

RESEARCHER INFORMATION SHEET

TRANSITION OF INFORMED CONSENT REQUIREMENTS TO CHIPER

THIS DOCUMENT CONTAINS IMPORTANT INFORMATION ABOUT TRANSITIONING INFORMED CONSENT REQUIREMENTS TO CHIPER. PLEASE FOLLOW THE INSTRUCTIONS BELOW CAREFULLY AND KEEP THIS INFORMATION SHEET FOR YOUR RECORDS.

What is RITHIM?

Research Improvements Through Harmonization in Manitoba (RITHIM) is a new provincial program developed to create a more efficient process for health research approvals in Manitoba.

What is CHIPER?

RITHIM has established the Committee for Harmonized Health Impact, Privacy, and Ethics Review (CHIPER) as the research ethics board for reviewing all health research in Manitoba.

RITHIM requires that all new health research projects involving human participants are reviewed and approved by CHIPER. This includes health research conducted by persons affiliated with regional health authorities, universities and colleges, and hospitals and health care facilities in Manitoba. In addition, current health research projects that previously obtained approval from a post-secondary institutional research ethics board have transitioned their ongoing oversight to CHIPER.

In accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research. As such, this Researcher Information Sheet describes the information to be provided to participants as part of their ongoing consent to participation. The directions below are to be applied to all *projects that do not have an REB-approved waiver of consent, regardless if they have not yet begun enrollment, are currently enrolling, or have participants in follow-up.*

Projects Obtaining Verbal Consent

During your next contact, please verbally notify all current participants of the information in the attached Participant Information Sheet and document the discussion in the research project file, if applicable.

Projects using a Consent Disclosure Statement

If your consent disclosure statement contains details about which organizations have access or may receive participants' research and/or medical records, then your statement should be revised to include CHIPER as one of these organizations.

If your consent disclosure statement contains contact information for an ethics board, then your statement should be revised to provide CHIPER's contact information as outlined below. If your consent disclosure statement is generic in nature and does not contain the abovementioned details, then no further action is required.



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If further contact with participants is planned, all current participants should be notified of the information in the attached Participant Information Sheet at their next contact. A description of the action taken should be documented in the research project file, if applicable.

Projects with Written Informed Consent Forms

- 1. Please distribute the attached Participant Information Sheet to all newly enrolled and current participants during your next contact. This Participant Information Sheet has been <u>pre-approved</u> by CHIPER for use. Please DO NOT alter any language in the information sheet without obtaining additional CHIPER approval.
- 2. Please amend your existing project informed consent forms with the updated information the next time you are updating your documents. Please DO NOT submit an amendment application in Harmony to merely update these details.

Guidance For Drafting New Informed Consent Forms

All new informed consent forms or participant-facing materials should refer to CHIPER as the health research ethics board in Manitoba that assures that the rights and welfare of human research participants are protected. Please use the contact information provided below. In the consent confidentiality section, where details are provided about organizations that have access to or may receive participants' research and/or medical records, please include CHIPER as one of these organizations.

RITHIM Program Officer CHIPER Research Ethics Board Telephone Number: 204-775-1096 / 1-866-248-4375 (toll-free) E-mail: CHIPER@researchmb.ca

CHIPER Office Address: Research Improvements Through Harmonization in Manitoba (RITHIM) A201 Chown Building 753 McDermot Ave, Winnipeg, Manitoba R3E 0T6 Canada

For any questions regarding these requirements, please contact CHIPER at CHIPER@researchmb.ca