FAQs for the Fraser Health Research Community During the COVID-19 Pandemic Wave 4 | 2021 October 26 [V4.0]

Following the Public Health Order issued July 7, 2021, Fraser Health has eased COVID-19 restrictions related to the conduct of research in the health authority and under health authority auspices.

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 apprised of and abide by Public Health Orders at all times.

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 Wave 4. 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. Many of our team members are working virtually off-site. 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 off-site for the foreseeable future. Review of research studies has resumed as per standard operating procedures. All submissions are reviewed as expeditiously as possible; however, we continue to face heavy submission volumes.

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

VACCINATION REQUIREMENTS FOR RESEARCHERS

In accordance with the public health order issued October 21, 2021, **everyone on-site at Fraser Health facilities is required to be fully vaccinated. This requirement applies to all research staff and investigators, as well as study monitors where applicable.**
Research personnel may be asked to produce their BC Vaccine Card and photo identification before entry into facilities. The Department of Evaluation and Research Services may conduct audits of research teams to ensure compliance with the vaccine requirements of the research

team and verify vaccination status. The Principal Investigator is responsible for ensuring their research teams are compliant with this requirement. Non-compliance may result in revocation of the Letter of Authorization to Conduct Research.

Principal Investigators will be required to submit a Declaration of COVID-19 Safety as part of their application for a Letter of Authorization. Studies currently underway or which have been provided an exemption/initiation approval already are not required to submit this declaration. However, these studies are required to comply with all vaccine and COVID-19 safety requirements as described in this document and in public health orders, and non-compliance may result in revocation of the Letter of Authorization to Conduct Research.

RESEARCH ACTIVITIES AND APPROVALS DURING WAVE 4 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, and 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 in the hospital, you must verify that these facilities are able to perform the activities as per the approved protocol. The study protocol must be fully assessed for operational feasibility prior to the start of the study. If applicable, add copies of signed Fraser Health DAR form to the study records. Email research.approvals@fraserhealth.ca to receive guidance about this process and/or to confirm that the feasibility assessment has been completed.

Am I required to submit a request to initiate new research or resume research procedures suspended due to COVID-19?
As of October 26, 2021, COVID-19 resumption/initiation applications are no longer required. However, all Principal Investigators must submit a COVID-19 Safety Declaration as part of the Application to Initiate a Project Record on the Fraser Health ROMEO Research Portal. In cases where physical access to Fraser Health clinical sites and/or participants is requested, submission of a COVID-19 safety plan may be required. Studies that meet the following conditions are not required to submit COVID-19 safety plans:

1. Studies that are conducted entirely virtually/remotely
2. Chart reviews and secondary data studies that involve no direct, in-person interaction with participants
3. Clinical trials conducted by Fraser Health clinicians

All other studies will be required to submit a modified COVID-19 Safety Plan.

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. Researchers must continue to use virtual methods for research activities wherever possible and feasible.
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 at the required intervals or frequency specified by Fraser Health guidance (currently twice per shift). 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, and use masks and PPE as appropriate. Research teams must follow their research safety plan and/or the policies and procedures of the site/unit in which the research occurs.
5. Research team members and research participants must follow the Guideline for Visitation in Acute Care while on site, including any provisions pertaining to masking and vaccination status.
6. In compliance with Public Health Orders, all research staff (whether FH employees, or external contracted research personnel, and trainees) must be fully vaccinated against COVID-19. Declarations to this effect will be required as part of the Application to Initiate a Project Record ROMEO form. Responsibility for ensuring compliance will rest with the Principal Investigator.

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 CIHR's Strategy for Patient-Oriented Research (SPOR). See more information about the BC SUPPORT Unit Fraser Centre here.
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?
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

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 any changes to the research plan
    b. New risks that may reasonably be anticipated, even if the research plan remains unchanged
2. Have the COVID-19 research-attributable risks (if any) been adequately addressed and communicated to research participants?
3. Is the REB satisfied that benefits of the research continue to outweigh the risks and that the research continues to meet the criteria for approval? 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 informed 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 should be advised of any potential risks of COVID-19 transmission resulting from the study procedures. 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 immune modulating agents)

Note: Resumption of in-person research will not necessarily increase participant risk.

[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.

[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 these changes to risks in the informed consent process be communicated[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 instead be conveyed to the FHREB 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 informed 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 #2 respecting clinical trials for medical devices and drugs relating to COVID-19 and determine how this impacts the conduct of their study.

If you are a clinician conducting an investigator-initiated clinical trial related to COVID-19 drug, Health Canada has issued specific requirements that applies to you as the study sponsor including how to report adverse events and how to protect patient safety and ensure data integrity. You can view the Health Canada guidelines here.

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 affect the conduct of specific clinical trials when applicable.

What about protocol deviations in relation to COVID-19?
We continue to see an increase in COVID-related protocol deviations; please ensure they are well documented to enable appropriate and efficient evaluation. Only protocol deviations that expose participants to increased risk, compromise the integrity of the study, alter participant eligibility, and/or significantly affect the privacy of 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.[5i] Consult Health Canada for more information.

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

Study Monitoring:
If on-site study monitoring visits are required, contact patrick.altejos@fraserhealth.ca to ensure compliance with current public health orders and Fraser Health requirements for vaccination and site access.

VIRTUAL RESEARCH ACTIVITIES

Can I work on research projects from home?
Yes. All research activities that can be conducted virtually should 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:

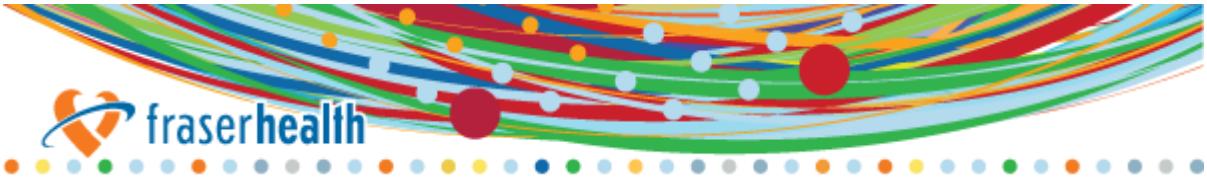
1. COVID19-related research. Research related to COVID-19 are the highest focus for contract review.
2. Review of non-COVID19-related research contracts will be reviewed as expeditiously as possible. However, there may be delays due to volume of new submissions and priority COVID-19-related clinical trial contract reviews.
3. Research contracts for clinical trials that have not received FHREB# will not be reviewed.

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 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 some funding organizations continue to experience disruptions and/or delays in their funding 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 adriel.orena@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

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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