FAQs for the Fraser Health Research Community During the COVID-19 Pandemic Phase 3 | 2020 December 01 [V3.0]

Fraser Health is working in partnership with the British Columbia (BC) Ministry of Health and the BC Centre for Disease Control (BCCDC) to respond to the COVID-19 pandemic. Fraser Health is focused on reducing risks for research participants, personnel, 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. Research that is delivering a direct and timely benefit to participants will continue to be prioritized.

Effective June 12, 2020, Fraser Health PARTIALLY RESUMED non-essential research procedures previously halted due to COVID-19. During the pandemic, research may proceed as per the guidance contained within this document ***until further notice****.*

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]
3. Reduce the risks of delays in resumptions/initiation 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

Researchers are expected to remain appraised of and abide by Public Health Orders at all times.

THANK YOU TO OUR RESEARCH COMMUINTY

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 3. We continue to experience heavy volumes as we work to get impacted research studies safely up and running at Fraser Health.

[1] 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 with limited onsite personnel. Most of our team members are working virtually offsite to comply with Public Health Orders for physical distancing. 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 virtually 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 ethical review of new clinical research related to COVID-19
2. Continuing ethical review of currently approved clinical trials
3. Renewal submissions
4. Amendments to currently approved protocols necessary to address changes related to COVID-19
5. 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 3 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 find out if Fraser Health service providers can accommodate my COVID-19 clinical research?
If your COVID-19 clinical study requires services from Fraser Health pharmacy, laboratory, pathology, or another service provider, the feasibility of operating your study at Fraser Health sites will need to be assessed. Please submit your study proposal to the Fraser Health Research and Evaluation COVID-19 Committee (RECC). Requests can be submitted to the RECC by contacting Research.Approvals@fraserhealth.ca

How do I apply to initiate new research or resume research procedures 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.

ALL suspended and new research activities must apply for COVID-19 Pandemic Research Approval. To apply, complete 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 guidance.

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 virtually 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 BC COVID-19 Self-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 virtual visits.

Other considerations;

1. If your research involves Indigenous participants or communities, you are advised to review this guidance for working with First Nations before finalizing your research logistics.
2. To ensure that studies focus on patient-identified priorities, researchers and research teams members are encouraged to adopt a patient-oriented research approach as outlined in the Canadian Institutes of Health Research (CIHRI)'s Strategy for Patient-Oriented Research (SPOR). See more information on Fraser Centre in the resources section below.
3. To ensure all individuals are included and represented in a more equitable manner, you are advised to utilize the BCCDC Language Guide. This language guide aims to make COVID-19 content more inclusive and prevent stigmatization of individuals and groups who are often inadvertently excluded from health advice.

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. However, a research ethics post-approval submission may be required if 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[2] 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

[2] 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.

How will the FHREB evaluate pre-and-post approval submissions during the COVID-19 pandemic?

All research teams must familiarize themselves with TCPS 2 interpretations related to the COVID-19 publicly declared emergency. New pre-and-post approval submissions to the FHREB will be assessed in relation to the following:

1. What additional risks can be considered research-attributable during the COVID-19 pandemic?
    a. New risks arising from changes to research plan for interacting with participants
    b. New risks that emerge, even if the research plan remains unchanged
    c. Changes in risk levels arising from changes to the participants' personal circumstances
2. Have the COVID-19 research-attributable risks been adequately addressed and communicated to research participants?
3. Is the REB satisfied that the research can proceed during the pandemic? The onus is on the researcher to provide justification that the research can proceed. Considerations include:
    a. Impact on Study Conduct and its Scientific Validity
    b. Impact on Risks and Benefits of Research
    c. Impact on the Consent Process
    d. Other Ethical Issues

How does COVID-19 impact study risks – in-person research[3]?

Where in-person interactions are being proposed, researchers need to consider whether their study participants need to be advised of any potential increased risks that they may be exposed to due to COVID-19. Some possible incremental research related risks may include:

- Risks associated with travel (e.g. public transit)
- Increased time within a health care facility
- Increased exposure to other patients, participants or people
- Increased risks in cases where the study intervention may heighten COVID-19 risks (e.g. studies using immunosuppressants)

Note: Resumption of in-person research will not necessarily always increase participant risk. Whether it does or not will depend upon the context of the study and the judgement of the Principal Investigator.

How does COVID-19 impact study risks – virtual research?

For example, if in-person follow-up moves to virtual follow-up, participants must be informed of confidentiality and security considerations and provided an opportunity to reaffirm or revoke their ongoing consent.

[3] UBC CREB Guidance during COVID-19

Will current participants need to re-consent?
TCPS 2 (2018), Article 3.3 states that consent shall be an ongoing process. Re-consent is required if changes to research procedures impact study risks and potential benefits. There may also be research-attributable risks to participants due to participating in research procedures in the COVID-19 environment that require re-consent.

How should changes to risks be communicated to research participants[4]?
If new risk information related to COVID-19 is necessary in the context of a specific research study, the information related to the new or incrementally increased risk, may be communicated to research participants in written or oral form. A written consent form addendum or discussion script, may be used to communicate COVID-related risk information to already enrolled participants. This should highlight the new information, reference the original consent and provide the participant with the choice of either continuing in the study or to withdraw.

