

1. What is the Research Approvals Processes Project (RAPP)?

RAPP is a Ministry of Health-led initiative working with British Columbia's health authorities to streamline the approval processes for health research projects taking place within multiple health authorities. The research processes covered by RAPP include those for <u>ethics reviews</u>, <u>privacy</u>, <u>data access</u>, <u>contracts</u>, <u>and operational approvals</u>.

2. What are the objectives of the RAPP?

- Establish a provincially coordinated and streamlined approach to research approvals.
- Reduce duplication and improve timeliness across interdependent research approval activities.
- Implement solutions proportionate to risk.
- Enable the health sector to efficiently support the conduct of high quality, multi-site research across the province.
- Support a stronger research culture within health care that will generate evidence-based improvements to care and outcomes for British Columbians.

3. What are the key challenges in the research approvals process that RAPP aims to address?

<u>Duplication</u>: Currently there is a substantial amount of redundancy in approval processes. Researchers are frequently asked the same questions across multiple applications, and the applications are reviewed multiple times between and within organizations.

<u>Inconsistency:</u> Health authorities take different approaches (e.g., forms, process, entry point). This contributes to misunderstanding, frustration, and delays.

<u>Ambiguity:</u> Researchers may not understand approval processes well, and restrictions/ denials are not always fully explained. Not all health authorities have clearly coordinated communications to support approval navigation.

4. Why is this project being undertaken?

While considerable progress has been made in key research approval process areas (e.g., ethics), researchers in British Columbia have identified lengthy and varied approval processes within the health authorities as a significant barrier to timely, relevant health research (*Research is Care*, 2021). As part of the 2023 *BC Life Sciences and Biomanufacturing Strategy* and the 2023 Ministry of Health Mandate Letter, the Province has committed to streamlining research approval processes as part of a commitment to building a research-positive culture. Simplifying the current approval processes will ease some of the time, financial and operational challenges currently placed on researchers by health authorities and the wider-research ecosystem.

5. Are Health Authorities responsible for all the research approval delays?

No, there are several reasons why a research project approval may move slowly or not at all, including research applications that require further details, greater clarity, or corrections. Not all research projects will be deemed feasible, due to capacity and other factors, or sufficiently relevant to be supported by the health authorities.

6. What organizations are currently involved?

RAPP is focused on research approvals that involve the regional health authorities, Provincial Health Services Authority and Providence Health Care. These organizations inform and drive the work of RAPP primarily through representatives in the Advisory Committee, and the four current Subject Matter Expert working groups. In total approximately 100 individuals are presently involved in RAPP, with more to come as the scope expands in later phases of this work.

7. How does RAPP engage with the First Nations Health Authority (FNHA)?

In cases where FNHA is contributing to processes or systems impacted by RAPP, FNHA will be involved in the changes.

RAPP aims to align with work happening in FNHA regarding research approvals, but recognizing that the history, need, and model is different from the other health authorities. It is not assumed that RAPP's streamlining will necessarily be adopted by FNHA.

Representatives from FNHA have been invited to all Subject Matter Expert working groups and Advisory Committee meetings to inform the direction, where possible. FNHA is invited to, and will be supported in, the adoption of whichever parts of RAPP align with their work and their processes.

8. How are universities and researchers involved in this work?

Universities have, and continue to, provide information to inform the RAPP initiative. The Vice-Presidents of Research at British Columbia's research-intensive universities are aware of and engaged in the RAPP initiative. Opportunities for further direct involvement of universities and researchers with the RAPP initiative are being developed and will be essential as RAPP moves into a more detailed stage of validating the success of streamlined approaches.

9. How is RAPP being undertaken?

RAPP is taking an iterative approach, based in consultation with stakeholders, stepwise implementation, reflection, and ongoing refinement. The approach can be described in three stages:

Stage 1: Discovery and Planning

RAPP began with an information gathering phase to set the project directions. This included:

- A jurisdictional scan which looked at Canadian provinces, United States, Europe, Australia and New Zealand:
- A literature review to identify best practices and compare models;
- Individual interviews were conducted with health authority and research system experts in British Columbia to understand the current landscape across all approval components; and.
- Workshops were held with health authority staff to present the initiative and gather input.

Coming out of this information gathering phase, five core components of the approvals process were identified as within the scope of the RAPP initiative: ethics review, operational review, privacy review, contracts agreement, and data access.

It was determined that these components would be reviewed and workshopped as independent workstreams, with cross-over as necessary. Participants acknowledged that each research approval process has a different history and is at a different phase of provincial streamlining.

Stage 2: Solutioning and Implementation

For each workstream, RAPP is developing blueprints (or draft "solutions") to meet stated objectives and to address the identified issues. These blueprints are then presented to -- and discussed with-- the relevant Subject Matter Expert (SME) working groups. The SME working groups have equal representation from each health authority to ensure that solutions are balanced and reflective of the unique needs of each health authority. Once solutions are validated by the SME working groups, assessment of case studies begin, with further refinement and validation, as needed.

Implementation of these validated solutions will take place across the health authorities. Implementation will look differently for each workstream. RAPP and the Ministry of Health will support, strengthen, and help guide the various implementation streams.

Stage 3: Review, Refinement, and Resourcing

Qualitative and quantitative feedback will be obtained and analyzed to determine where advancements were made, what local and wide-scope impacts occurred, and what improvements are needed. SME working groups will continue to be engaged to further refine and validate solutions. Processes will be developed to continue this iterative work to ensure researchers and administrators continue to be heard and supported.

10. Research approval processes are inherently interconnected, why were they organized into separate workstreams?

The individual workstreams allow for a deeper analysis and more nuanced understanding by ensuring the voices of relevant experts are elevated and heard. The Advisory Committee brings together leaders from all workstreams to support cross-stream thinking, planning, and awareness.

The project team is committed to developing a process that is coherent and easy to navigate for researchers and administrators across the different approval processes.

11. Will RAPP be evaluated?

Yes, RAPP will be formally evaluated and it will use an iterative approach allowing for continuous learning and improvement.

12. How will RAPP be beneficial to British Columbians?

Research is an integral tool for improving health outcomes. High-quality evidence and innovation enhances the safety, sustainability, and effectiveness of health sector diagnostics, therapeutics, and services for British Columbians. By streamlining processes British Columbia's health sector will be able to conduct more efficient and timely research. Research conducted within the health sector strengthens a culture of evidence, continuous improvement; research advances care that is inclusive, culturally safe, and trauma informed; and it supports retention and attraction of talented researchers and healthcare providers.

13. How is industry involved in RAPP?

Industry is not directly represented in the work underway through RAPP. The streamlined approval processes will benefit all kinds of multi-site research, including that undertaken by industry, such as industry sponsored clinical trials.

14. How can I find out more about RAPP?

Health Research BC website hosts background overviews and regular updates about RAPP. https://healthresearchbc.ca/initiatives/rapp/

If you have any questions or require additional information about RAPP, please email RAPP@gov.bc.ca.