FAQs for the Fraser Health Research Community During the COVID-19 Pandemic Phase 2 | 2020 June 16 [V2.1]

Fraser Health is working in partnership with the British Columbia (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 and a provincial state of emergency on March 18. On May 19 BC transitioned from Phase 1 to Phase 2 of its Restart Plan. We are updating our research community on how their research may be impacted by Phase 2. We will continue to actively follow new directives and revise research guidances as the situation evolves.

Effective June 12, 2020, Fraser Health will PARTIALLY RESUME non-essential research procedures as per the guidances contained within this document ***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.*

Our resumption process will be extended or retracted as needed and reflects the following key principles:
1. Ensure the safety of research participants, their families, staff, and research personnel
2. Confirm that research studies have plans to minimize the potential spread of COVID-19[1][2]
3. Reduce the risks of delays in resumptions of non-COVID-19 research
4. Limit adverse impact on the integrity of ongoing research studies
5. Continue to monitor the COVID-19 pandemic and provide updated guidance as the situation evolves

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THANK YOU TO OUR RESEARCH COMMUNITY

The Fraser Health Department of Evaluation and Research Services (DERS) would like to extend our appreciation and gratitude to our research community for their support, patience, and perseverance while we diverted our resources and attention to essential COVID-19 research. We recognize the sacrifices you have made to support us during this time. We ask kindly for your continued understanding as we navigate Phase 2 and experience heavy volumes as we work to get impacted research studies safely up and running again at Fraser Health.

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[1] WorkSafe BC COVID-19 and returning to safe operation - Phase 2
[2] WorkSafe BC Health Care and COVID-19 Safety

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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 continue to operate remotely offsite for the foreseeable future. Non-essential research submissions will be processed on a case-by-case basis in accordance with Research Ethics Office resources and capacity.

Submissions will be prioritized in accordance with the following criteria:

1. Initial ethics review of new clinical trials related to COVID-19
2. Initial ethics review of new clinical research related to COVID-19
3. Continuing ethics review of currently approved clinical trials
4. Renewal submissions
5. Amendments to currently approved protocols necessary to address changes related to COVID-19
6. Continuing ethics review of approved non-essential research
7. All other submissions will be processed as expeditiously as possible

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

RESEARCH ACTIVITIES AND APPROVALS DURING PHASE 2 OF THE COVID-19 PANDEMIC

An important note to COVID-19 researchers:
Fraser Health highly recommends that COVID-19 clinical research (e.g., clinical trials, registries, biobanks) be submitted to the COVID-19 Clinical Research Coordination Initiative (CRCI) for review. Additional details regarding the CRCI initiative is found here.

How do I apply to resume or initiate research activities suspended due to COVID-19?
Fraser Health suspended all non-essential research in Phase 1 at the *Institutional Level*. Research studies permitted to operate or granted an exemption during Phase 1 **do not** need to apply for institutional approval to resume research activities.

To apply for approval to resume research activities at Fraser Health sites, the research team must follow the following steps:

1. Develop a COVID-19 research safety plan
2. Obtain pre-approval from relevant Fraser Health Site Director(s)/Department Head(s)
3. Download and complete the *Institutional Application to Conduct Research During the COVID-19 Pandemic* form. This form may be submitted as follows:
    a. Fraser Health studies – REB@fraserhealth.ca
    b. Harmonized studies – sarah.flann@fraserhealth.ca

What should my COVID-19 research safety plan include?
COVID-19 research safety plans will vary depending on study type. Fraser Health Infection Control 2019 Coronavirus Updates (2019-nCoV) and WorkSafe BC should be reviewed for site-specific safety guidances.

Some general safety considerations include:

1. Research must not introduce additional risk of COVID-19 transmission to staff, patients or families who are working in, or receiving services at Fraser Health.
2. All activities that can be performed remotely must continue to do so.
3. If a researcher or research team member must come to work, they need to assess their own health using the daily self-screening assessment tool or other applicable screening checklist. If a researcher or research team member is experiencing any COVID-19 symptoms, they should inform their supervisor and not come to work.
4. Researchers and research staff must maintain a distance of two meters between persons at all times, must comply with the maximum occupancy of each office or open workstation, and disinfect shared workspaces, as per their approved research program/unit safety plan.
5. Researchers, research team members and research participants must follow the Fraser Health Essential Visitor guidelines while on site. Sponsor/industry representatives are not currently considered “essential visitors” and are not permitted on site at this time without operational approval.
6. As part of the safety plan, research participants must be pre-screened for COVID-19 exposure and symptoms, as per Fraser Health guidelines, prior to attending Fraser

Health facilities for procedures or tests. Alternatively, where possible, amendments to the original study application should be made to conduct remote/virtual visits.

Do I need to submit an updated research ethics amendment?
The Fraser Health Research Ethics Board (FHREB) **did not** suspend ethical approvals during Phase 1. A research ethics post-approval submission is not required unless any of the following apply:

1. The study must change its research protocols or procedures to conform to public health, institutional, and/or departmental COVID-19 safety requirements
2. The study is harmonized with another REBC[3] institution where the external institution requires a Post-Approval Activity (PAA) be submitted in UBC RISe to resume research activities
3. A COVID-19 aim is being added to the currently FHREB approved study protocol

How do I report study changes related to COVID-19 to the FHREB?
Any PAA or emails sent to the FHREB that relate to COVID-19 must be named accordingly so that they can be more easily tracked and actioned. For example, the email 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 FHREB in accordance with sponsor and FHREB 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

[3] 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.

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

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. Regulated clinical trials should notify the FHREB in an acknowledgment request.

What if I do not plan to resume research activities at this time? Do I still need to renew my ethics approval if my study is not currently operating due to COVID-19?
Yes. The FHREB will continue to review study renewals and closeouts, and these should be submitted as per usual.

REMOTE RESEARCH ACTIVITIES

Can I work on research projects from home?
Yes. All research activities that can be conducted remotely must continue to do so. Examples of this include remote/virtual research sessions, literature reviews, data analysis and funding applications.

Online 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.

RESEARCH CONTRACTS AND AGREEMENTS

Are research contracts still being reviewed?
Yes. Research contract reviews will be prioritized in accordance with the following criteria:

1. COVID19-related research. Research related to COVID-19 are still the highest focus for contract review.
2. Research that are permitted to operate or granted an exemption during Phase 1. Please refer to ***How do I apply to resume research activities suspended due to COVID-19?*** (page 3 of this document)
3. Review of research contracts that were in active negotiations with the research sponsors prior to the start of Phase 1 restrictions can continue, provided that the turnaround for reviews may experience some delays due to COVID-19-related clinical trial contracts being the highest focus for review.
4. Research contracts for clinical trials that have not received FHREB# will not be reviewed.

NOTE:

- IF you are conducting a Research Registry requiring a contracts, the contract and data access agreement (DAA) will be reviewed by the Fraser Health Privacy Office prior to execution
- Sponsors must provide a draft contract for review to DERS. DERS will not draft a contract for sponsors.

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 or postponed or cancelled competitions. 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. Since DERS staff continue to work remotely, failure to provide an email notification of documents sent by mail may lead to a significant delay in processing.

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