Where ongoing consent is obtained orally, the process must be documented in the study log. In cases where it is necessary to obtain written ongoing consent (e.g. if a Sponsor requires that such changes be in writing) an addendum may be developed. In either case, it is not necessary to submit a separate post-approval activity to the FHREB. This information should however, be conveyed to the applicable REB at the time of the next annual renewal, or next study amendment, as applicable.

If re-consent is required, please submit a PAA to amend the currently approved participant information consent form(s) (ICF) or an addendum to the ICF.

Can consent be obtained electronically?
TCPS 2 (2018) Article 3.12 requires evidence of consent be documented. The extent to which electronic consent may be used depends on the type of study. Written consent in a signed statement is mandatory in some cases such as in the Health Canada's *Food and Drugs Act.* Health Canada may waive this requirement but this is considered on an individual case basis, negotiated between the Investigator/Sponsor and Health Canada. For more detailed guidance, please consult the following resources:

Guidance Notes and Regulatory Requirements for Informed Consent in Research During a Pandemic: COVID-19 by Clinical Trials BC, Fraser Health, and Research Ethics BC
UBC Clinical Research Ethics Board Guidance Note on Electronic Consent

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.

[4] UBC CREB Guidance during COVID-19

My study is regulated by Health Canada, are there COVID-19 specific orders?
Yes, researchers should consult the Health Canada Interim Order respecting clinical trials for medical devices and drugs relating to COVID-19 and determine how this impacts the conduct of their trial.

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.

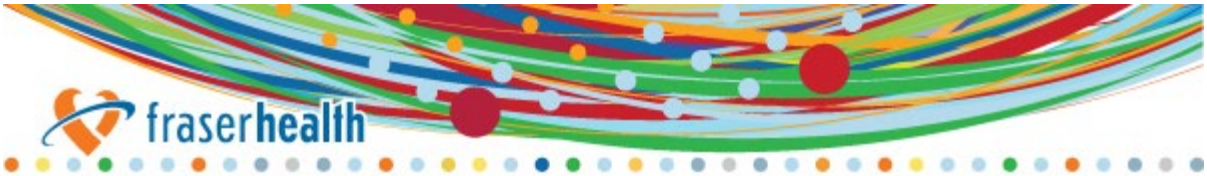
What about protocol deviations in relation to COVID-19?
We expect that there will be an increase in protocol deviations; please ensure they are well documented, to enable appropriate evaluation for the trial. Only protocol deviations that expose participants to increased risk, compromise the integrity 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 the deviations may place participants at risk, sponsors will not be required to report these deviations to Health Canada.[5]

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.

[5] Health Canada Management of clinical trials during the COVID-19 pandemic: Notice to clinical trial sponsors



VIRTUAL RESEARCH ACTIVITIES

Can I work on research projects from home?

Yes. All research activities that can be conducted virtually must continue to do so. Examples of this include virtual research sessions, literature reviews, data analysis, study planning, grant writing, and funding applications may proceed

Online access to databases housed in Fraser Health servers and library materials will be maintained.

Virtual work must be conducted in compliance with Fraser Health Privacy Policy and Information Security Standards.

What information is required to conduct research sessions virtually?

Please review the Fraser Health Guidance for Researchers using Virtual Tools and Teleconferencing Options for extensive details on privacy, security, and informed consent requirements.

RESEARCH CONTRACTS AND AGREEMENTS

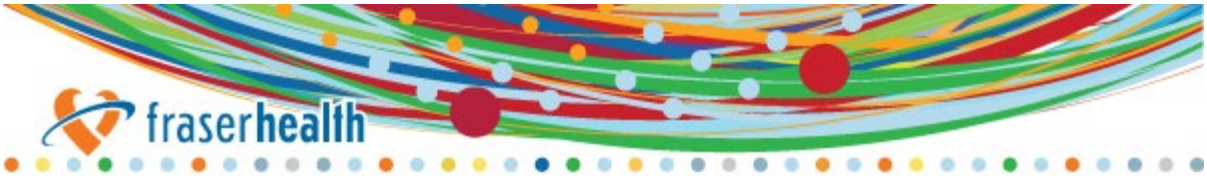
Are research contracts still being reviewed?

Yes. Research contract reviews will be prioritized in accordance with the following criteria:

1. COVID19-related research. Research related to COVID-19 are the highest focus for contract review.
2. Research that are granted an exemption as per the ***RESEARCH ACTIVITIES AND APPROVALS DURING PHASE 3 OF THE COVID-19 PANDEMIC*** section.
3. Review of non-COVID19-related research contracts will be reviewed as expeditiously as possible. However, there may be delays due to volume of new submissions and priority COVID-19-related clinical trial contract reviews.
4. Research contracts for clinical trials that have not received FHREB# will not be reviewed. If your study is harmonized, please provide the UBC H#.

NOTE:

- IF you are conducting a Research Registry requiring a contract, the contract and data access agreement (DAA) will be reviewed by the Fraser Health Research Privacy Advisor and Privacy Office prior to execution. For more information, please contact Dean Simmons (dean.simmons@fraserhealth.ca)
- 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 virtually, 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**
- **BC SUPPORT Unit Fraser Centre**

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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