

ROUGE VALLEY HEALTH SYSTEM

ADMINISTRATIVE MANUAL

CATEGORY: RESEARCH

NUMBER: ADMIN-RE-40

SUBJECT: REB REVIEW PROCEDURES

DATE: 2006/06

REVISED: 2008/12

ISSUED BY: RESEARCH ETHICS BOARD

PAGE: 1 of 4

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PURPOSE

The purpose of the 'REB Review Procedures' policy is to provide a structure, system, process and procedure to ensure that the scientific, ethical, safety and privacy review is conducted by the Rouge Valley Health System (RVHS) Research Ethics Board (REB) prior to and during the conduct of clinical studies that impact the internal RVHS patient and staff populations, including but not limited to, admitted patients and outpatients visits in hospital clinics.

STANDARD

The RVHS REB acts in compliance with all laws, policies, standards and guidelines governing human research, which are applicable to a submitted research study, including but not limited to: the International Conference on Harmonization for Good Clinical Practice (ICH/GCP) Guidelines, as set forth in Part C Division 5 under the *Canadian Foods and Drugs Act*; the Tri-Council Policy Statement (TCPS), "Ethical Conduct For Research Involving Humans"; the Declaration of Helsinki; and the *Personal Health Information Protection Act* (PHIPA), in accordance with generally accepted clinical practices.

The TCPS sets forth standards for the conduct of research involving human subjects. The RVHS REB is responsible for overseeing the rights, welfare, protection and dignity of human subjects participating in research conducted at RVHS.

GUIDELINES

1. All research that involves human subjects or involves human remains, cadavers, tissues, biological fluids, embryos or fetuses and is conducted at RVHS, requires RVHS REB written approval before the study may commence (TCPS 1.1), except as specified below:
 - Program evaluation, quality assurance studies, performance review or testing within usual educational requirements (TCPS 1.1 d).
2. All investigators are required to submit proposals as outlined in the attached Table. Incomplete applications will not be processed.
3. All RVHS REB approvals are for one year, following full approval. Investigators are required to submit an Annual Report for projects that last longer than one year. An annual submission that is 8 weeks overdue will be interpreted to mean that the study is discontinued. The RVHS REB study file will be deemed closed.
4. A final report is required for all study projects, upon completion.

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5. The RVHS REB has adopted a proportionate approach to REB review as indicated in TCPS Article 1.6. Full review by the RVHS REB shall be the default requirements for all research involving human subjects, as follows:

Full REB Review:

- All new study applications, except research protocols that involve no more than minimal risk, as indicated in Expedited Review criteria.
- All major study amendments.
- All significant adverse events (SAEs) – Note, detailed reports regarding local SAEs must be submitted to the Chairperson within 7 days of the event. Delayed submissions will be investigated by the RVHS REB and actions will be taken accordingly.
- All annual renewals of approved projects.

Expedited Review:

The following reviews involve minimal risk and may be approved by (2) REB members as follows: the chair and the research manager OR the research manager and a designated member of the REB:

- Protocol revisions responding to conditional REB approval.
- Minimal risk interventions, such as education of RVHS employees, following departmental approval.
- Health Record Research (ie. secondary use of data), adhering to privacy legislation and following health record departmental approval.

Expedited approvals are reported to and considered for ratification at the next REB meeting, to enable the REB to maintain surveillance over the decisions made on its behalf (TCPS 1.6).

Departmental Review:

Ethics review of research that is conducted by undergraduate students, as part of their course work, is delegated to departmental level approval. The Department shall have written policies and procedures issued by the RVHS departmental approval process, and in compliance with TCPS Article 1.4. Departments are encouraged to consult with the Research Manager regarding research policy development.

6. When the REB is reviewing research in which a member of the REB has a personal interest in the research under review, conflict of interests principles obligate that the REB member not be present when the REB is discussing or making its decisions (TCPS Article 1.12).

