

# NHRMC Research Fee Schedule

**IRB Fees for all Funded Studies** (Please contact the research dept if you have questions about what constitutes a funded study)

## **IRB Initial Review: \$2,500.00**

This fee includes initial review of the following documents:

- Application
- Informed Consent
- Protocol
- Investigator Brochure
- Recruitment Materials
- Correspondence from the Board

## **Continuing Annual Review: \$1,000.00**

This fee includes annual renewal (if the Board determines the study needs to be reviewed at different intervals due to the risk or nature of the study, the fee is **\$1000/each renewal**). The following documents are reviewed:

- Annual Renewal Report
- Request for Renewal
- Safety Issues (Serious Adverse Events[SAE], DSMB reports, etc)
- Correspondence from the Board

## **Amendments and Updates: \$250**

- Protocol and/or Informed Consent Amendments
- Correspondence from the Board

## **Commercial IRB (Western IRB [WIRB]) Review:**

See WIRB fee schedule (contact Research Finance Coordinator).

An additional one time preparation fee of **\$1000** will be paid to the NHRMC Research office for: Reviewing informed consents for NHRMC HIPAA and compliance language, periodic audits of WIRB activity, and serving as the site contact for ongoing communication.

An Agreement has been implemented between WIRB and NHRMC; no other commercial IRBs may be used for Industry sponsored studies.

## **NHRMC Research Regulatory Fees**

### **Preparation for IRB Submission: \$1000**

- Preparing the IRB application
- Preparing the Informed Consent, if applicable
- Collecting CVs and Financial Disclosures
- Obtaining signatures
- Setting up regulatory binders and other study related material for start-up

### **Continuing Annual Review: \$500.00**

- Preparing the Annual Renewal documents for IRB review
- Collecting data on research activity from the CTMS and Study Coordinators
- Obtaining signatures

### **Amendments and Updates: \$100**

- Preparing IRB documents to report Protocol and/or Informed Consent Updates or Amendments
- Obtaining signatures

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## Administrative Fees

### **Start-up Fee: \$4000**

This fee includes Contract Preparation and Operational/Study Logistics Planning

### **Contract Preparation:**

- Review and revisions to the Agreement
- National Coverage Determination (NCD)
- ProForma and Budget negotiations
- Internal reviews and approvals (Legal Affairs and/or Compliance may be consulted if needed)
- Obtaining signatures and executing the Agreement
- EPIC Research billing build (need CPT, ICD, EAP and Charge Master) and ongoing oversight to ensure compliant research billing per CMS guidelines, including internal audits

### **Study Logistics Planning:**

- Distribute study information to departments to determine operational and financial feasibility
- Meetings with department manager or designee to plan and establish study charges
- Communication and training for departmental staff
- Departmental billing for research services
- Epic/EMR build (i.e.: IND in Willow and study specific order sets where applicable)
- Storage and Inventory of Investigational Drug or Device and study material (lab kits, dry ice)

### **Department Set-up fees: Range \$1000-\$1500** (depending on the complexity of the study)

This fee includes reviewing protocols for feasibility at the department level and for services provided (i.e.: Laboratory, Pharmacy, etc). Additional fee per item/task may be charged depending on the study

### **Contract Amendments:** \$100

### **Record Retention:** \$500 (may be more if greater than required by Federal Regulations)

### **Close Out Fees:** \$500

**Note:** Additional fees may be requested for query resolution, monitor site visits and research training. Fringe benefits must be included in calculations for staff time and effort to perform research services.

### **Fringe Benefit Rate is 35%**

### **Indirect Cost Rate is 28%** (overhead costs including space, lights, use of equipment)

**Biostatistician Fees** will be determined on a case by case basis

Documentation of NHRMC IRB actions will not be provided for studies with outstanding balances.

Please make your check payable to **New Hanover Regional Medical Center** and remit to:

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NHRMC Research Finance Coordinator  
SEAHEC  
2511 Delaney Avenue  
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