

Criteria and Process for the Evaluation and Approval of Research Ethics Committees for purposes of Section 29 of *The Health Information Protection Act*

Defining Research

For purposes of applying section 29, *The Health Information Protection Act* (HIPA) does not define “research”. The Act does, however, provide some guidance with respect to what is not considered to be research. For example, the use and disclosure of personal health information would not be considered research:

- For the purpose of arranging, assessing the need for, providing, continuing, or supporting the provision of, a service requested or required by the individual;
- Where, in the opinion of the trustee, disclosure is necessary for monitoring, preventing or revealing fraudulent, abusive or dangerous use of publicly funded health services;
- Where the disclosure is being made to a standards or quality of care committee established by one or more trustees to study or evaluate health services practice in a health services facility, health region or other health service area that is the responsibility of the trustee;
- Where the disclosure is being made to a health professional body or a prescribed professional body that requires the information for the purposes of carrying out its duties pursuant to an Act with respect to regulating the profession;
- Where the disclosure is being made for the purpose of obtaining payment for the provision of services to the individual or planning, delivering, evaluating or monitoring a program of the trustee;
- Or for any other purpose identified in sections 26, 27 and 28 of HIPA.

Criteria to be used for Evaluating Research Ethics Committees for the Purpose of being Approved by the Minister of Health under Section 29 of HIPA

In order to be eligible for and to retain the approval of the Minister of Health under section 29 of *The Health Information Protection Act* (HIPA), a research ethics committee must meet the following criteria:

Membership

The research ethics committee should consist of at least five members, including both men and women, of whom:

- at least two members have broad expertise in methods of research;
- at least one member is knowledgeable in ethics;
- at least one member is knowledgeable in law;
- at least one member has no affiliation with the institution, but is recruited from the community served by the institution.

There is an expectation that over time members of a research ethics committee that has been approved by the Minister of Health will become knowledgeable in privacy matters

including protecting an individual's privacy and maintaining the confidentiality of their personal health information.

The appointment terms of the members of the research ethic committee should be staggered to balance the need to maintain continuity with the need to ensure diversity of opinion and the opportunity to spread knowledge and experience gained from research ethics committee membership throughout the institution and community.

Governance of the Research Ethics Committee

The research ethics committee must operate under the sponsorship of a research institution, university, regional health authority, or a public body.

The research ethics committee will adhere to the *Tri-Council Policy Statement* regarding the acceptable number of research ethics committees within an institution and the relationships among research ethics committees.

The number of face-to-face meetings held by a research ethics committee for the purpose of reviewing research projects (protocols) in a given year and the regular attendance of committee members at these meetings should be sufficiently regular so as to ensure that members maintain an appropriate level of expertise and competency, and to ensure timely review of research requests.

The number of research projects (protocols) reviewed by a research ethics committee in a given year should be sufficient enough to ensure that members maintain an appropriate level of expertise and competency. Although there is no definitive number of reviews that a research ethics committee should undertake, it is recommended that a research ethics committee should be undertaking a minimum of 50 reviews per year.

Role of the Research Ethics Committee

Except where otherwise stated by the criteria set out in this document, the research ethics committee will, at a minimum, adhere to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* regarding all standards and practices involving an ethics review of a research project (protocol). Depending on the mandate of the research ethics committee (e.g. a biomedical verses a behavioural research ethics committee), other standards and practices may need to be adhered to including the *Therapeutic Products Directorate Guidelines/ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) Harmonized Tripartite Guideline (September 1997)* entitled the *Good Clinical Practice: Consolidated Guideline* (specifically section 3 identifies the duties of an Institutional Review Board/Independent Ethics Committee as they relate to these standards and practices), and the *Food and Drug Regulations-Amendment (Schedule No. 1024-Clinical Trial Framework)*. By way of background, these three sets of standards do the following:

- The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* describes the policies of the Medical Research Council (MRC), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC). Through Acts of Parliament the MRC, NSERC, and SSHRC were created and funded to promote, assist and undertake research in the domains indicated in their names. In discharging their mandates, the Councils promote research that is conducted according to the highest ethical standards. The Councils have therefore adopted this policy as the standard of ethical conduct for research involving human subjects. As a condition of funding, as a minimum, researchers and their institutions are required to apply the ethical principles and the articles of the policy.

- The *ICH Good Clinical Practice: Consolidated Guideline* (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization. This guideline is to be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.

- The amendments in the *Food and Drug Regulations-Amendment (Schedule No. 1024-Clinical Trial Framework)* introduced regulatory requirements for the sale and importation of drugs for use in human clinical trials. The new requirements are located in Division 5 of the regulations and apply to clinical trials in humans using both new and old drugs. The amendment regulations became effective September 1, 2001 and incorporated the following features:
 - a 30-day default review period for applications to sell a drug for the conduct of human drug clinical trials in Canada in Phases I and III of development;
 - clear and transparent requirements for application, information, amendments, notification, labelling, record keeping and adverse drug reaction reporting;
 - introduction of an inspection system against internationally accepted good clinical practice principles and good manufacturing practices; and
 - clear authority to refuse an application, suspend or cancel the sale of drugs for use in clinical trials in Canada where they do not meet the updated regulatory requirements.

