

RESEARCH REVIEW COMMITTEE (RRC) - TERMS OF REFERENCE

ST. BONIFACE GENERAL HOSPITAL

RESEARCH INVOLVING HUMANS

TERMS OF REFERENCE

September 2007

PREAMBLE:

St. Boniface General Hospital values and promotes its collaborative role in research and is committed to ensuring that research conducted within its jurisdiction meets the highest scientific, ethical, and legal standards.

The review process of the SBGH Research Review Committee (RRC) is to ensure that clinical research conducted at SBGH is adequately funded for any hospital resource utilisation; has received appropriate SBGH departmental approval; meets the applicable regulatory, ethical, and good clinical practice guidelines; and has received appropriate peer review. The Manitoba Personal Health Information Act (PHIA) stipulates that an institutional review committee is required to approve the disclosure of personal health information for research purposes.

To guide the review process, the RRC utilizes the **Food and Drugs Act Regulations** of Canada; **The Declaration of Helsinki (Scotland, 2000)**; **Good Clinical Practice: Consolidated Guideline, 1997** (adopted verbatim from the **International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use**) published by Health Canada; the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (1998)**; and the **Health Ethics Guide (2000)** of the Catholic Health Association of Canada. In addition, the RRC is responsible for ensuring that clinical research complies with the **Personal Health Information Act of Manitoba (PHIA)** and the **Mental Health Act of Manitoba**.

The Personal Health Information Act (Act 51) stipulates that an institutional research review committee is required to approve the disclosure of personal health information for research purposes. While the RRC recognises that the Research Ethics Boards have been vested with the responsibility to review research applications for PHIA compliance, the RRC retains responsibility for ensuring that compliance with this legislation is in place.

The Hospital, in collaboration with the Office of Clinical Research (OCR) and other qualified individuals/departments, will develop and facilitate education on the regulations, guidelines, standards, policies, and ethics requirements for the conduct of clinical research for staff, students, researchers, patients, families and members of the general public.

RESEARCH REVIEW COMMITTEE (RRC) - TERMS OF REFERENCE

AUTHORITY

The Board of the Hospital vests the RRC with the authority to approve, reject, propose modifications to, or terminate all proposed or ongoing research involving humans within the institution's jurisdiction on grounds of non-compliance with legislation, ethics guidelines, or resource feasibility considerations.

RESEARCH POLICY

1. The review and conduct of clinical research at St. Boniface General Hospital (the Hospital) must comply with the guidelines, standards, and regulations of the Health Canada Food and Drugs Act, Good Clinical Practice: Consolidated Guideline, the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, legislation pertaining to disclosure of personal health information, and the Catholic Health Association of Canada.
2. Ethical review is required for all research involving human subjects and encompasses both basic and applied research across varied disciplines (medicine, nursing, allied health). An extensive listing of the scope of research requiring ethical review is found in the Tri-Council Policy Statement - Appendix 1.
3. It is the role of the Research Review Committee (RRC) to ensure that all research projects conducted within the jurisdiction of the Hospital have undergone the appropriate review processes.
4. Clinical research must be conducted in accordance with the St. Boniface Hospital Clinical Research Standard Operating Procedures.

RESEARCH SUBJECT TO RRC REVIEW

SBGH Policy VI-360 states that all research involving humans which uses St. Boniface services, records, staff or patients must have the approval of the Research Review Committee (RRC). The definition of Research Involving Humans according to the policy is:

Research Involving Humans: As defined by the Tri-Council Policy Statement, Section I, Article 1.1 (a) research is "a systematic investigation to establish facts, principles or generalizable knowledge". Research carried out by anyone associated with St. Boniface whether financed by grants, contracts or gifts, budgeted funds of St. Boniface, or without specific financing, will be regarded under the terms of this policy as being research involving human subjects if:

- a human is subjected to procedures, the purpose of which go beyond the subject's need for prophylaxis, diagnosis or therapy

RESEARCH REVIEW COMMITTEE (RRC) - TERMS OF REFERENCE

- a human is subjected to procedures which are experimental but which do not necessarily go beyond the subject's need for prophylaxis, diagnosis or therapy
- procedures are used in which an invasion of privacy may be involved, for example, by examination of records, by interviews, by observations, by administration of a questionnaire or test, or by audio or video recording
- it includes any research involving human remains, cadavers, tissues, or biological fluids. St. Boniface will not sanction any research involving the use of embryos or foetuses/foetal tissue.

