Rapid Ethics Review Process for Provincial Clinical Studies Pertaining to COVID-19

Are you planning to conduct a clinical research study pertaining to COVID-19 in BC?

The clinical Research Ethics Board (REBs) from across the province have agreed to a rapid ethical review process for provincial clinical studies about COVID-19.

What studies are eligible for this Rapid Review process?

We are focusing on ensuring that clinical studies that are intended or have the potential to be implemented in multiple locations across the province are approved as quickly as possible, and without duplication of research ethics reviews.

What is a clinical study?

Clinical research has the goal of improving the diagnosis, and treatment (including rehabilitation and palliation), of disease and injury; improving the health and quality of life of individuals as they pass through normal life stages. Clinical research usually encompasses research on, or for the treatment of, patients. (Canadian Institutes of Health Research)

How does this apply to Health Canada regulated sponsored clinical trials?

Clinical trials that have Qualified Investigators at each ‘site’ can still benefit from the rapid review process. Research Ethics BC will work with the REBs in the province to facilitate a ‘provincial’ level approval of the protocol and informed consent forms (ICFs), helping other sites in BC to quickly obtain ethical approval for their site.

What if I have not identified collaborators yet at all the institutions?

During the COVID-19 crisis, you can start your research ethics application for one or more institutions, identifying the known collaborators, and add more later. The REBs will include all institutions if the study is intended or has the potential of being provincial in scope, allowing for initial ethical review and approval for the sites where you are ready to start the study. When collaborators are identified for other sites, the Principal Investigator for the study will need to submit an amendment to add their names to the research ethics application.

What if I only want to conduct the study at one or two locations?

Please ensure you are clear of your intentions for the research when you submit the research ethics application. The research will still receive a rapid review, but it will not include all institutions in the
province. If you change your mind later, other collaborators can be added at that time by amendment. Rapid ethical review for local considerations by the new institutions added will still be applicable.

**What are my responsibilities in this process?**

Ensure you have considered the applicability of your research for patients across the province.

Use the RISe application to submit your research study if it involves patients or data from more than one of the institutions listed here:

- Fraser Health
- Interior Health
- Island Health
- Northern Health
- Vancouver Coastal Health
- Providence Health Care
- BC Cancer
- Children’s and Women’s Health Centre of BC

If you have not used RISe before, please contact us and we will help you get started.

Connect with the proposed institutions for your research as soon as possible, and prior to ethical review being completed where possible. We have included a list of contacts for the Research Ethics BC network of institutions on our website at: [https://researchethicsbc.ca/rapid-review-process/](https://researchethicsbc.ca/rapid-review-process/)

**What can I expect from the REB?**

The REB that conducts the provincial initial review will do so within five working days from receipt. You will deal with only one REB for the process, and they will ensure other institutions will be notified of the ethics review process.

**Are there any fees involved?**

Fees for ethical review are only required for for-profit sponsored clinical trials. Where multiple sites will be activated in the province, REBC will work with the sponsor to arrange fee payment to the institutions involved.

**Does this mean that I can start my study at all locations right away?**

You may only start your study when you have received institutional approval/operational approval in addition to the ethics approval. This process can vary by institution, so we recommend you contact the institution as soon as you know you wish to conduct research there. Key contacts can be found on our website at: [https://researchethicsbc.ca/rapid-review-process/](https://researchethicsbc.ca/rapid-review-process/)

**Where can I get more information?**

On our website at: [https://researchethicsbc.ca/rapid-review-process/](https://researchethicsbc.ca/rapid-review-process/) and by email to pvidal@bcahsn.ca or tfleming@bcahsn.ca. At this very busy time, we encourage you to contact us directly rather than your local REB as we may be able to respond quicker due to REB workloads.