



SOP Number and Title	1.0 Authority and Purpose of CHIPER
Revision Date (Current Document)	July 29, 2020
Effective Date	August 1, 2020 (subject to change)
Review Date	August 1, 2021
Approving Body	Provincial RITHIM Committee
Responsible Officer	Director, RITHIM

## 1 INTRODUCTION

The purpose of this standard operating procedure (SOP) is to:

- a. State the organizational authority under which the Committee for Harmonized Health Impact, Privacy, and Ethics Review (CHIPER) is established and empowered;
- b. Define the purpose of CHIPER;
- c. State the principles governing CHIPER to assure that the rights (including privacy) and welfare of research participants are protected;
- d. State the principle governing CHIPER as it relates to impact assessment by institutions where research will be conducted and
- e. State the authority of the REB.

## 2 SCOPE

This SOP pertains to CHIPER Boards that review human participant health research applications and associated reporting (e.g., protocol applications, adverse events, etc.) in compliance with applicable regulations and guidelines.

## 3 RESPONSIBILITIES

The Director of RITHIM, all personnel in the RITHIM office, and all members of CHIPER Boards are responsible for ensuring that the requirements of this SOP are met.

## 4 DEFINITIONS

See Glossary of Terms.

## 5 PROCEDURE



CHIPER will maintain and follow all written policies and procedures consistent with federal and provincial regulations, good clinical practice, and ethics principles or guidelines, and privacy legislation when reviewing health research protocols.

## 5.1 Statement of Organizational Authority

- 5.1.1 Research Improvements through Harmonization in Manitoba (RITHIM), an arms-length program of Research Manitoba, has authorized the Committee for Health, Impact, Privacy, and Ethics Review (CHIPER) to review health research involving human participants in Manitoba.
- 5.1.2 CHIPER is established and empowered under the authority of RITHIM. RITHIM requires that all health research involving human participants be 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. Research led by investigators from outside of Manitoba who propose to conduct health research in Manitoba are required to submit protocols to CHIPER for its approval. No research shall be initiated without the full review of, and approval by, CHIPER.
- 5.1.3 CHIPER's reviews are multi-focal, including:
  - assessment of ethical considerations;
  - assessment of privacy considerations relative to the Personal Health Information Act of Manitoba (CHIPER has authority under the Personal Health Information Act to approve researcher requests for access to personal health information held by a Trustee); and
  - incorporation of operational impact assessments from institutions where research will be conducted.

## 5.2 Purpose of CHIPER

- 5.2.1 CHIPER's purpose is to protect the rights (including privacy) and welfare of human participants participating in health research.
- 5.2.2 CHIPER reviews the health research to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection (including, but not limited to, the *Food and Drugs Act* and applicable *Regulations*, the International Council on Harmonization Good Clinical Practice Guidelines; the Declaration of Helsinki; the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human, and where applicable, US Federal Regulations); as well as the Personal Health Information Act of Manitoba;
- 5.2.3 CHIPER's reviews of research are guided by a duty to ensure the health research is of sufficient importance to outweigh the intrusion into an individual's privacy, and to protect



the privacy of individuals during the collection, use, disclosure, security, retention and destruction of their personal health information; and

- 5.2.4 CHIPER receives operational impact assessments from institutions where research will be conducted; these operational impact assessments are incorporated into the overall assessment and approval of research reviewed by CHIPER.

### 5.3 Governing Principles of CHIPER

5.3.1 CHIPER is guided by *ethical principles* regarding all research involving human participants including:

- Respect for Persons:
  - Recognize the intrinsic value of human beings and the respect and consideration they are due; and
  - Incorporate moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.
- Concern for Welfare:
  - Aim to protect the welfare of participants, and, in some circumstances, to promote the welfare in view of any foreseeable risks;
  - Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation; and
  - Ensure that participants are not exposed to unnecessary risks.
- Justice:
  - Obligation to treat people fairly with equal respect and concern; and
  - Vulnerable or marginalized people may need to be afforded special attention.

5.3.2 CHIPER's reviews of research are guided by *a duty to protect the privacy of individuals* in the collection, use, disclosure, security, retention and destruction of personal health information.

5.3.3 CHIPER's reviews of research *respect institutional autonomy* to determine the impact of research, and to ensure that CHIPER will not approve research in the absence of institutional approval.

### 5.4 CHIPER Authority

5.4.1 CHIPER is established to review all health research protocols involving human participants in Manitoba. This includes health research conducted by persons affiliated with regional health authorities, universities and colleges, and hospitals and health care facilities in Manitoba. Health research led by investigators from outside of Manitoba who propose to conduct research in Manitoba are required to submit protocols to CHIPER for its approval.

5.4.2 CHIPER has the authority to ensure that all health research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants. Specifically, CHIPER has the authority to:

CHIPER SOP 1.0

Authority and Purpose of CHIPER

Version 1: July 29, 2020



- Establish the ethics review processes, and provide research ethics oversight to ensure the ethical conduct of the research;
- Approve, require modifications to, or disapprove, any research activity that falls within its jurisdiction;
- Ensure that the researcher has protocols and procedures to protect the rights, safety, and welfare of research participants;
- Request, receive, and share any information involving the research that CHIPER considers necessary to fulfil its mandate, while maintaining confidentiality and respecting privacy;
- Conduct continuing review to protect the rights, welfare and privacy of research participants;
- Suspend or terminate the approval for the research;
- Place restrictions on the research; and
- Take any actions considered reasonably necessary, and consistent with CHIPER policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under CHIPER’s jurisdiction.

## 5.5 Research Subject to US Regulations

CHIPER shall apply the requirements of the applicable US regulations to the extent that they vary from the protections set out in the applicable Canadian regulations and guidelines.

## 6 REFERENCES

See References.

## 7 REVISION HISTORY

Date/Version	Summary of Changes
July 29, 2020/01	Original version