Research Improvement Through
Harmonization in Manitoba
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SOP Title	Duties of CHIPER Members
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Responsible Officer	RITHIM Director

1 INTRODUCTION

This policy and procedure describe the duties of the members of the Committee for Harmonized Health Impact, Privacy and Ethics Review (CHIPER).

2 GENERAL POLICY STATEMENT

Each CHIPER member's primary duty is the protection of the rights and welfare of individuals who are participants in research. In order to fulfill their duties, CHIPER members must be versed in policies and regulations governing human participants' protection, and health and/or biomedical research ethics.

3 DEFINITIONS

See glossary of terms.

4 RESPONSIBILITY

This SOP applies to all CHIPER members including the Chairs and Vice-Chairs.
The CHIPER Chairs, with support from the RITHIM staff, are responsible for clearly articulating all required duties of CHIPER members.
CHIPER members (and alternates) are responsible for fulfilling their duties as specified in this procedure.

5 SPECIFIC POLICIES AND PROCEDURES

5.1 Attendance

5.1.1 Members are expected to attend the regularly scheduled meetings, when the Chair has identified that their presence is required. Not all members are required at all meetings.

5.1.2 CHIPER members must notify the CHIPER office if they will be absent for a meeting so that an appropriate alternate may be identified to attend.

5.1.3 CHIPER members are expected to be available for the entire meeting, not just the sections for which they have been assigned as reviewers.

5.2 Terms of Duty

All members of CHIPER including the Chairs and Vice-Chairs are expected to commit to terms of one, two or three years (renewable) as per their letters of appointment.

5.3 Duties

5.3.1 All CHIPER members attending a meeting are expected to review the relevant materials submitted for each item under review, to submit comments in advance of the meeting, to be prepared to discuss each agenda item, and to provide input at the convened meeting;

5.3.2 CHIPER consists of members from institutions and cities throughout Manitoba, and all members are expected to provide input on their local institutional and geographic context, as applicable.

5.3.3 Each CHIPER member is expected to provide input to CHIPER reviews in accordance with their expertise and/or affiliation.

5.3.3.1 Public or community member(s) are expected to provide input regarding their knowledge about the local community, and to be able to discuss issues and research from that perspective.

5.3.3.2 Non-scientific member(s) are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. Non-scientific members should advise CHIPER if additional expertise in a non-scientific area is required to assess whether the protocol adequately protects the rights and welfare of subjects. Non-scientific member will comment on whether the consent document is comprehensible to study participants.

5.3.3.3 Scientific member(s) are expected to contribute to the evaluation of a study protocol on its ethical, scientific, and statistical merits, and on matters related to standards of practice. Scientific members will also advise CHIPER if additional expertise in a scientific or non-scientific area is required to assess whether the protocol adequately protects the rights and welfare of subjects.

5.3.3.4 Member(s) knowledgeable in relevant law are expected to alert CHIPER to legal issues and their implications, but they do not to provide formal legal opinions nor do they serve as legal counsel to CHIPER.

5.3.3.5 Member(s) knowledgeable in research ethics are expected to alert and to advise CHIPER on ethical issues and options.

5.3.3.6 Member(s) knowledgeable in privacy are expected to alert and to advise CHIPER on privacy issues.

5.3.3.7 Ad hoc advisors are individuals with competence in special areas that may be required beyond, or in addition to, that available on CHIPER (e.g., an expert in the area of natural health products). An ad hoc advisor may be required to submit a written report, and to participate via teleconference or to attend the meeting to provide expertise for the benefit of CHIPER's discussions. The ad hoc advisor's attendance is not counted towards quorum or in voting regarding any protocol under review.

5.3.4 Chair: The CHIPER Chair must be knowledgeable in the applicable regulations, guidelines and policies governing human research protections and the conduct of research. The duties of the CHIPER Chair are outlined in CHIPER SOP 1.1 (CHIPER Chair Terms of Reference), and include the following:

- ensures that the review process conforms with the SOPs and with all applicable regulations and guidelines;
- leads convened meetings;
- normally does not participate in voting but may cast a vote to break a tie;
- is empowered to use delegated review and approval procedures for any submissions that qualify for delegated review (e.g., protocol revisions, modifications or amendments, consent form revisions, protocol deviations, serious adverse events, safety updates, etc.);
- conducts delegated reviews, or delegates to an appropriate CHIPER member, the authority to conduct a delegated review when appropriate;
- is empowered to suspend the conduct of research which has been deemed to place participants at unacceptable risk, until there is a subsequent full review and decision by CHIPER;
- is empowered to suspend the conduct of research if it is determined that an Investigator is not following CHIPER 's policies or procedures, until there is a subsequent full review and decision by CHIPER; and
- may delegate (in writing) any of Chair responsibilities, as appropriate, to other qualified individuals including the Vice-Chair.

5.3.5 Vice-Chair: As delegated in writing, the Vice-Chair assists or acts on behalf of the Chair in CHIPER matters and at CHIPER meetings, either on a continuing basis, or on a case-by-case basis. The CHIPER Vice-Chair is responsible for performing duties as described in CHIPER SOP 1.2 (CHIPER Vice-Chair Terms of Reference).

5.4 Online Reviews

All reviews are submitted via the online system and are available for all CHIPER members and CHIPER office personnel to access.

5.5 Designated Reviews

CHIPER utilizes a primary and secondary reviewer model. Reviewers are normally assigned by the CHIPER Chair or designate, based on workload, on members' expertise and experience, and in consideration of potential conflicts. In addition, impact reviews are completed at the institutions where research will be conducted.

5.5.1 The Primary Reviewer:

- conducts an in-depth review of the assigned study/studies;

- completes the review in the online system at least 24 hours prior to the meeting;
- presents an assessment of the research protocol at the CHIPER meeting, leads the discussion, and recommends a decision regarding approval of the research; and
- may be required to review additional material (e.g., Investigator responses) for the purpose of final approval.

5.5.2 The Secondary Reviewer:

- conducts an in-depth review of the assigned study/studies;
- completes the review in the online system at least 24 hours prior to the meeting;
- presents an assessment of the research protocol at the CHIPER meeting, adds to the discussion, as appropriate, and recommends a decision regarding approval of the research;
- may be required to review additional material (e.g., Investigator responses) for the purpose of final approval; and
- in the event that the primary reviewer is unable to lead the discussion, the secondary reviewer or the Chair will do so.

5.5.3 The Institutional Reviewer:

- co-ordinates an impact review of the assigned study/studies;
- completes a review in the online system at least 24 hours prior to the meeting;
- sends institutional impact approval and comments in the online system for discussion at the meeting or presents an assessment of the impact at the CHIPER meeting, adding to the discussion as appropriate, and recommending a decision regarding approval of the research protocol; and
- may be required to review additional material (e.g., Investigator responses) for the purpose of final approval.

5.6 Training and Education

Members are expected to participate in education activities.

5.7 Conflict of Interest

CHIPER members are expected to follow conflict of interest procedures.

6 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).
3. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, Section 3.
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 Part 56.107. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.107.
5. FDA Information Sheets: FAQ Section II, Question17.