A research ethics committee that has been approved by the Minister may be requested to review a research project (protocol) for purposes of section 29 of HIPA. Upon receiving such a request there is no obligation on the part of the research ethics committee to accede to the request if the committee is not in a position to conduct the review (for

example, the research ethics committee may not have the time or the resources available to conduct the review).

Review of Research being Conducted in Other Jurisdictions or Countries

Where a trustee or a designated archive uses or discloses personal health information for research purposes, the project must undergo an ethics review by a research ethics committee approved by the Minister of Health pursuant to section 29 of HIPA. This rule applies whether the research project is being conducted in Saskatchewan, in another province/territory or in another country.

Process of Evaluating a Research Ethics Committee for Approval by the Minister

For the purpose of evaluating and determining whether a research ethics committee meets the established criteria for approval by the Minister of Health under section 29 of HIPA, Saskatchewan Health requires a research ethics committee to provide in a written application the following information about its committee:

- its membership including the member's position, the member's expertise, and gender (this could be in the form of a general summary of these items – detailed resumes or curricula vitae are not required);
- the dates upon which the appointment terms of the committee members expire;
- a brief description of the knowledge that a member(s) of the committee has gained regarding privacy matters including protecting an individual's privacy and maintaining the confidentiality of their personal health information;
- a brief description of the mandate, authorities and responsibilities of the research ethics committee;
- the number of face-to-face meetings held by the research ethics committee in a given year;
- the number of research projects (protocols) that the committee reviews in a given year;
- the process undertaken by the committee in conducting a review of a research project (protocol) including matters related to continuing ethics review, conflicts of interest and any other processes that the committee is responsible for;
- a statement declaring that the research ethics committee is complying with the standards and procedures of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and/or with other standards and practices required to be adhered to by the committee including the *Therapeutic Products Directorate Guidelines/ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) Harmonized Tripartite Guideline (September 1997)* entitled the *Good Clinical Practice: Consolidated Guideline*, and the *Food and Drug Regulations-Amendment (Schedule No. 1024-Clinical Trial Framework)*.

Once it has been determined by Saskatchewan Health that the information submitted by the research ethics committee meets the criteria as outlined in this document, a recommendation will be put forward to the Minister of Health for the approval of the research ethics committee for purposes of section 29 of HIPA.

To ensure that the research ethics committee that has been approved by the Minister continues to meet the criteria outlined in this document, the research ethics committee will be asked on a regular basis (i.e. every 12 to 18 months) to identify any changes that have taken place regarding their structure, mandate or practice. Any changes will then be evaluated to ensure compliance with the criteria.

Research Ethics Committees to be Considered for Approval by the Minister of Health for Purposes of Section 29 of HIPA

Trustees under HIPA may use or disclose personal health information for research purposes involving researchers not only within Saskatchewan but also outside the province. Out-of-province research requests come from researchers within institutions that have established research ethics committees. Research ethics committees from outside of Saskatchewan will be considered for approval upon application and provided they meet the same criteria as Saskatchewan-based research ethics committees.

Consideration will be given to standards and procedures for research ethics committees other than the *Tri-Council Policy Statement* or other standards identified in this document if:

- the research ethics committee seeking approval is located outside of Saskatchewan or Canada; and
- it can be demonstrated that the standards followed by that research ethics committee are similar to those of the *Tri-Council Policy Statement*.

APPENDIX “A”

Section 29

The Health Information Protection Act

Use and disclosure for research

29(1) A trustee or a designated archive may use or disclose personal health information for research purposes with the express consent of the subject individual if:

- (a) in the opinion of the trustee or designated archive, the research project is not contrary to the public interest;
- (b) the research project has been approved by a research ethics committee approved by the minister; and
- (c) the person who is to receive the personal health information enters into an agreement with the trustee or designated archive that contains provisions:
 - (i) providing that the person who is to receive the information must not disclose the information;
 - (ii) providing that the person who is to receive the information will ensure that the information will be used only for the purpose set out in the agreement;
 - (iii) providing that the person who is to receive the information will take reasonable steps to ensure the security and confidentiality of the information; and
 - (iv) specifying when the person who is to receive the information must do all or any of the following:
 - (A) return to the trustee or designated archive any original records or copies of records containing personal health information;
 - (B) destroy any copies of records containing personal health information received from the trustee or designated archive or any copies made by the researcher of records containing personal health information received from the trustee or designated archive.

(2) Where it is not reasonably practicable for the consent of the subject individual to be obtained, a trustee or designated archive may use or disclose personal health information for research purposes if:

- (a) the research purposes cannot reasonably be accomplished using de-identified personal health information or other information;
- (b) reasonable steps are taken to protect the privacy of the subject individual by removing all personal health information that is not required for the purposes of the research;
- (c) in the opinion of the research ethics committee, the potential benefits of the research project clearly outweigh the potential risk to the privacy of the subject individual; and
- (d) all of the requirements set out in clauses (1)(a) to (c) are met.