

SOP: GA 106 Version No: 1 Effective Date: 01/01/07	IRB REVIEW FEES	Supersedes Document: None
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1. PURPOSE

The purpose of this policy is to define the guidelines for payment of fees by sponsors for review of research projects by the Institutional Review Board (IRB). This policy covers all areas within the Sparrow Health System for which the IRB has authority or designated responsibility for the conduct of research involving human subjects.

2. POLICY

Payment of the IRB Review fees is regarded as a contractual responsibility of between the investigator and the sponsor. The investigator has the responsibility to inform sponsors of these fees, and establish the sponsor's responsibility to pay these fees upon being invoiced. Investigators and sponsors should be aware that these fees are due even if, after complete review, the IRB does not approve the study. Because the IRB commits its full resources to each review, the fees are due in full from the sponsor, even if subjects are never enrolled, the study is terminated before objectives are reached, or a contract is never finalized.

The IRB fees have been given careful consideration and are consistent with fees charged at other institutions.

The IRB will use these fees to:

- Off-set some of the administrative costs associated with increasing regulatory and related staffing requirements.
- Provide continuing education and training to IRB members and investigators with respect to federal regulations and ethical guidelines for conducting research involving human subjects.
- Offer nominal grants to be awarded to resident-physicians for financial assistance in conducting research.

The IRB Review fees apply to all clinical research projects conducted at authorized Sparrow Health System facilities, except institution-supported and research determined to be Exempt from Full IRB Review under federal regulations and IRB policies. The IRB reserves the right to waive fees. A Waiver of Fees will be considered in a case-by-case basis for unfunded studies with a letter from the investigator justifying the waiver.

3. GUIDELINES

- A. The IRB will charge investigators as follows:
- a. the sum of \$1500 or such other amount it shall deem appropriate for initial review of all protocols.
 - b. the sum of \$500 or such other amount it shall deem appropriate for annual / continuing review of all protocols for the duration of the project(s).
 - c. the sum of \$500 or such other amount it shall deem appropriate for revisions / amendments to the existing protocol, consent form or other study documents.

- B. Those investigators who have not received a Waiver of the IRB Review Fee shall be responsible for payment to the IRB at the time of submission of a new protocol. Payments will be due thirty (30) days from receipt of the application by the OROC (Office of Research Oversight and Compliance).
- C. In the event an investigator fails to pay these fees in a timely fashion, the IRB may disqualify an investigator from submission of further applications until reimbursement for review is made.
- D. The research application will be considered incomplete and the IRB determination letter will not be issued until payment is received in full.

There may be other indirect costs associated with the research not covered by these administrative fees.

4. SCOPE

These policies and procedures apply to Sparrow Health System’s designated research community.

5. RESPONSIBILITY

The IRB Administrator is responsible for reviewing submissions to determine applicability for IRB Review fees, initiating invoices to investigators for industry-sponsored or other for-profit entity sponsored research submissions, and processing payments according to institutional guidelines.

IRB Administrator and IRB Chair, or his designee, will be responsible for waiving IRB fees, when determined to be appropriate.

6. APPLICABLE FEDERAL REGULATIONS AND GUIDELINES

None

7. REFERENCES TO OTHER APPLICABLE IRB SOPs

This SOP affects all other IRB SOPs.

8. ATTACHMENTS

GA 106-A (Invoice/Receipt)

9. PROCESS OVERVIEW

The Standard Operating Policies and Procedures (SOPs) will be reviewed on a yearly basis. New regulations will be incorporated into existing SOPs, when appropriate, or a new SOP will be written.

The IRB Administrator, the institution’s signatory official, and the office of Corporate Compliance, will jointly review the fees and policy annually.

10. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Administrator</i>	Review research submissions for applicability (e.g. industry-sponsored or other for-profit entity sponsor)	
<i>IRB Chairperson or designee</i>	Make determination on waiving IRB fees.	

<i>IRB Administrator</i>	<p>If the study qualifies for IRB Review fees, the IRB Administrator will initiate an invoice to be sent to the investigator. The invoice will include 1) research study title, 2) the IRB project number, 3) the investigator's name, 4) the sponsor, 5) date project received, 6) type of review, 7) the assessed fee, 8) terms, and 9) procedure for payment.</p> <p>Checks shall be made payable to Sparrow Hospital, and remitted to the OROC.</p>	
<i>IRB Coordinator</i>	Initiate invoice to investigator for applicable review.	GA 106-A (Invoice)
<i>IRB Administrator</i>	Upon receipt of payment, the IRB Administrator shall provide the investigator with a receipt which documents the date payment was received, and will include 1) the IRB project number and protocol title, 2) type of review, 3) date the study is scheduled for IRB review, and 3) the amount of the payment received.	GA 106-A (Receipt)
<i>IRB Administrator</i>	Track billing and deposit payment of IRB fees through institution accounting department. Monitor and administer special account (for continuing education and resident grants).	
<i>IRB Administrator and IRB Chairperson or designee</i>	Award nominal (\$100-\$500) grants for resident-driven research, if funds available.	
<i>IRB Administrator</i>	Update policy and archive hard copies of previous policy.	
<i>Institutional Official (Signatory Official)</i>	Sign revised policy, if appropriate.	