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RITHIM FAQ – June 2022

Please visit regularly as these FAQs will be updated as additional questions are received from stakeholders.

We encourage you to share the link to this document with colleagues, students, staff, and stakeholders.

Research Improvements Through Harmonization In Manitoba (RITHIM) launched on January 1, 2022.

An important first step to launching RITHIM were **amendments to the Personal Health Information Act (PHIA)**. The amendments were proclaimed on January 1, 2022, and enabled:

- Formal implementation of the RITHIM program
- Establishment of the Provincial Health Research Privacy Committee (PHRPC) as the authority to provide approval for research projects requesting **USE** of personal health information maintained by any Manitoba Trustee, including government or government agencies
- Establishment of the Committee for Harmonized Health Impact, Ethics and Privacy Review (CHIPER) to approve research projects requiring privacy review prior to PHRPC decision.

A transition plan was developed to launch RITHIM, to comply with the changes to PHIA and allow for necessary changes to policies and procedures within stakeholder organizations to occur.

To support research, temporary changes were minimized during this initial implementation of RITHIM.

The full RITHIM program, including the electronic Provincial Research Administration System (RITHIM PRAS) will be implemented later in 2022.



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CHANGES FOR JANUARY 1, 2022 - Required to comply with PHIA legislation

Personal Health Information/Privacy Applications

- The PHIA amendments brought a **NEW REQUIREMENT** for researchers. Effective January 1, 2022, PHRPC is the **ONLY** committee that has authority to provide approval for research projects requesting **USE** of personal health information in Manitoba, however, maintained by any Trustee, including government or government agencies.
 - Trustees retain the authority to approve **DISCLOSURE** of personal health information maintained by that Trustee (grant access and provide data).
 - To determine if your research requires PHRPC review please visit [Does my Project Require PHRPC Review?](#)
 - For additional information on PHRPC, including submission forms, please visit: <https://www.rithim.ca/phrpc-overview>.
- PHRPC REQUIRES satisfactory confirmation that the proposed research project has been approved by CHIPER, prior to its decision.
 - For the initial January 1, 2022, implementation, CHIPER is now responsible for ensuring that a Research Ethics Board has approved a research project prior to PHRPC decision.
 - Researchers DO NOT have to complete an application for CHIPER.
 - The form and mandate of CHIPER will evolve with the full implementation of the RITHIM Program.
 - For this initial implementation, CHIPER does not conduct an ethics review and therefore, has been established as a smaller committee with members from the existing University of Manitoba Health Research Ethics Board (HREB) and Biomedical Research Ethics Board (BREB) memberships. Additional members will join CHIPER once the full launch of the RITHIM program occurs later in 2022.



Organizational Impact Applications

- Researchers will continue to use existing processes. Trustees retain the authority to approve **DISCLOSURE** of personal health information maintained by that Trustee (grant access and provide data).

Research Ethics Board Applications

- Researchers will continue to use existing processes. Ethics Board approval is required as input to CHIPER and PHRPC decisions.

RITHIM – Additional Questions?

The focus of these FAQs is the changes following the launch of RITHIM on January 1, 2022. Additional information about the electronic Provincial Research Administration System (RITHIM PRAS) and implementation of the full RITHIM mandate will be forthcoming later in 2022.

Still have questions? Please email rithim@researchmb.ca.

What do the acronyms mean?

CHIPER - Committee for Harmonized **H**Health **I**Impact, **P**Privacy, and **E**Ethics **R**Review – Committee for Harmonized Health Impact, Privacy, and Ethics Review – CHIPER was established on January 1, 2022, and will evolve with the launch of RITHIM PRAS later in 2022.

- As of January 1, 2022, CHIPER was established as required by the PHIA legislative changes, in order to approve research projects prior to a decision by the new Provincial Health Research Committee (PHRPC).
- Later in 2022, CHIPER will become the new provincial health research ethics board replacing the other health research ethics boards province-wide. It will continue to operate under RITHIM and will meet monthly with PHRPC to review applications. It will review all health research ethics applications in Manitoba.



