

ADMINISTRATIVE MANUAL

CATEGORY: RESEARCH

SUBJECT: RESEARCH OFFICE FEES

DATE:

REVISED:

ISSUED BY: RESEARCH ADMINISTRATION

PAGE:

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PURPOSE

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.

STANDARD

The Research Ethics Board (REB) for Scarborough and Rouge Hospital (SRH) acts in compliance with all legislation, 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 Food and Drugs Act; the Tri-Council Policy Statement (TCPS 2), '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. SRH REB is responsible for overseeing the rights, welfare, protection and dignity of human subjects participating in research conducted at SRH.

GUIDELINES

- SRH is supportive of clinicians who wish to participate in research involving human subjects.
The role of the SRH REB is to 'approve, reject, propose modification to, or terminate any proposed or ongoing research involving human subjects which is conducted within, or by members of the institution' (Article 1.2).
'REBs shall examine the budgets of clinical trials to assure that ethical duties concerning conflict of interest are respected' (Article 1.3).
The clinical fees for specific services of the Institution associated with the Study (including the local REB costs) will be invoiced on the 10th day of January, April, July, and October on a consecutive basis until study completion to cover the specified costs and expenses of the Institution for the conduct of the Study. For chart review studies, the Principal Investigator or delegate will be invoiced based on the current fees charged by health records. Payee agrees to pay the clinical fees and/or health records fees within 30 days of receipt of invoice.
Research administration will recover for ALL hospital costs, including the cost of research administration, as

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stated in TCPS 2 Article 7.3: **“Recovery of utilization costs for institutional and other resources (such as radiological and diagnostic services) should be considered essential, and should be in addition to any overhead charge stipulated by the institution”** (Article 7.3).

6. The Initial REB Application fee includes but is not limited to, the following services:
 - o Legal review of the CTA (2 hours)
 - o SRH negotiations with the Sponsor (1 hour), Independent Clinical Research
 - Organization, Site PI and Study Coordinator
 - o SRH review/revisions to the CTA (2 hours)
 - o CTA budget review
 - o Departmental review for Budget Impact (2 hours)
 - o Facilitation & co-ordination of REB submissions
 - o Review by a Clinical Bioethicist (1 hour)
 - o Review, critique and approval/proposed modifications/termination of REB submissions
 - o REB correspondence regarding REB submissions
 - o Office/Clerical services

7. The REB Application Fee is due at the time of the REB application and is non-refundable. The REB Application fee is for any application submitted to the REB for review, regardless of whether the review is done by full or delegated board. This fee assists in covering the overhead costs of the REB.

8. **FMTU Resident studies** will not be charged REB fees and will not require a Fee waiver.

9. **Self-funded studies and studies sponsored by national research organizations grants** (ie. CIHI, ICES, etc.) may request a waiver of the REB application fee in writing and include with the original REB application submission. The SRH REB will approve the request if operational resources are in place to support the conduct of the study. Grant sponsored studies that do not have fee waiver approval, will be charged a lesser fee than third party or industry sponsored studies.

10. Any study requiring a major amendment after it has received previous REB approval will be subject to a Major Amendment Review fee. Major amendment includes significant changes to the protocol, consent forms or investigator brochure. This is at the discretion of the research manager.

11. Studies that require adding of additional staff after REB application receives initial approval will be charged a credentialing fee per person. Credentialing involves ensuring the person has necessary access to SRH systems and has completed the appropriate requirements such as confidentiality for such access.

12. Unpaid invoices and SRH 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.**

13. SRH Research Administration will invoice additional hourly charges to the Site Principal Investigator, if a Clinical Trial Agreement requires greater than 1 hour of detailed scrutiny by Legal Counsel.

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- 14. Incomplete applications will delay approval and result in increased Research Administration costs thus a further fee will be applied (using standard interest formulae) and/or the trial will be terminated.
- 15. **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.**
- 16. The SRH REB will review only the studies that impact the internal SRH patient population, including but not limited to, admitted patients and outpatient visits in hospital clinics. Study protocols that are solely conducted in individual physician’s practices will not be eligible for review by SRH REB.
- 17. Research Administration Fee list is attached as Appendix A. Please note that the fees are subject to change, please contact the SRH Research office for up to date pricing.
- 18. For all clinical trials, an electronic copy of the Clinical Trial Agreement (CTA) shall be emailed to the Research Manager prior to submission of the Research Ethics Board Application for review and revision, if required.

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: Senior Leadership Team

Approved by: Board of Directors

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Appendix A

| Description | SRH |
|--|---------|
| REB application: | |
| Industry or 3 rd Party Funded | \$ 2500 |
| Grant funded studies | \$ 1500 |
| Major Amendments | \$ 250 |
| Credentialing | \$ 100 |
| Overhead fees/IA | 30% |
| | |
| | |
| | |

All fees are subject to change without notice

** Current health records fees are available from SRH health records department.

