POLICY AND PROCEDURE MANUAL

PBRC		**POLICY NO. 106.00**
Section:	**GENERAL**	**Effective Date: 03/17/2009**
Subject:	**GOOD CLINICAL PRACTICE TRAINING**	**Review:**
Source:	**EXECUTIVE DIRECTOR**	**Revision:** **Revised**

PURPOSE

It is the purpose of this policy to provide guidance for the education and training on good clinical practices (GCP) to all personnel that interface with research participants, research participant biological specimens, or research participant data. This includes but is not limited to the following: PI / faculty, outpatient clinic, inpatient clinic, imaging, research kitchen, exercise testing, clinical chemistry, stable isotope, exercise intervention staff, students, graduate students, post-docs and instructors, and visiting scholars. Basic scientists who have access to clinical data or specimens are also included.

RESPONSIBILITY

All PBRC employees that are involved with clinical trials research involving human volunteers are required to complete the Good Clinical Practices training module annually.

AUTHORITY

The Executive Director is responsible for ensuring that all employees have completed their GCP training on an annual basis. This authority may be delegated to a member of the Quality Improvement Committee.

SCOPE

The Pennington Biomedical Research Center is a member of the Collaborative Institutional Training Initiative Group and participates in a web-based GCP training program.

Modules included in the GCP training include the following:

1. GCP Introduction
2. Overview of New Drug Development
3. International Conference on Harmonization (ICH)
4. FDA Regulated Research and ICH

5. Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices
6. Investigator Obligations in FDA-Regulated Clinical Research
7. Managing Investigational Agents According to GCP Requirements
8. Conducting Clinical Trials of Medical Devices
9. Informed Consent: An Ongoing Process
10. Detection and Evaluation of Adverse Events
11. Reporting Serious Adverse Events
12. Monitoring of Clinical Trials by Industry Sponsors
13. Audits and Inspections in Clinical Trials