

INTRODUCTION

This document represents the abridged form of the Regulatory Framework for the conduct of Research at St. Mary's Hospital Center. The purpose of this document is to summarize the major guidelines that govern research ethics review, approval, and ongoing monitoring of studies taking place at St. Mary's Hospital Center, and to serve as a convenient tool to disseminate this information to St. Mary's Hospital Center researchers. The abridged version does not in any way constitute an exhaustive set of policies and procedures. Where applicable, reference is made to federal and provincial guidelines, as well as the appropriate chapter in the full version of the Regulatory Framework. The complete version of the Regulatory Framework is available for on-site consultation at the Research Review Office of the St. Mary's Research Centre. All questions related to this document, and/or to St. Mary's Hospital Center research ethics policies and procedures, may be directed to the Research Review Office (ext. 3698), or research.stmary@ssss.gouv.qc.ca.

RESEARCH ETHICS COMMITTEE

The Research Ethics Committee (REC) is an administrative body established to protect the rights and welfare of human subjects in research activities conducted under the auspices of St. Mary's Hospital Center. The Research Ethics Committee is under the authority of the Board of Directors of St. Mary's Hospital Center. REC policies and procedures are in keeping with provincial, federal, and international guidelines.

MANDATORY DECLARATION OF RESEARCH ACTIVITIES

As per Measure #3 of the *Plan d'action ministériel*, all researchers are obliged to **declare** to the Institution all of their research activities, those within St. Mary's as well as those conducted in other institutions including private clinics, and they are obliged to ensure that they are reviewed and approved according to scientific, financial, and ethical norms in practice. Furthermore, all research protocols that are either administered by St. Mary's, or conducted within the hospital, must be **registered** at St. Mary's, whether or not the principal investigator (PI) is a member of the hospital staff.

RESEARCH PROTOCOLS REQUIRING REVIEW

Under Article 2.1(a) of the Tri-Council Policy Statement (2010) (TCPS2), "***All research that involves living human subjects requires review and approval by an REB(Research Ethics Board)***". According to the same Article, "Research" is defined as 'an undertaking intended to extend the knowledge through a discipline inquiry or systematic investigation'. However, "***studies relating directly to assessing the performance of an organization or its employees or students, within the mandate of the organization or according to the terms and conditions of employment or training***" are excluded from review. Generally speaking, quality assurance protocols do not require research ethics review; however, this is not always the case. If in doubt about whether a project should be submitted for review, please consult with the Chair of the REC.

TYPES OF REVIEW

Depending on the type of research protocol, the review process may involve various steps in order to ensure that the study is in compliance with all accepted scientific, ethical, and administrative policies.

- **Scientific review** is required for all protocols involving human subjects in order to assure that the study has scientific merit. This requirement is waived for chart review studies and quality assessment studies, and other minimal risk studies not involving human subjects.
- **Human subjects review** is required for all protocols involving human subjects. These protocols require free and informed consent from study participants. It should be noted that, while the initial consent to participate is generally in writing, a subject may verbally withdraw from participation in research *at any time*. Please note that protocols involving access to medical records without the research subject's consent require authorization from the Vice President of Professional Services.
- **Expedited ethics review** may be applicable for protocols carrying minimal risk to human subjects, and protocols not involving human subjects. This decision is at the discretion of the Chair of the REC.
- **Protocols involving human drug trials must obtain**, in addition to REC approval, approval by the Therapeutic Products Directorate of Health Canada. The REC must thoroughly review and monitor essential aspects of a trial, including the presence of clinical equipoise, integrity of the free and informed consent process, potential conflicts of interest among researchers, use of placebo controls, and any restrictions placed on the analysis and dissemination of the study results.
- **Pharmacy review** is required for all protocols involving experimental drugs. These protocols should obtain the authorization of the St. Mary's Hospital Center Chief of Pharmacy. Experimental drugs in research should be subject to the same controls defined in sections 116 and 117 of *An Act respecting Health Services and Social Service*.
- **Protocols involving more than one site** may undergo a specialized review process. For protocols involving more than four sites in the *Réseau de la santé et des services sociaux*, specific provincial guidelines apply. For protocols involving only McGill-affiliated hospitals, it is the particular process indicated in the agreement with McGill that may undergo.
- **Financial review** is required for all protocols for which expenses are to be incurred at St. Mary's., which ensures that the budget information is reasonable, and the allocation of funds is not causing any potential conflict of interest with the Principal Investigator.
- **Legal review** is required for all protocols involving any type of contract. As per Ministry requirements, for all protocols funded by private industry, pertinent sections of the contract should be sent to the Research Ethics Committee for the purposes of reviewing any potential conflicts of interest.
- **Hospital resource review** is required for all protocols involving the use of St. Mary's Hospital Center resources (e.g. personnel, equipment, space). These protocols must obtain approval from the respective department heads before the protocols can receive full institutional approval.

MANAGEMENT OF RESEARCH SUBJECT COMPLAINTS AND CASES OF RESEARCH MISCONDUCT

Any complaints related to care and services received or ought to have been received by a research subject or related to a physician, dentist or pharmacist involved in research projects are forwarded directly to St. Mary's Ombudsman, who will handle all complaints as per the User Complaint Examination Procedure by-law of St. Mary's Hospital Center. The application through the Regulatory Framework will respect MSSS guidelines for management of complaints related to research. Cases of research misconduct can be treated via the institution's user complaint process (i.e. St. Mary's Ombudsman).

MANAGEMENT OF DATA BANKS AND RESEARCH FILES

All researchers who wish to access existing databases containing personal and confidential patient information, or who wish to create new data banks with such patient information, must submit their request as a research proposal to the REC. The proposal should include measures on the type of data to be collected, how and for what purpose will the data be used, and how patient information will be secured to ensure the protection of the patients' confidentiality, including details on obtaining the participant's free and informed consent to have access to her/his medical information.

MANAGEMENT OF CONFLICT OF INTERESTS, DOUBLE REMUNERATION, AND INCORPORATION OF RESEARCHERS

Under Article 7.3 & 7.4 of the TCPS2, "**Researchers and REB members shall disclose actual, perceived or potential conflicts of interest to the REB**". *To identify and address conflicts properly, REC should be provided with details on the research project, budgets, commercial interests, consultative relationships and other relevant information.* The Research Ethics Committee must verify whether or not the researcher has any potential conflicts of interests in the research study.

FINANCIAL MANAGEMENT OF RESEARCH

Financial review, approval, and monitoring of research protocols ensure that research-related expenditures are properly identified and not charged to the Hospital's global budget. They also ensure that sound financial management principles are applied to all authorized research at St. Mary's Hospital Center, and that investigators fulfill their responsibilities for proper reporting of research expenditures. A detailed budget must accompany any protocol submitted to the Research Review Office if expenses are to be incurred at St. Mary's Hospital Center.

The Ministry outlines the required overhead contributions from "private enterprise (non-governmental)" with respect to contractual research activities undertaken at hospital centers and research institutes. The current overhead charge is 30%.

Current charges for the review of industry-funded protocols will be invoiced to the Sponsor.

*The full version of the Regulatory Framework is available at the Research Review Office (RRO)