

**Metro Health  
IRB Fees and Invoicing**

|                      |                   |                             |            |                      |              |
|----------------------|-------------------|-----------------------------|------------|----------------------|--------------|
| <b>Section</b>       | Clinical Research | <b>Former Policy Number</b> | None       | <b>Policy Number</b> | CR(HRP) D130 |
| <b>Original Date</b> | 06/01/2010        | <b>Effective Date</b>       | 06/01/2010 | <b>Next Review</b>   | 06/01/2013   |

**Δ Indicates Change**

**Policy:** This Policy is implemented to support the Human Research Protection Program at Metro Health Hospital.

**Purpose:** The purpose of this policy is to describe the fee structure and invoicing process for charges incurred as a result of research review activities performed by the Metro Health IRB.

**Scope:** All Metro Health Hospital and Metro Health Enterprise employees, medical staff and other individuals who are engaged in funded human subject research and to all members of the Metro Health IRB (including full and alternate members), all staff members supporting the IRB, and others who may interact with the MH IRB to contribute to the review of human research activities

**General:**

**I. Fee Schedule**

The Metro Health Office of the IRB will invoice for services rendered for review of human research proposals in accordance with the following fee schedule:

|                   | <b>Initial Review</b> | <b>Annual Continuing Review</b> | <b>Revisions/ Amendments/ Adverse Events</b> |
|-------------------|-----------------------|---------------------------------|--|
| <b>Full Board</b> | <b>\$ 2,000</b>       | <b>\$ 750</b>                   | <b>\$ 500</b>                                |
| <b>Expedited</b>  | <b>\$ 1,500</b>       | <b>\$ 500</b>                   | <b>\$ 500</b>                                |
| <b>Exempt</b>     | <b>\$ 500</b>         | <b>\$ 0</b>                     | <b>\$ 0</b>                                  |

**II. Process**

- A. The Metro Health Office of the IRB will invoice a fee for all industry sponsored study submissions, continuing review submissions and modifications to previously approved research as follows:
  - 1. Initial Submission: Full Board Review: \$2000.00
  - 2. Initial Submission: Expedited Review: \$1500.00
  - 3. Continuing Review: Full Board Review: \$750.00
  - 4. Continuing Review: Expedited Review: \$500.00
  - 5. Modifications to Previously Approved Research: \$500.00
  - 6. New Information (unanticipated problems/adverse events): \$500.00
  - 7. Exempt Determinations: \$500.00
- B. Fees will be charged following each fully convened monthly IRB meeting where approval was granted.
- C. Payment will be due within forty-five (45) days of invoicing study sponsor, contract resource organization (CRO) or funding source.
- D. Fees for continuing review will be invoiced annually until a study completion form is submitted to the Office of the IRB.
- E. The Principal Investigator (PI) is responsible for ensuring all contracts with research sponsor(s) describe the applicable Metro Health IRB fees. The Metro

Health Office of the IRB will notify the PI if sponsor payment is not received within allotted time to solicit his/her participation in negotiation of payment.

- F. Payment of IRB fees is the contractual responsibility of the study sponsor and is not considered to be a part of the final study budget unless explicitly stated as a line item within the budget. IRB fees are assessments of actual costs resulting from IRB resources and services rendered during the review of the research submission. Fees are due in full even when the IRB review does not result in approval, subjects are not enrolled into the study or the study is terminated before the objectives are achieved.
- G. The Director of Research has the flexibility to alter or waive IRB fees in extenuating circumstances. This determination will be documented and submitted to the Office of the IRB.

**Materials** Metro Health W-9

**References** None

**Related Metro Health Policy** None

**Input/Review** Metro Health Risk and Compliance  
Metro Health General Counsel

**Issued By** Clinical Research Department

**Approving Committee(s)**      None \_\_\_\_\_ Committee(s) \_\_\_\_\_ Date \_\_\_\_\_

**Director or VP Approval** \_\_\_\_\_ **TYPE:** Carmen Heaney, RN, BSN, CCRC, CIP  
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