12.0 Investigator Responsibilities

12.1 Policy

Investigators are ultimately responsible for the conduct of research. Research must be conducted according to the signed Investigator statement, the investigational plan and applicable regulations for protecting the rights, safety, and welfare of subjects under the Investigator's care. Investigators may delegate research responsibility. However, Investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

The following procedures describe the Investigator responsibilities in the conduct of research involving human participants.

12.2 Definitions

Principal Investigator ("PI", "Co-I" or "Investigator"): is an individual who conducts research or under whose immediate direction research is conducted; or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. NIH PHS 398

Investigator means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. FDA 21 CFR 50.3.25(d)

Researcher: is the PI and/or Investigator.

Research Team: is defined as the Investigator and other individuals, also known as key personnel, who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the protocol.

12.3 Investigators

12.3.1 Principal Investigators

For the purposes of this institution, Principal Investigators must be on staff (paid employee), adjunct faculty, or a member of the faculty of one of the institutions affiliated with the Pennington Biomedical Research Center. Professionals in training (graduate students, post-doctoral researchers, interns, and residents) are permitted to be Principal Investigators as long as permitted by their home institution policies. Fellows may be Principal Investigators if they have attending privileges at the

Institution. In order to serve as a Principal Investigator, any person who is not a member of the regular faculty must have at least one regular faculty member as a Co-Investigator on the project.

12.3.2 Change in Principal Investigator

If there is a change in the PI, the outgoing Investigator must submit a modification to previously approved research to notify the IRB that he or she has relinquished the responsibilities of the Investigator to the person named, or will do so on a specific date. The newly named Investigator notifies the IRB that he or she has read the protocol and agrees to accept the responsibilities of the Investigator.

12.3.3 Student Investigators

Students may not serve as Investigators. They must have a Pennington Biomedical Research Center employee who fulfills the Investigator eligibility criteria and who will serve as Investigator on the study. (See Policy 302 Human Research Protections Program Policy section 1.3.2 for the definition of Principal Investigator)

12.4 Responsibilities

In order to satisfy the requirements of this policy, Investigators who conduct research involving human subjects must:

1. Develop and conduct research that is in accordance with the ethical principles in the Belmont Report
2. Develop a research plan that is scientifically sound and minimizes risk to the subjects
3. Have sufficient resources necessary to protect human subjects, including:
    - Access to a population that would allow recruitment of the required number of subjects
    - Sufficient time to conduct and complete the research
    - Adequate number of qualified staff
    - Adequate facilities
    - A process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions
    - Availability of medical or psychological resources that subjects might require as a consequence of the research
4. Assure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or otherwise qualified to

perform such under the laws of Louisiana and the policies of Pennington Biomedical Research Center

5. Maintain a list of appropriately qualified persons to whom they have delegated significant clinical trial-related duties.
6. Assure that all key personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based
7. Protect the rights and welfare of prospective subjects
8. Ensure that risks to subjects are minimized:
    - By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
    - Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
9. Recruit subjects in a fair and equitable manner
10. Obtain and document informed consent as required by the IRB and ensuring that no human subject is involved in the research prior to obtaining their consent
11. Have plans to monitor the data collected for the safety of research subjects
12. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, include additional safeguards in the study to protect the rights and welfare of these subjects
13. Have a procedure to receive complaints or requests for additional information from subjects and respond appropriately
14. Ensure that pertinent laws, regulations, and Institutional procedures and guidelines are observed by participating Investigators and research staff
15. Ensure that all research that qualifies as human subjects receives IRB review and approval in writing before commencement of the research
16. Comply with all IRB decisions, conditions, and requirements
17. Ensure that protocols receive timely continuing IRB review and approval
18. Report unanticipated problems involving risk to subjects or other or any other reportable events to the IRB
19. Obtain IRB review and approval in writing before changes are made to approved protocols or consent forms

20. Seek IRB assistance when in doubt about whether proposed research requires IRB review.
21. Follow the clinical trial's randomization procedures, if any, and ensures that the code is broken only in accordance with the protocol. If the clinical trial is blinded, the researcher promptly documents and explains to the Sponsor any premature unblinding.
22. A qualified physician (or dentist, when appropriate), who is a researcher or a co-researcher for the clinical trial, is responsible for all clinical trial-related medical (or dental) decisions (not applicable to independent IRB's).
23. Inform participants when medical care is needed for other illnesses of which the researchers become aware.
24. If medically necessary and the participant agrees, the researcher will inform the participant's primary physician or specialist about their participation in the clinical trial.
25. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the researcher makes a reasonable effort to ascertain the reason, while fully respecting the participant's rights.
26. Provide evidence of his or her qualifications through up-to-date curriculum vitae or other relevant documentation requested by the sponsor, the IRB, or the regulatory authority.
27. Familiar with the appropriate use of the investigational product, as described in the protocol, in the current Investigator Brochure, in the product information, and in other information sources provided by the sponsor.
28. During and following a participant's participation in a clinical trial, the researcher ensures that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the clinical trial (not applicable to independent IRBs).
29. Ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor.
30. Permit monitoring and auditing by the sponsor and inspection by the appropriate regulatory authority.
31. Report all serious adverse events (SAEs) to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The researcher follows regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and the IRB.

