PENNINGTON BIOMEDICAL RESEARCH CENTER
LSU

DATE: April 4, 2018

MEMORANDUM FOR: Pennington Biomedical Investigators & Research Staff

FROM: Paula Rhode Brantley, Ph.D.
Chair, Institutional Review Board

SUBJECT: Research with Human Subjects

The Pennington Biomedical Research Center's Human Research Protection Program (HRPP) is committed to protecting the rights and welfare of human subjects. The Pennington Biomedical Institutional Review Board (IRB) must review all human research proposed by any employee of PBRC or any individual specifically authorized to conduct human subjects research on behalf of the institution. This requirement is based upon our assurance given to the U.S. Department of Health and Human Services that the institution follows the ethical principles of the Belmont Report for all human research as well as the legal requirements of the Code of Federal Regulations, Title 45, Part 46 for human research conducted or supported by any U.S. federal department or agency adopting the "Common Rule."

Investigator Responsibilities

Investigators can not commence research until IRB approval and any other required prior approvals (e.g., biosafety approval; departments or divisions that require approval of the use of their resources) are in place. Investigators are also responsible for ongoing requirements in the conduct of approved research that include, in summary:

- obtaining and documenting informed consent of subjects or subjects' legally authorized representatives prior to the subjects' participation in the research, unless these requirements have been waived by the IRB;
- obtaining prior approval from the IRB for any modifications of the previously approved research, including modifications to the informed consent process and document;
- ensuring that requests for continuing review and notification of study completion (final report) are submitted to the IRB;
- promptly reporting to the IRB any unanticipated problems involving risks to subjects or others and/or reports of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB.

Investigators are obligated to ensure that all members of the research staff engaged in human research are qualified and provide evidence of their understanding of the federal rules and regulations as well as of the Pennington Biomedical policies and procedures concerning research with human subjects. In addition, the release of funds, whether from external or internal sponsors, that support a PI's or co-investigator's research with human subjects, requires similar evidence. For students engaged in research with human subjects, both the student and his or her faculty advisor should provide the required evidence.

Failure to follow the policies and procedures governing research with human subjects can lead to suspension and termination of research and/or the suspension of federal funds.

How to determine if your activity is "Research with Human Subjects"

Activities that are not human research (e.g., scholarly and journalistic activities such as oral history, journalism, biography, literary criticism, legal research, and historical scholarship; educational activities such as class projects not intended for use outside of the course; quality improvement limited in application to the project's immediate setting; case reports) do not require IRB review. If there is uncertainty about whether a proposed activity meets the regulatory definitions of "research" with "human subjects" you can contact the IRB office, visit the HRPP website for Guidance on Determining Which Activities Require IRB Review (http://www.pbrc.edu/hrpp/guidance/) or submit a "Not Human Subjects Research" request through PBRC IRB's electronic management system, IRBManager.

Training

Pennington Biomedical has contracted with the Collaborative Institutional Training Initiative (CITI) Program to provide online human research training. All PBRC investigators and research staff who are engaged in research with human subjects are required to complete the appropriate CITI training course every three (3) years and have a valid CITI completion certificate as confirmation prior to conducting any research. The CITI modules span a variety of areas including the assessment of risk, informed consent, and research involving vulnerable populations such as children or prisoners. The required modules can be completed in more than one sitting at the researcher's convenience. Previous coursework from another institution that is not commensurate with PBRC requirements will not be accepted. In some cases, previous coursework will transfer after the researcher completes steps in CITI to add affiliation with Pennington Biomedical Research Center.

For the Regulatory Compliance Training policy or step-by-step CITI training requirements and instructions, visit the HRPP website at: http://www.pbrc.edu/hrpp/requirements/

Contacts

For questions concerning the PBRC IRB, human research protections or human research training, contact Shemetra Owens, HRPP Director, at 225.763.2693 or shemetra.owens@pbrc.edu or irb@pbrc.edu.

All PBRC HRPP/IRB Resources are located on the HRPP website at: http://www.pbrc.edu/hrpp/.

The direct links for all HRPP Policies and IRB forms and instructions can be found at: http://www.pbrc.edu/hrpp/policies/ and http://www.pbrc.edu/hrpp/forms/.

Thank you for your continued assistance in ensuring that Pennington Biomedical meets its obligations in this vital compliance area.

cc: John Kirwan, PhD, Executive Director
Leigh Lamonica, JD, Director of Legal and Regulatory Compliance
Shemetra Owens, Director, Human Research Protection Program
W Patrick Gahan, MD, Co-Chair, Institutional Review Board