PENNINGTON BIOMEDICAL RESEARCH CENTER
LSU

AAHRPP Standards

Investigator Responsibilities for Research Involving Human Subjects

Regulatory Landscape

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About AAHRPP

The Benefits of Accreditation

By obtaining AAHRPP accreditation, Pennington is now part of an elite group of institutions internationally renowned for promoting exceptional ethical and professional standards in the conduct of human subjects research. Also, in working towards accreditation, Pennington implemented a number of improvements to the Pennington Biomedical Research HRPP Program in an effort to become re-accredited, including the revision of HRPP Policies and Procedures, and providing more education on human subjects research.

Accreditation equals gold star

Pennington has been accredited since December 13, 2013.

The Association for the Accreditation of Human Research Protection Programs, Inc., (AAHRPP) is an independent accrediting body that works to protect the rights and welfare of research participants and promote scientifically meritorious and ethically sound research by fostering and advancing the ethical and professional conduct of persons and organizations that engage in research with human participants. AAHRPP achieves its mission by using an accreditation process based on self-assessment, peer review, and education. As the "gold seal," AAHRPP accreditation offers assurances—to research participants, researchers, sponsors, government regulators, and the general public—that an HRPP is focused first and foremost on excellence.

The Accreditation Process

It Takes Several Steps

Application Preparation

The first step in earning accreditation is to conduct a self-assessment, where you evaluate your Human Research Protection Program and make improvements.

Council review

AHRPP's Council on Accreditation reviews the application, Draft Site Visit Report and your response, and determines your accreditation status.

On-site evaluation

A team of experts reviews your materials and schedules an on-site visit. During the visit, the team evaluates your program's performance with respect to the AAHRPP Accreditation Standards

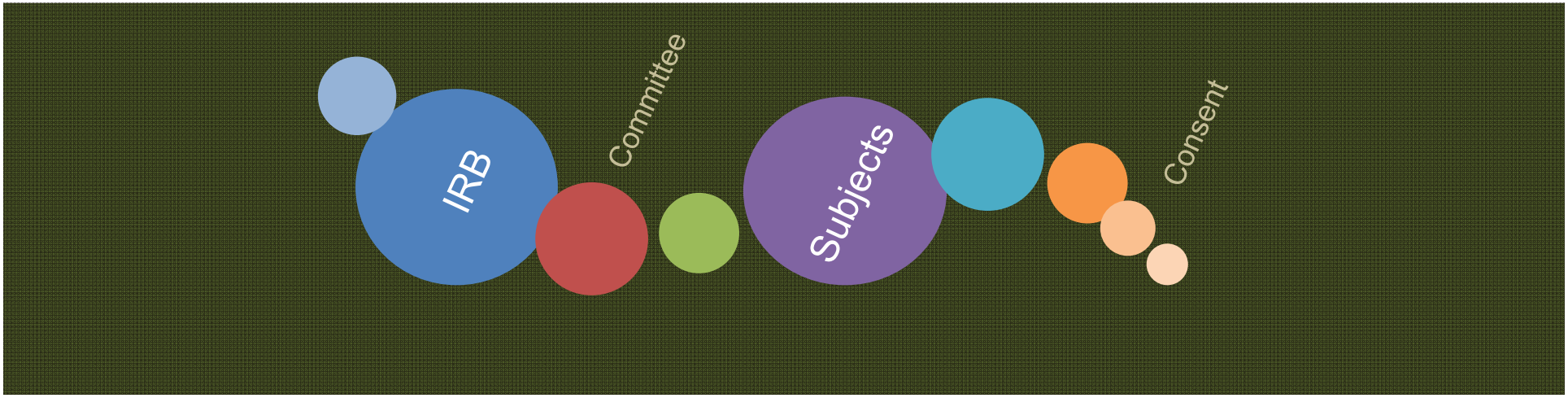
Notification of accreditation status

Your Organization receives a report detailing the status of your accreditation. Organizations that have achieved accreditation must be re-evaluated three years following their initial accreditation, and every five years after that, in order to remain accredited.

Accreditation uses a set of objective Standards to evaluate the quality and level of protection that an Organization provides research participants. Through accreditation, an Organization can demonstrate the overall excellence of its research program by providing the most comprehensive protections for research participants. The intensive self-assessment is the first and most important step in the process that results in continuous improvement.

What is an HRPP?