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RITHIM - Research Improvements Through Harmonization In Manitoba - RITHIM is a new provincial program for harmonizing health research reviews in Manitoba. An initial implementation of RITHIM began on January 1, 2022, which included the creation of CHIPER and PHRPC. Later in 2022, the role of RITHIM will expand to include its full mandate and introduce RITHIM PRAS, the new software solution to support applications and reviews.

PHRPC - Provincial Health Research Privacy Committee - Provincial Health Research Privacy Committee - PHRPC replaced Manitoba Health's Health Information Privacy Committee (HIPC). Effective January 1, 2022, PHRPC is the **ONLY** committee that has authority to provide approval for research projects requesting **USE** of personal health information in Manitoba, however, maintained by any Trustee, including government or government agencies. PHRPC is made up of members appointed by Manitoba's Health Minister.

PI - Principal Investigator - The lead researcher on a team who is responsible for the overall conduct of a research project including:

- conducting all research and research-related activities ethically;
- managing the activities of all members of the local research team, in compliance with all applicable policies, guidelines, and regulations; and
- authorizing activity and expenses on a funded research project.

RITHIM PRAS - Provincial Research Administration System - RITHIM PRAS is RITHIM's electronic application that will be the single point of entry for all health research ethics, privacy, and impact applications and reviews. It is currently in development, and we expect it to be ready later in 2022.



What changes for PIs on January 1, 2022?

- **Personal Health Information/Privacy assessment**
 - The PHIA amendments brought a **NEW REQUIREMENT** for researchers. Effective January 1, 2022, PHRPC is the **ONLY** committee that has authority to provide approval for research projects requesting **USE** of personal health information in Manitoba, however, maintained by any Manitoba Trustee.
 - Trustees retain the authority to approve **DISCLOSURE** of personal health information maintained by that Trustee (grant access and provide data).
 - To determine if your research requires PHRPC review please visit [*Does my Project Require PHRPC Review?*](#)
 - With the launch of RITHIM PRAS later in 2022, a single electronic application form will be used, eliminating the need for this separate form.
 - Please complete a PHRPC Application Form at <https://www.rithim.ca/phrpc-submission-information> and email one (1) signed copy along with the required supporting documentation to PHRPC@researchmb.ca.
 - Any proposed changes to a research project that was previously approved by the HIPC or PHRPC must be reported to PHRPC for review and approval. Please complete a Protocol Amendment Form at <https://www.rithim.ca/phrpc-submission-information> and email one (1) signed copy along with the required supporting documentation to PHRPC@researchmb.ca.
 - For all applications that received conditional approval from the HIPC committee prior to January 1, 2022, applicants have one (1) year from the date of the conditional approval to resubmit to the HIPC for review. The HIPC chair is being retained for a period of one (1) year to facilitate the completion of conditional approvals. Please email the required documentation and responses to the conditional approval letter to HIPC@gov.mb.ca for review and full approval. If the requested information is not submitted within this time period, a new application will need to be submitted to PHRPC.
 - For applications involving First Nations, Metis, or Inuit populations and communities, evidence of appropriate approvals is required by PHRPC before it will render a decision.



- **Organizational Impact Applications**
 - Researchers should continue to use existing processes. Trustees retain the authority to approve **DISCLOSURE** of personal health information maintained by that Trustee (grant access and provide data).
- **Research Ethics Board Applications**
 - Researchers will continue to use existing processes. Ethics Board approval is required as input to CHIPER and PHRPC decisions.
 - Researchers are not required to submit applications for CHIPER review. RITHIM staff will work with REB staff to coordinate inclusion of approved studies for CHIPER review.

What changes for REBs on January 1, 2022?

- Researchers will continue to use existing processes. Ethics Board approval is required as input to CHIPER and PHRPC decisions.
- For studies where a researcher has submitted a PHRPC application, RITHIM staff will work with REB staff to coordinate inclusion of approved studies for CHIPER review

How do applications flow through the committees as of January 1, 2022?