32. Report adverse events or laboratory abnormalities identified in the protocol as critical to safety evaluations to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.
33. For reported deaths, the researcher supplies the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).
34. Provide written reports to the sponsor, the IRB, and, where applicable, the organization on any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.
35. If the researcher terminates or suspends a clinical trial without prior agreement of the sponsor, the researcher informs the organization, sponsor, and the IRB.
36. If the IRB terminates or suspends approval of the clinical trial, the researcher promptly notifies the sponsor.
37. Upon completion of the clinical trial, the researcher informs the organization; the IRB with a summary of the trial's outcome; and the regulatory authority with any reports required.
38. The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority (ies) and which was given approval/favorable opinion by the IRB.
39. The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

    Regulations & Guidelines: FDA 21 CFR 312.53(c) (1); 21 CFR 312.60; 21 CFR 312.61; 21 CFR 312.62; 21 CFR 812.43(c) (4); 21 CFR 812.100; 21 CFR 812.140, GCP

12.5 Training / Ongoing Education of Investigators and Research Team

As stated above, one component of a comprehensive HRPP is an education program for all individuals involved with research subjects. Pennington Biomedical Research Center is committed to providing training and an on-going educational process for Investigators and members of their research team related to ethical concerns, Federal and State regulatory requirements and Pennington Biomedical Research Center policies for the protection of human subjects. Research teams consist of anyone working directly with human subjects or with identifiable data or biological specimens for research under the purview of the Institution. This includes Investigators, research nurses, coordinators, students, faculty and technicians working with identifiable data. It is the responsibility of the Investigator to ensure that the research team is compliant

with all initial and ongoing education as required by Pennington Biomedical Research Center polices and regulatory requirements.

This requirement is mandatory regardless of funding sources. The requirements also apply to research that is considered exempt from IRB review.

Regulations & Guidelines: DHHS 45 CFR 46.102(d): 45 CFR 46.102(f); FDA 21 CFR50.3(c); 21 CFR 50.3(g); 21 CFR 50.3(j); 21 CFR 56.102(c); 21 CFR 56.102(l)

12.5.1 Initial Education

All Investigators, research team and key personnel are required to complete CITI training every three years as per Pennington Biomedical Research Center Policy 106.00. This policy is managed and tracked by the Director of Legal and Regulatory Compliance.

New research protocols and applications for continuing review will not be accepted or receive final approval until all sub-Investigators and members of the research team have completed the education requirements.

12.5.2 Waiver of Initial Education

If Investigators or members of their research team have successfully completed human subject research training equivalent to that required by the Institution within the last year, they may request a waiver of the requirement for initial education. Please contact the Director of Legal and Regulatory Compliance for more information about obtaining a waiver of education.

12.5.3 Continuing Education and Recertification

All Investigators and members of their research teams must meet Institutional continuing education requirements every three years after certification of initial education for as long as they are involved in human subject research. There is no exception to this requirement. Acceptable refresher modules at the CITI web-based training site must be completed. See PBRC Policy 106.00 for more information.

Investigators must submit evidence of continuing education prior to the expiration of their training certification. New research protocols and applications for continuing review will not be accepted from Investigators who have not submitted satisfactory evidence of continuing education.

Investigators who are also IRB Chair, IRB members, or IRB staff will satisfy the training requirements for IRB members and staff described in this policy under PBRC Policy 106.00.

12.5.4 Investigator Notification of Responsibilities

All policies and procedures including Investigator responsibilities, training and education, guidances and contact information for the HRPP are listed on the HRPP website found at www.pbrc.edu/HRPP. Investigators are notified via email of changes to the HRPP and are directed to the HRPP website which details the changes.

12.5.5 Investigator Concerns

Investigators who have concerns or suggestions regarding Pennington Biomedical Research Center HRPP should convey them to the HRPP Director, Institutional Official or other responsible parties regarding the issue, when appropriate. The Institutional Official or HRPP Director will research the issue, and when deemed necessary, convene the parties involved to form a response for the Investigator or make necessary procedural or policy modifications, as warranted. In addition, the IRB Chair and/or the HRPP Director will be available to address Investigators' questions, concerns and suggestions.