

SOP Title	CHIPER Composition
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Approving Body	RITHIM Organization Committee
Responsible Officer	Director (RITHIM)

1 PURPOSE

This procedure describes the composition requirements for the membership of the Committee for Harmonized Health Impact, Privacy, and Ethics Review (CHIPER).

2 GENERAL POLICY STATEMENT

Individual members of CHIPER must be qualified through training, experience, and expertise to ascertain the acceptability of proposed research protocols in terms of ethics and privacy principles, and applicable regulations, guidelines, and standards pertaining to human subject protection and privacy.

To ensure complete and adequate reviews, CHIPER must include appropriate diversity. Therefore, selection of members considers professional (scientific and non-scientific) expertise as well as clinical and research experience to assess the protocols submitted for review. In addition, diversity in regards to gender, cultural background, and institutional affiliation will also be a priority.

CHIPER will include members appointed by the Minister of Health, Seniors and Active Living, to ensure that the long-term goals of the Province are represented in meetings. The membership of CHIPER will reflect members from the breadth of institutions served by CHIPER, including members from a range of research-based health fields. The CHIPER skills matrix (appended to this policy) will be used by RITHIM staff to ensure that an appropriate balance of experience and expertise is maintained in the composition of CHIPER.

3 RESPONSIBILITY

This procedure applies to all CHIPER members, including the Chairs and Vice-Chairs. The RITHIM Director and/or the CHIPER Coordinator, and the CHIPER Chairs are responsible for ensuring that the CHIPER SOP 1.3

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composition of CHIPER meets the applicable regulatory requirements. The Provincial RITHIM Committee (PRC) approves the final nominations for CHIPER Chairs, Vice-Chairs, and members.

4 SPECIFIC POLICIES AND PROCEDURES

4.1 Selection of CHIPER Members

- 4.1.1 In order to ensure diverse representation to the best of the selection committee's ability, members will be asked and be able to, but not be required to, self-identify their gender, orientation, cultural background, and/or disability.
- 4.1.2 In the selection of CHIPER members, equal consideration shall be given to qualified persons of all genders, with the membership not consisting of a significant majority by any one gender.
- 4.1.3 Every effort will be made to include qualified and skilled individuals from diverse ethnocultural communities in the makeup of CHIPER.
- 4.1.4 The CHIPER membership will include a range of representatives with expertise in both urban and rural health issues across Manitoba.
- 4.1.5 The CHIPER membership will not consist entirely of members of any one profession.
- 4.1.6 Members will be selected based on the needs of CHIPER as outlined below, and per applicable regulations, guidelines, and standards.

4.2 Composition of CHIPER

- 4.2.1 The membership of CHIPER will be in compliance with Health Canada (Division 5, Part C.05.001 of the Food and Drug Act), Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans, December 2010 (TCPS2), and the Personal Health Information Act (PHIA) in the Province of Manitoba.
- 4.2.2 The CHIPER committee will have a maximum of 50 roster members, the majority being appointed by Research Manitoba through PRC.
 The Minister of Health, Seniors & Active Living shall appoint at least one representative from nominations received from each of the following:
 - the College of Physicians and Surgeons of Manitoba;
 - the College of Registered Nurses of Manitoba;
 - the College of Pharmacists of Manitoba; or
 - the Manitoba chapter of the Canadian Health Information Management Association.
- 4.2.3 Both CHIPER panels (biomedical research and health research) must have a member who is designated as a public (or community) representative. Public representatives are

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- persons who are not health professionals or employees of health institutions in the province. Public representatives are not affiliated with any research sponsors, the institution(s) or site (s) where research is to be conducted and are not part of the immediate family of a person submitting a protocol for review.
- 4.2.4 CHIPER's roster must have members who are knowledgeable about Indigenous research and Indigenous research perspectives. Where protocols under review involve or affect Indigenous populations, CHIPER panels shall include one member with expertise in Indigenous research and Indigenous research perspectives.
- 4.2.5 A member may not fulfill more than two mandatory representative capacities and disciplines.
- 4.2.6 CHIPER's roster of members and each CHIPER panel will consist of a majority of members who are Canadian citizens or permanent residents.
- 4.2.7 Each member of CHIPER will collectively have the qualifications and experience to review and evaluate the science, ethics, privacy, and impact of the proposed research.
- 4.2.8 The Director of RITHIM, the CHIPER Coordinators, and the CHIPER Chairs monitor the CHIPER membership composition for appropriate membership in relation to the nature and volume of protocol submissions. The RITHIM Director, CHIPER Coordinators, or designee will update the CHIPER membership roster as necessary.
- 4.2.9 The CHIPER office will maintain a membership roster with the following details regarding CHIPER members:
 - name;
 - term of appointment (start and end dates);
 - earned degrees;
 - representative capacities in relation to the CHIPER skills matrix;
 - institutional affiliation;
 - self-identification;
 - community affiliation (for community representatives); and
 - experience (e.g., board certifications such as the Office of Human Research Protections [OHRP], licenses, etc.) sufficient to describe each member's anticipated contributions to CHIPER's review function.

