Regional Office of Research Services

Research procedures during the COVID-19 pandemic

(Last revision: April 7, 2020)

This document is a living document and it will be updated as the situation evolves. Please consult the following sites for the most recent updates:

Government of New Brunswick - Coronavirus

Vitalité Health Network

Procedures for ongoing research projects (actively recruiting or active but not recruiting)

Subsequent to the proclamation of a **state of health emergency** by the government of New Brunswick (March 19, 2020), the Vitalité Health Network's Regional Office of Research Services asks all research teams to follow the following procedures**:**

- Cease all direct contact with research participants, unless there are risks for the safety of participants (example: if the study is providing a treatment to the participant).
    - Substitute in-person visits for remote visits during the pandemic as stated in the memo of March 23, 2020.
- Assess the risks of your research protocols (in consultation with your sponsor), and consider other solutions for follow-up assessments that reduce or eliminate the need for direct contact (example: telephone or virtual meeting on specific platforms; postal distribution of study medications).
    - **Special vulnerabilities**: potential participants and individuals who are not normally considered to be vulnerable may become so during this state of health emergency, and those who are already considered to be vulnerable may become even more so.
    - **Projects by medical students and residents**: Students are encouraged to continue their projects, however, in-person contact with the patient is not authorized. If you need help to modify an existing protocol, please contact the Regional Office of Research Services or your assigned research coordinator.
    - **Funded studies**: If any of your research projects have received funding with activity reports due relatively soon, you are advised to contact the funding agency and discuss how your study may be affected by the current pandemic and/or if an extension is permitted**.**
- If you have to submit a notice, an amendment or a deviation from the research protocol or other procedures related to the project, submit these documents to the REB as soon as possible for delegated review. Indicate clearly that these requests are being submitted because of the COVID-19 pandemic.
    - Also attach any correspondence from the sponsor concerning changes to procedures for visits.
    - Any approvals from the REB for modifications related to the pandemic will be valid only during the pandemic. When the state of health emergency is lifted and there is no more identified risk, research activities are to continue as indicated in the research protocol approved by the REB. If any modifications extend after the state of health emergency, a protocol modification shall be submitted to the REB for approval.
- Any other application not related to the pandemic should be processed and submitted to the REB following the usual procedures and timelines.

- Ethics approval obtained during this period for projects not related to COVID-19 does not guarantee that the researchers will be able to carry out their research as planned during the pandemic. During this period and as mentioned in this document, it is important to follow the procedures implemented by the Regional Office of Research Services.

Work off-site / no in-person contact with participants

- **Accessibility:** Please note that access to patients' data or files may be significantly restricted during this period**.**

- **Storage of secured data:** Encrypted USB keys or encrypted password-protected Vitalité Health Network laptops are the only data storage media permitted for research data.

Data collection by members of the Regional Office of Research Services

Efforts will be maintained to collect data from the research projects under way. Because of the pandemic, collection processes under way may be slowed down or stopped to prioritize collecting data supporting a research activity related to COVID-19.

New study activations / recruitment of new participants / follow-up visits

Please consider the fact that activation of a new study will very probably be delayed, unless it is part of an accelerated study into COVID-19. If a sponsor has questions or concerns about this directive, please contact the Regional Office of Research Services.

- For interventional studies, recruitment may be slowed down (in agreement with the sponsor and the principal researcher), if it is safe to maintain it.

    - In order to minimize participant visits, medication used in the study shall, if possible, be mailed directly to the patient, following the recommendations of the sponsor. To the extent possible, follow-up visits shall be via telephone.

- For non-interventional studies, recruitment of new participants is suspended until further notice.

    - This does not apply to retrospective studies that use existing data sources (that is, no patient contact).

Utilization of the Network's professional services as part of a research project

Some research projects require the use of the pharmacy, diagnostic imaging, laboratory medicine and other services to carry out an intervention as indicated in the study protocol. However, access to these services may be restricted or put on hold during the COVID-19 pandemic. Please review your protocols and the status of current participants in the study to see whether any elements in the study are affected by the temporary elimination or reduction of these services. Contact the Regional Office of Research Services if you have any questions about the activities of your study and how they may be affected.

- The notice in the COVID-19 bulletin (no. 2 • March 19, 2020) indicates that all nonessential professional services are suspended in Vitalité Health Network. For a detailed list of the non-emergency services affected, visit the Vitalité Health Network's website.

Recommendations for new research project submissions

Prioritization of new submissions

The members of the Regional Office of Research Services will continue to assess applications for new research projects until advised otherwise by leadership. However, the staff of the Regional Office of Research Services may be deployed elsewhere to maintain essential operations during the COVID-19 pandemic. For that reason, staff may not be able to assess new applications and help to get them launched.

Moreover, during this period the following applications will have priority:

- Any project related to research on the novel coronavirus (COVID-19);
- Any modifications to active study protocols because of COVID-19 (example: deviations from the protocol).

Once these requests have been assessed, we will examine non COVID-19 projects (that is, clinical trials and non-interventional research projects).

If you have any questions concerning these recommendations, please contact the Vitalité Health Network's Regional Office of Research Services or Ethics Office.

*Inspired by the Horizon Health Network document *Guidance Document for Research during COVID-19 Pandemic*.