POLICY AND PROCEDURE MANUAL

PBRC	POLICY NO. 381.00	ORIGIN DATE: 10/1/2017
IMPACTS:	CLINICAL RESEARCH	LAST REVISED: 7/1/2018
SUBJECT:	PROCEDURES FOR ESTABLISHING MEDICAL OVERSIGHT OF RESEARCH	EFFECTIVE: 10/1/2017
SOURCE:	Office of the Executive Director	VERSION No. 2

PURPOSE

To formalize procedures for establishing medical oversight of research.

POLICY

Medical oversight is defined as having a Pennington Biomedical or other study designated physician named as Medical Investigator (MI) on the protocol. Medical oversight of drug/device studies and studies that are greater than minimal risk is required. Similarly, medical oversight is required for interpretation of medical tests, such as interpretation of clinical chemistry values, including pregnancy tests. All NIH-sponsored studies and any other study that collects adverse events requires an MI who is a physician. This is also required by ICH Good Clinical Practices.

Determination of the need for medical oversight will occur when the budget request is routed for the project through Sponsored Projects. Additionally, the IRB can require medical oversight over and above this policy. Specifically, the following checklist will be added to the Clinical Study Information Form that is used when routing a budget:

Is this a drug/device study or is the study greater than minimal risk? *Yes / No*

If Yes, medical oversight is needed.

Is this study using imaging devices (i.e. MRI, CT, DEXA)? *Yes/No*

If Yes, medical oversight is needed.

Is this study collecting adverse events? *Yes/No*

If Yes, medical oversight is needed.

Does this study require medical laboratory tests that need to be interpreted by a physician of record or other legally authorized medical professional ordering the test such as clinical chemistry values or pregnancy tests? *Yes / No*

If Yes, medical oversight is needed.

Is the study an ancillary or sub study to another main study in which an MI is required? *Yes / No*
If yes, medical oversight needed. Unless there are compelling circumstances, MI of main study must be assigned to the ancillary or sub study.

OVERSIGHT

The Executive Director and/or his or her designee will oversee this policy.

PENNINGTON BIOMEDICAL RESEARCH CENTER LSU

Policy Committee Secretary's Attestation

Date of Policy Committee Meeting: Approved by expedited email review 7/18/18

Policy #: 381.00 - Procedures for Establishing Medical Oversight of Research

Date of Approval: 7/18/2018

Publication Date: 718/2018

Effective Date: 7/1/2018

Anne Duke
Anne Duke, Policy Committee Secretary

7/18/18
Date

Approval by the Executive Director

John Kirwan, PhD
Executive Director

7/30/18
Date