4.3 CHIPER Chairs and Vice-Chairs

- 4.3.1 There will be two (2) CHIPER Chairs and two (2) Vice-Chairs at any given time: a Chair and a Vice-Chair for reviewing biomedical research applications, and a Chair and a Vice-Chair for reviewing health research applications.
- 4.3.2 PRC is responsible for appointing the Chairs and Vice-Chairs and will also appoint CHIPER members based on the recommendation of the Chairs.



- 4.3.3 Whenever possible and practicable, the CHIPER Chairs will be selected from CHIPER members with at least two years of experience who have expressed interest in becoming the CHIPER Chair and who are familiar with the applicable regulations and guidance documents.
- 4.3.4 Whenever possible, the Vice-Chairs will be selected from members with expertise in the review of privacy.

4.4 Ad Hoc Advisors

- 4.4.1 At the discretion of the Chair(s), individuals with expertise and competence in special areas may be asked to assist in the review of issues that require expertise beyond, or in addition to, that available on CHIPER.
- 4.4.2 An ad hoc advisor may be asked to participate via teleconference or to attend the meeting to provide expertise in the panel's discussions.
- 4.4.3 All ad hoc advisors shall sign a Confidentiality and Conflict of Interest Agreement.
- 4.4.4 An ad hoc advisor does not contribute directly to CHIPER's decision and their presence shall not be used in establishing quorum.
- 4.4.5 Documentation of key information provided by an ad hoc advisor shall be summarized in the CHIPER minutes and any subsequent report will be placed in CHIPER's files.

4.5 Membership and Quorum at CHIPER Meetings

Each CHIPER panel (for biomedical research and for health research) will normally consist of no fewer than seven (7) members and no more than 15 members, excluding the Chairs of each panel and any institutional delegates.

- 4.5.1 Quorum for the conduct of a CHIPER meeting will be a minimum of seven (7) duly appointed CHIPER members and including:
 - diverse gender representation;
 - a Ministerial appointee;
 - a public (or community) member;
 - a member knowledgeable in ethics;
 - a member knowledgeable in privacy;
 - two members with expertise in relevant research areas; and
 - for biomedical research projects, a member with legal expertise.

In the event that quorum is not achieved, the meeting may proceed only if the Chair(s) deems that the number and range of expertise present is adequate for the conduct of reviews. Decisions without a quorum are not valid or binding and will require an approval at a subsequent meeting that meets quorum.

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4.6 Institutional Delegates

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- 4.6.1 CHIPER will maintain a roster of institutional delegates who are appointed by the institutions they represent. It is the responsibility of institutions affiliated with RITHIM to inform the RITHIM Director if there are changes in institutional delegates.
- 4.6.2 When an application to CHIPER is accepted for review, it will be assigned to reviewers to assess ethics and privacy. At the same time, the application will be sent for impact review to the institutional delegate(s) where the research will take place.
- 4.6.3 It is the responsibility of the institutional delegate(s) to ensure that the application is reviewed by appropriate individuals at the institutions to assess impact and feasibility. The institutional delegate(s) is responsible for providing feedback to the CHIPER committee within the identified timeline (ten business days) either by submitting written comments and approval before the committee meeting, or by attending the CHIPER review committee meeting to discuss issues with the application.
- 4.6.4 Impact review and comments will be discussed as part of the review at the CHIPER meeting. In the event that the institutional impact assessment(s) has not been received at the time of the CHIPER meeting and review, the Chair may defer consideration of an application or an application may receive provisional CHIPER approval until the institutional delegate indicates that the application has satisfied requirements for impact review.

5 REFERENCES

- 1. Health Canada (Division 5, Part C.05.001 of the Food and Drug Act).
- 2. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans, December 2010 (TCPS2).

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3. Personal Health Information Act (PHIA) for the Province of Manitoba.

6 APPENDIX: CHIPER SKILLS MATRIX