-date information and guidance from partner institutions regarding research operations during the COVID-19 pandemic is centrally compiled and maintained by REBC here.

REMOTE RESEARCH ACTIVITIES

Can I work on research projects from home?
Yes, research activities that can be conducted remotely and safely without in-person contact can continue. Examples of this research work include manuscript preparation, literature reviews, data analysis, and funding applications.

On-line access to databases housed in Fraser Health servers and library materials will be maintained.

Remote work must be conducted in compliance with Fraser Health privacy policy and information security standards.

GRANT FUNDING AND FINANCIAL ADMINISTRATION

Can I continue to submit applications for new funding opportunities?
Yes, preparation of new funding applications can continue. Please note that several funding organizations have delayed application deadlines. Contact the organizations directly to confirm updated deadlines.

Can I submit financial documents for payment (e.g., Employee Expense Reimbursements, invoices, Requests for Payment, etc.)?
Yes, submission of financial documents can continue, although there is a possibility of a delay with processing. If you are planning to submit any research-related financial documents to DERS by mail, please notify ashley.kwon@fraserhealth.ca to discuss potential electronic options.

Resources for Researchers

Fraser Health Department of Evaluation and Research Services Resources:

- **Fraser Health Clinical Research Start-Up Toolkit**
- **Fraser Health Funding Opportunities for Your Research**
- **Fraser Health Research Ethics and Other Approvals**

External Resources:

- **Clinical Trials BC** has important information and updates on their website for clinical researchers. Consultation services are also available at this time for clinical trial management during a public health emergency.
- **Research Ethics BC** maintains updated information from partner institutions across BC regarding Research Ethics Office operations during the COVID-19 pandemic.

NOTE: Please ensure you have consulted guidance from your home Research Ethics Board as home institution guidance will take precedence over more general advice provided by REBC and other centralized bodies.

Contact Information

For general questions and concerns:

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For research ethics questions:

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[i] Adapted from the University Health Network https://research.utoronto.ca/covid-19

[ii] https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/management-clinical-trials-during-covid-19-pandemic.html