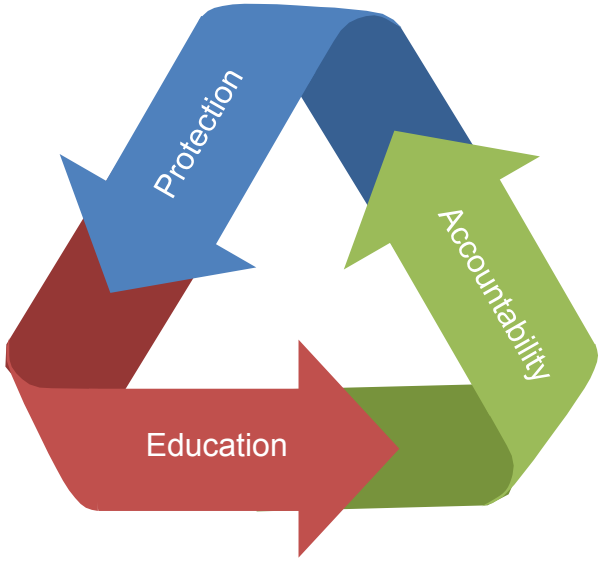
Not Just the IRB



- In the past (before 2001), most people associated human subject research as IRB centric.
- Currently, most institutions have switched to the concept of a Human Research Protection Program (HRPP)
- IRB is an integral, central part of the HRPP but it is not the HRPP
- Responsibility for protection of research participants falls on everyone in the HRPP.

The Functions of the HRPP

Developing a Culture of Compliance



Protection
The program's most basic function is to develop and implement policies and practices that ensure the adequate protection of research participant.

Education
Educating members of the research community to maintain a culture of compliance with regulations and institutional policies relevant to the protection of human subjects..

Accountability
The system is a set of interdependent components interacting to achieve a common aim; the protection of research participants

This Institution's Human Research Protection Program (HRPP) is a comprehensive system to ensure the protection of the rights and welfare of subjects in human research. The Human Research Protection Program is based on all individuals in this Institution along with key individuals and committees fulfilling their roles and responsibilities described in Policy 302.

The Components

1 Institutional Official

Oversees HRPP; obligates the institution to the Terms of the Federal-wide Assurance

2 Institutional Review Board

Review and have authority to approve research

3 Investigators and Research Staff

Conducts the research; interacts with participants

4 Legal & Regulatory Compliance

Provides legal advice; assures compliance and adherence to federal and local law

5 Sponsored Projects

review contracts and funding agreements

6 Pharmacy

Provides guidance to investigators in relation to the management of the study drugs.

7 Research Computing Group

Interfaces with Investigator to ensure data integrity

8 Recruiting

Provides screening and determine preliminary eligibility of participant

9 Research Participant

Makes Informed decisions to participate.

10 Committees (Radiation Safety, Institutional Biosafety)

Provides additional review, if necessary

11 License & Technology

Manages intellectual property and transfer of materials between institutions

12 Clinics (Inpatient, Outpatient, TEC)

Under the direction of the Investigator completes all clinical, medical and interventional procedures and processes

"Investigators are ultimately responsible for the conduct of research."

Opening Statement in PBRC Policy 12: Investigator Responsibility

Investigator Responsibility

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 Investigators 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.

Definition

Policy 302 and 12

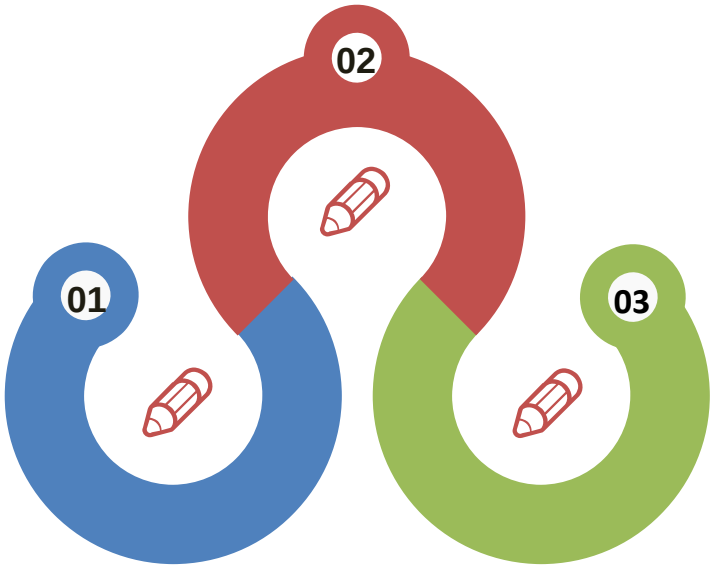
Principal Investigators must be on faculty or staff member at PBRC, adjunct faculty, or a member of the faculty of one of the institutions affiliated with the Pennington Biomedical Research Center.

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)

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.

AAHRPP Standards



Domain I – THE ORGANIZATION

This Domain describes the structural characteristics of the entity that assumes responsibility for the HRPP and applies for accreditation. The organizational structure is the means by which the Organization meets the range of responsibilities of the HRPP.

Domain II – THE INSTITUTIONAL REVIEW BOARD

Within a HRPP, responsibilities must be delegated for providing ethical review and oversight of research. These responsibilities are be distributed differently in different organizations; in many organizations, the Institutional Review Board (IRB) along with the support personnel and systems provide these functions.