ACTIVITIES EXEMPT FROM RRC REVIEW

Internal St. Boniface information gathering activities undertaken for the purpose of evaluating choices, assessing client satisfaction, product or service enhancements are not considered research and do not require RRC review and approval. Information gathering activities are not considered research involving humans when they exhibit none of the criteria listed in the research involving humans definition above, and:

- the primary aim is to diagnose problems, identify appropriate solutions, provide advice for management, or assess performance.
- the data collected is primarily designed to affirm satisfaction with the status quo or is intended to be used to lead to quality improvements

THE RESEARCH REVIEW COMMITTEE PURPOSE

The Research Review Committee (RRC) is entrusted with the responsibility to review research proposals / protocols involving human subjects to be carried out at St. Boniface General Hospital in keeping with the Hospital's Research Policies and Standard Operating Procedures. The RRC will ensure that the review of research proposals is carried out in a timely and fair manner.

FUNCTION

The RRC will attend first and foremost to the dignity, safety, and interests of research subjects and prospective subjects.

The RRC will operate according to the guidelines, standards, and regulations of the Health Canada Food and Drugs Act; Good Clinical Practice: Consolidated Guideline; the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans; the Declaration of Helsinki; provincial legislation pertaining to disclosure of personal health information; and the Catholic Health Association of Canada.

The RRC will be responsible for ensuring that research protocols involving human subjects have received appropriate scientific/peer review, ethical review, resource utilisation / feasibility review, required approval from Health Canada, and comply with provincial legislation pertaining to personal health information.

RESEARCH REVIEW COMMITTEE (RRC) - TERMS OF REFERENCE

MEMBERSHIP

The RRC will consist of twelve (12) members:

- Chief Medical Officer
- Chief Nursing Officer
- Executive Director of Research,
- Chief Financial Officer,
- Research Pharmacist
- Representative from Medical Records,
- Representative from the Office of Clinical Research,
- Clinical Ethicist,
- Allied Health representative,
- Nursing Research representative,
- Clinical Research Nurse or Coordinator,
- Physician with expertise in clinical research (appointed by the Chief Medical Officer and the Chief Nursing Officer in consultation with appropriate Program Leaders and Department Heads)

The CEO will be an ex-officio member.

A Chair and Vice-Chair will be selected from the above members.

The RRC Chair is authorised to appoint other members with particular expertise if this is necessary or required for the proper review of protocols.

Appointed members will be rotated regularly with the intent that they will serve three (3) year terms, with not more than three members being changed on an annual basis.

Alternate RRC members replace regular RRC members who are unable to attend convened meetings of the RRC. Alternate members are listed on the membership list maintained in the RRC office and have qualifications comparable to the applicable regular member. The RRC list specifies which members the alternate is qualified to replace. Terms of appointment, length of service and duties are identical to regular RRC members. Alternates attending a meeting or conducting a protocol review have all the authority of regular RRC members and are provided the same training and protocol review application materials as the regular membership. The only exception is that if, the regular member and his/her alternate attended the same convened meeting, only one individual may vote. Individuals serving as alternates may be alternates for more than one RRC member.

Members of the RRC must avoid and declare individual and institutional conflicts of interest.

RESEARCH REVIEW COMMITTEE (RRC) - TERMS OF REFERENCE

CHAIRPERSON

The Chair of the RRC shall be appointed by the CEO in consultation with the CMO and CNO. The Chair will usually serve for a one year term, but is not limited to one year and may be re-appointed.

The RRC will appoint a Vice-Chair to assist with the work of the RRC. The Vice-Chair will assume the role of Chair if the Chairperson is unable to attend.

PROCESS

A copy of all research proposals, including budgets must be submitted to the Chair of the RRC. Members of the RRC will receive either a copy of the complete proposal or the application form not less than 5 days prior to scheduled meetings of the RRC.

The RRC will endeavour to operate by consensus. In reviewing proposals, the RRC may:

- approve a protocol without revision;
- approve a protocol pending revision(s);
- not approve a protocol.

If consensus cannot be reached following the review of a particular protocol, the matter will be resolved by a vote of the RRC members.

In the event that a protocol is not approved, the Principal Investigator(s) may have an opportunity to consult with the Chairperson of the RRC, or arrange to appear at a meeting of the RRC for consultation.