- Researchers are responsible to submit applications for organizational impact review
- Researchers are responsible to submit applications to REBs for ethics review
- Researchers are responsible to submit applications to PHRPC for privacy review (if required)
 - To determine if your research requires PHRPC review please visit [Does my Project Require PHRPC Review?](#)
 - REB and PHRPC applications should be submitted at the same time.
- Researchers DO NOT have to complete an application for CHIPER.
 - RITHIM staff work with REB staff to coordinate inclusion of applicable studies for CHIPER review.
- CHIPER meets to ensure that REB approvals are in place prior to rendering a PHRPC decision.



What changes for Organizational Impact Reviews on January 1, 2022?

- Researchers will continue to use existing processes.
- Trustees retain the authority to approve **DISCLOSURE** of personal health information maintained by that Trustee (grant access and provide data).
- Trustee approval for **DISCLOSURE** may require PHRPC approval for **USE**. Please visit [Does my Project Require PHRPC Review?](#) to determine which research project require PHRPC approval.

What forms will PHRPC use until the electronic application system launches?

- Please complete a PHRPC Application Form at <https://www.rithim.ca/phrpc-submission-information> and email one (1) signed copy along with the required supporting documentation to PHRPC@researchmb.ca.
- Any proposed changes to a research project that was approved by the HIPC or PHRPC must be submitted to PHRPC for review and approval. Please complete a Protocol Amendment Form at <https://www.rithim.ca/phrpc-submission-information> and email one (1) signed copy along with the required supporting documentation to PHRPC@researchmb.ca.

What if a project was conditionally approved by a REB or HIPC prior to January 1, 2022?

- If a project was conditionally approved by HIPC:
 - For all applications that received conditional approval from the HIPC committee prior to January 1, 2022, applicants have one (1) year from the date of the conditional approval to resubmit to the HIPC for review. Please email the required documents and responses to the conditional approval letter to HIPC@gov.mb.ca for review and full approval. If the requested information is not submitted within this time period, a new application will need to be submitted to the PHRPC.
- If a project was conditionally approved by an REB:
 - Please submit the required documents and additional information using the existing forms and processes on the original REB website.



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How are post-approval forms such as amendments/annual renewals/study closures, etc. handled after January 1, 2022?

- If a project was approved by PHRPC:
 - Any proposed changes to a research project that was approved by the HIPC or PHRPC must be submitted to PHRPC for review and approval. Please complete a Protocol Amendment Form at <https://www.rithim.ca/phrpc-submission-information> and email one (1) signed copy along with the required supporting documentation to PHRPC@researchmb.ca.
- If a project was approved by a REB:
 - Please submit post-approval forms using the existing forms and processes on the original REB website.

Do I need to submit PHRPC and REB applications at the same time?

- Yes. This helps us harmonize the review process and will save applicants' time! We ask that researchers submit applications for PHRPC and REB approval at the same time if both are required.
- With the launch of RITHIM PRAS later in 2022, a single electronic application form will be used, eliminating the need to submit multiple applications.

Have post-secondary institutions outside of the University of Manitoba been involved in the development of RITHIM?

- Yes, RITHIM has had consultation with and participation from many post-secondary institutions, the health system and service delivery organizations, government and industry.



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How is health research involving First Nations, Metis or Inuit affected by RITHIM's launch?

- Evidence of appropriate approvals is required by PHRPC.
- With the launch of RITHIM PRAS, later in 2022, applicants will submit evidence of the appropriate approvals within RITHIM PRAS.
- Numerous Indigenous groups have been engaged in the creation of questions on our electronic application form.

What are the timelines for PHRPC Review?

- PHRPC meets to review applications once a month. Feedback and decisions are communicated to applicants according to published [schedules](#).
- PHRPC REQUIRES satisfactory confirmation that the proposed research project has been approved by CHIPER, prior to its decision.