MARKHAM STOUFFVILLE HOSPITAL CORPORATION	**Research Administrative Fees and Processes**
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PURPOSE AND SCOPE:
The purpose of the 'Research Administrative Fees' policy is to provide a structure, system, process and procedure to:

- Recover all hospital costs incurred during the conduct of clinical research studies (including, but not limited to, recovery of fees for specific services of the hospital and the cost of research administration).
- Ensure that the research administration recovery fees/processes comply with applicable legislation and regulations.

POLICY STATEMENT(S):
The MSH 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 Pact C Division 5 under the Canadian Food and Drugs Act, the Tri-Council Policy Statement (TCPS2), "Ethical Conduct For Research Involving Humans"; the Declaration of Helsinki; and the Personal Health Information Protection Act (PHIPA), 2004, in accordance with generally accepted clinical practices.

The TCPS2 sets forth standards for the conduct of research involving human subjects. The MSH REB is responsible for overseeing the rights, welfare, protection and dignity of human subjects participating in research conducted at MSH.

PROCEDURES:
1. MSH is supportive of clinicians who wish to participate in research involving human subjects.

2. "REBs shall ensure clinical trial budgets are reviewed to ensure that conflicts of interest are identified and minimized, or otherwise managed," (Article 11.11).

3. The clinical fees for specific services of the Institution associated with the Study (including the local REB costs) will be invoiced by the office of research on a quarterly basis until study completion. For chart review studies, the Principal Investigator or delegate will be invoiced according to the Study Cost Estimate Form – Health Records.

5. The office of research will recover for all hospital costs, including the cost of research administration.

6. For all clinical trials, a copy of the Clinical Trial Agreement (CTA) shall be provided to the office of research prior to submission of the Research Ethics Board Application for review and revision, if required.

7. The MSH REB Application Fee for all *Industry sponsored or supported studies* is $3,000.00

   The Initial Application fee includes but is not limited to, the following services:
   - Legal review of the CTA (2 hours)
   - MSH negotiations with the Sponsor (1 hour), Independent Clinical Research Organization, Site PI and Study Coordinator
   - MSH review/revisions to the CTA (2 hours)
   - CTA budget review
   - Departmental review for Budget Impact (2 hours)
   - Facilitation & co-ordination of REB submissions
   - Review by an Ethicist (1 hour)
   - Review, critique and approval/proposed modifications/termination of REB submissions
   - REB correspondence regarding REB submissions
   - Office/Clerical services
   - Note: Fees for delegated reviews will be determined upon submission

   The fee for a Major Amendment Review is:
   $500.00

8. The REB Application Fee is due at the time of the REB application and is non-refundable.

9. Unpaid invoices and MSH payee terms negotiated with a Site Principal Investigator that are overdue by 60 days, or failure to recover for hospital costs could result in termination of clinical trials.

10. Fees will be reviewed annually and adjusted as may be required to reflect the costs of professional services or the cost of hospital resources for management and ongoing evaluation of Clinical Trials.

11. National Research Organizations (i.e., CIHI, ICES, etc.) who submit grant sponsored clinical trials, may request a waiver of the REB application fee in writing and include with the original REB application submission. The MSH REB may approve the request if operational resources are in place to support the conduct of the study.

12. An annual report is required for all projects that last longer than one year (TCPS2, Article 6.14), and a final report must be submitted upon completion of the study.

DEFINITION(S):
Not Applicable.

REFERENCE(S):
1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. www.pre.ethics.gc.ca
2. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guideline for Good Clinical Practice. www.ich.org
3. The Personal Health Information Protection Act. www.ipc.on.ca

RELATED DOCUMENTS:
Not Applicable.

RESPONSIBILITY:

Required Endorsements	Sponsor	Approval Authority
	Manager, Office of Research	Research Ethics Board (REB)

DOCUMENT HISTORY:

Type	Individual/Committee	Date	Outcome
Draft	Research Ethics Board	23/07/2018	New Document; Approved

APPENDICES:
Appendix A: Study Cost Estimate Form – Health Records

RESEARCH ETHICS BOARD

Appendix A: Study Cost Estimate Form – Health Records

This form must be completed by the Medical Records Department when costs are generated.

MSH Local Principal Investigator:
Full Title of Study:

The Principle Investigator is responsible for ensuring that all Departments impacted by the study have been properly informed by sending a copy of the protocol to the appropriate Director of the appropriate Corporate or Clinical Department. This form must be signed by both the investigator and the Director of the Department whether costs will be incurred or not. This ensures that the MSH Research Ethics Board is informed that the proposed impacted department has been notified, have agreed, and have the resources required to carry out the study.

Services	Estimated Cost
Materials	$ .00
Labour	$ .00
Off-Setting Savings	$ .00
Administrative Fees (includes cost of initial report writing if needed)	$ 250.00
Total Fixed costs	$ 250.00
Off Site Chart Retrieval Cost – $ 32 per chart	□ Applicable or □ Not Applicable # of Charts x 32 = $
Charts of Microfilm - $ 5.00 per chart	# of Charts x 5 = $
Photocopying – ($ 2.50 per page)	# of pages X 2.50 = $
Total Cost plus GST	
Training to access on line charts (up to 2hrs.)	$ 100.00
Estimated Total Cost	$ .00

The Health Records department is prepared to absorb _____% of the estimated cost of this study.
Note: Any additional costs generated by the study will be assumed by the investigator.

Additional Notes: (Between investigator(s) and Health Records department)

Print Name MSH Local Investigator:	Signature of MSH Local Investigator:	Date
Print Name Medical Records Department Director/Delegate	Signature of Same	Date