In the event that such consultation with the Principal Investigator does not resolve any outstanding issues, an independent review process that ensures fairness and due process has been established by the RRC. The independent review process shall consist of the Principal Investigator identifying a 3rd party reviewer of their choice to provide comments directly to the RRC. In addition, the RRC will identify a 3rd party reviewer to provide comments directly to the RRC. Both 3rd party reviewers will be provided with a copy of the supporting documentation submitted to the RRC. Comments may be in written form, via a telephone conference, or in person at the discretion of the RRC Chair.

Once the RRC membership has received and reviewed the comments from both 3rd party reviewers, a final decision will be made by consensus of the committee. This final decision will not be subject to any additional independent review processes. The Principal Investigator will be provided with copies of the reviewers' comments and the appeals committee comments (in an anonymous format) along with the final decision.

If a protocol has been reviewed by an external REB and there is a difference of opinion, the decision of the St. Boniface General Hospital RRC shall be binding for any research carried out at St. Boniface General Hospital.

RESEARCH REVIEW COMMITTEE (RRC) - TERMS OF REFERENCE

QUORUM

A quorum shall consist of the Chair/Vice-Chair and 50% plus 1 majority of the Core RRC membership.

Example: 1 Chair /Vice-Chair + 5 RRC Members + 1 = 7 total membership

If there is not a quorum of members, the meeting may still proceed provided:

- a total of 6 members (including Chair/Vice-Chair) are present and the Chair/ Vice-Chair determines there is enough expertise present to conduct the meeting,
- OR;
- a total of 5 members (including Chair/Vice-Chair) are present. The Chair/Vice-Chair must determine there is enough expertise present to conduct the meeting and review comments have been received from at least one absent member. Minutes, including discussion of the absent member(s) comments are to be circulated to the remainder of the members for their review. Decisions from the meeting will be considered approved once a quorum of members have reviewed and approved the minutes.

Decisions of the RRC will be communicated in writing to Principal Investigators by the Chair of the RRC.

EXPEDITED REVIEW

Expedited review for research access may be justified for Minimal Risk studies or where there are “unusual or compelling circumstances” to initiate the study prior to access to full RRC approval. Unusual or compelling circumstances would be considered, for instance, where no standard therapy exists and the patient is critically ill.

Minimal risk is defined as “the risks or harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance or routine physical or psychological examinations or tests.” (Freedman, Fuks and Weijer, Hastings Centre Report, 1993). Minimal risk to the subject must take into consideration physical risks, psychological risks, social risks, and economic risks.

All expedited reviews of any research study will be conducted by an RRC subcommittee consisting of the Chair or Co-Chair of the RRC, plus two additional members of the RRC. The subcommittee must review all documents submitted for expedited review. For clinical trial research one member of the subcommittee must have medical research experience. Individuals that may have direct or indirect involvement in the research project cannot serve on the subcommittee.

To be considered for expedited review, the subcommittee must ensure that the research protocol is:

RESEARCH REVIEW COMMITTEE (RRC) - TERMS OF REFERENCE

- scientifically sound
- that the study does not involve a vulnerable population
- that the study poses no more than minimal risk as outlined previously

and

that the following documents are provided for review:

- copy of REB approval letter
- copy of the REB approved consent form
- all required signatures on the submission forms parts A, B and C
- a copy of the study proposal/protocol.
- Health Canada letter of “no objection”
- a copy of any questionnaires to be used in the study
- the proposed study budget
- HIPC or other approvals as necessary
- Agreement for Access to Personal Health Information for Research Purposes

In addition, all necessary pharmacy and required laboratory systems and supports must be in place and all correspondence confirming operational issues such as inservice and staff education must have been addressed.

Any conditions that must be met before the study can be implemented will be noted in the response letter to the Principal Investigator. A copy of the approval letter for the study must be provided to the individuals responsible for the various departments impacted in the implementation of the study.

A copy of all submission documents and studies approved through expedited review must be provided to the full Research Review Committee at its next scheduled meeting. At that time, additional requests may be made and approval for the study to proceed may be amended by the Committee.

MEETINGS

The RRC shall meet no less than ten (10) times a year and minutes of proceedings will be maintained in the Office of Clinical Research.

REPORTING

The RRC will receive study enrolment numbers and progress twice annually from the Office of Clinical Research.

An annual report outlining the work of the RRC is to be prepared by the Committee and submitted to the Board of Directors through the CEO.