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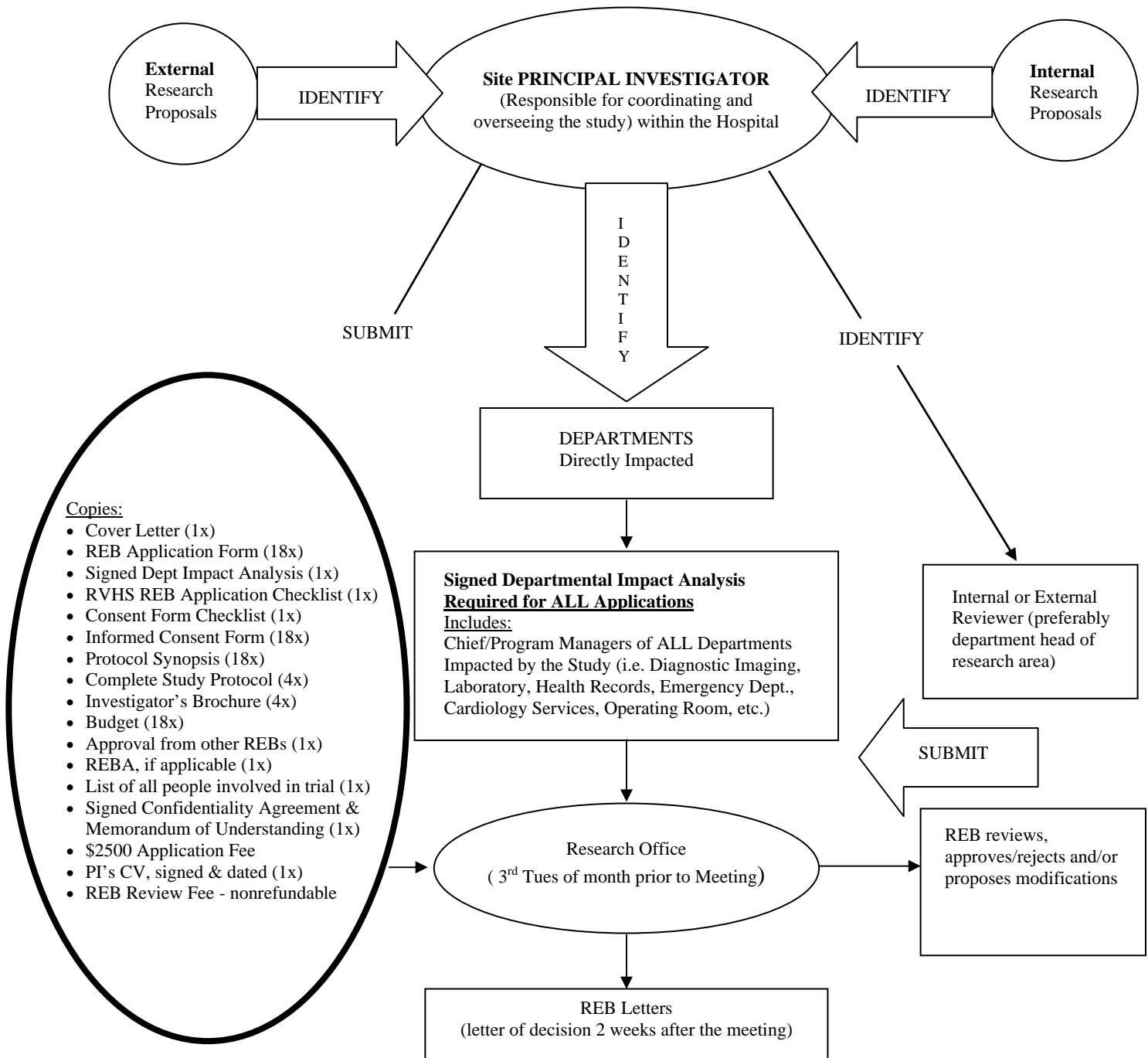
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Table: Research Ethics Board Application Process



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REFERENCES

1. Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada (2005). TRI-COUNCIL POLICY STATEMENT Ethical Conduct for Research Involving Humans, www.pre.ethics.gc.ca
2. www.wma.net

Reviewed by: Medical Advisory Steering Committee, (2005/12)
Executive Team, (2006/05)
VP Performance Improvement, Professional Practice & CNE, (2008/12)

Approved by: Board of Trustees –Quality Committee, (2006/06)
VP Performance Improvement, Professional Practice & CNE, (2008/12)