

Research Improvements Through Harmonization in Manitoba A201 Chown Building 753 McDermot Avenue Winnipeg, MB R3E 0T6

RITHIM APPROVAL

Principal Investigator: Not Applicable

Advisor: Not Applicable

Harmony Project ID: Not Applicable

Project Title: Participant Information Sheet - Health Research Ethics Review Transition to CHIPER

Sponsor: Not Applicable

APPROVED DOCUMENTS:

Participant Information Sheet - Health Research Ethics Review Transition to CHIPER, Version Date: June 20, 2025

Committee for Harmonized Health Impact, Privacy, and Ethics Review (CHIPER)

CHIPER Board: BREB, HREB

CHIPER Review Type: Delegated CHIPER Approval Date: June 26, 2025 **CHIPER Renewal Date:** Not Applicable

CHIPER has reviewed the above-named research project and has found it to be acceptable on ethical grounds for research involving human participants. CHIPER is constituted and operates in accordance with the current Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and the applicable laws and regulations of Manitoba.

In respect to clinical trials, CHIPER complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Products Regulations, and the Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations of Canada and carries out its functions in a manner consistent with Good Clinical Practices.

Dr. John Arnett

John Arnett, MD

Chair, CHIPER Health Research Ethics Board Research Manitoba

Dr. Lindsay Nicolle
Dr. Lindsay Nicolle
Dr. Lindsay Nicolle (Jul 23, 2025 08:00:09 CDT)

Lindsay Nicolle, MD

Chair, CHIPER Biomedical Research Ethics Board

Research Manitoba

CONFLICT OF INTEREST

Any Principal or Co-Investigators of this research project who are members of CHIPER or PHPRC did not participate in the review or voting of this project.

CONDITIONS OF APPROVAL

- Approval is granted for the research and purposes described in the application form and supporting documents only.
- Approval is contingent on compliance with any First Nations, Métis, and/or Inuit research approval(s) applicable for the project
- Any modification to the application, protocol or research materials must be submitted for approval prior to implementation.
- The Principal Investigator has the responsibility for any other administrative or regulatory
 approvals that may pertain to this research project and for ensuring that the authorized
 research is carried out in accordance with governing law.
- A Renewal or Project Completion Form must be submitted prior to the above expiry date.
 Research cannot be conducted without a current ethics approval. Submit 4-6 weeks ahead of the expiry date.
- If participants have a negative experience (either physical, psychological or emotional) you are required to submit the adverse event in accordance with RITHIM reporting guidelines.
- If there is a deviation from the approved project, you are required to submit the deviation in accordance with RITHIM reporting guidelines.
- Any new information that may affect the welfare or consent of participants must be submitted in accordance with RITHIM reporting guidelines.
- Any suspension or cancellation imposed by a funding agency or regulatory body that is related to this research project must be submitted in accordance with RITHIM reporting guidelines.
- Any findings that may have ethical implications or may affect the decision of the CHIPER must be submitted in accordance with RITHIM reporting guidelines.
- When a project has been completed or terminated, a Project Completion Form must be submitted.

CHIPER Approval Certificate Pt Info Sheet

Final Audit Report 2025-07-23

Created: 2025-07-21

By: Elizabeth Lylyk (elizabeth.lylyk@researchmb.ca)

Status: Signed

Transaction ID: CBJCHBCAABAAX_qo5BIWg3CnCX8RqTLiocfZGds7sPiR

"CHIPER Approval Certificate Pt Info Sheet" History

- Document created by Elizabeth Lylyk (elizabeth.lylyk@researchmb.ca) 2025-07-21 5:39:57 PM GMT
- Document emailed to Dr. John Arnett (jarnett@hsc.mb.ca) for signature 2025-07-21 5:44:55 PM GMT
- Email viewed by Dr. John Arnett (jarnett@hsc.mb.ca)
- Document e-signed by Dr. John Arnett (jarnett@hsc.mb.ca)
 Signature Date: 2025-07-22 9:01:44 PM GMT Time Source: server
- Document emailed to Dr. Lindsay Nicolle (lindsay.nicolle@umanitoba.ca) for signature 2025-07-22 9:01:45 PM GMT
- Email viewed by Dr. Lindsay Nicolle (lindsay.nicolle@umanitoba.ca) 2025-07-23 12:57:23 PM GMT
- Document e-signed by Dr. Lindsay Nicolle (lindsay.nicolle@umanitoba.ca)
 Signature Date: 2025-07-23 1:00:09 PM GMT Time Source: server
- Agreement completed. 2025-07-23 - 1:00:09 PM GMT