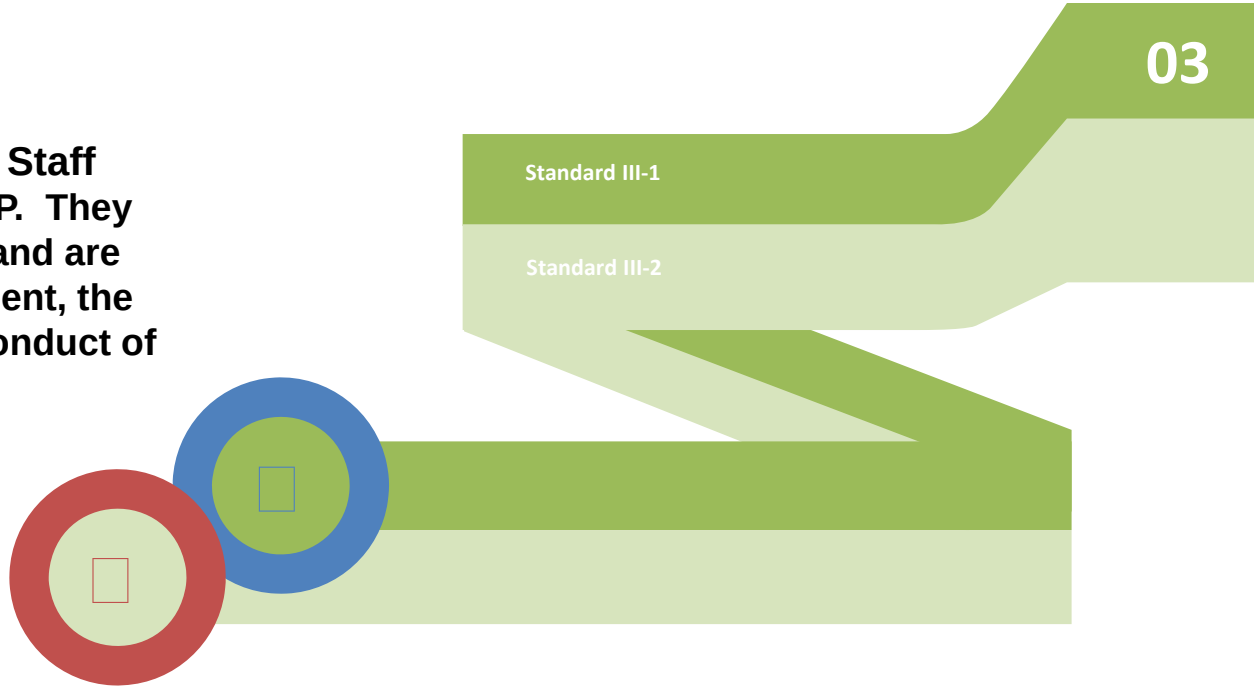
Domain III – Researcher* and Research Staff

The environment in which Researchers and Research Staff conduct research and the type of research they conduct influence their roles and responsibilities. *Term Investigator will be used interchangeably.

Domain III

Investigators and Research Staff

Researchers and Research Staff play a pivotal role in the HRPP. They are creating new knowledge and are responsible for the management, the integrity of the design, and conduct of the research.



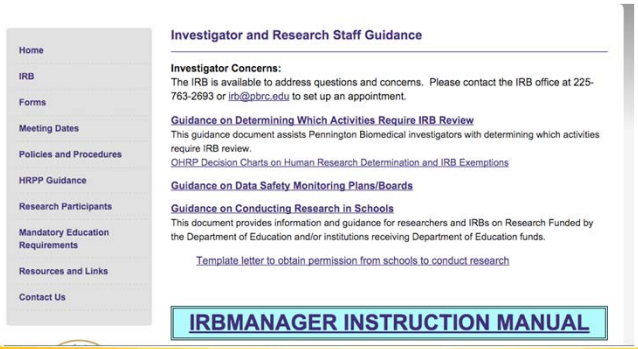
Standard III-1

In addition to following applicable laws and regulations, Investigators and Research Staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, Investigators and Research Staff have the protection of the rights and welfare of research participants as a primary concern.

Element III.1.A.

Element III.1.A. Researchers and Research Staff know which of the activities they conduct are overseen by the Human Research Protection Program, and they seek guidance when appropriate.

- PBRC 302.00 - Human Research Protection Program Policy
  - **Know** the Definitions of Agent, Engaged in Human Research, Human Research, Human Subjects as Defined by DHHS, Research as Defined by DHHS, Research as Defined by FDA
- HRPP 3.0 IRB Review Process
  - Human Subjects Research Determination policy states the IRB will make the determination on whether the research is involves human subjects.
- HRPP 2.0 Investigator Responsibilities
  - **Seek IRB assistance when in doubt about whether proposed research requires IRB review.**
- HRPP Guidance document – Human Research Determination assist investigators in determining what activities require IRB review.



http://www.pbrc.edu/hrpp/guidance/

Element III.1.B.

Researchers and Research Staff identify and **disclose** financial interests according to organizational policies and regulatory requirements and, with the Organization, manage, minimize, or eliminate financial conflicts of interest.

- HRPP Policy 3.0 IRB Review Process
  - Investigator Conflicts of Interest policy states research applications ask protocol- specific questions regarding conflict of interests for Investigators and key research personnel.
- PBRC Policy 401.00 **Individual Conflict of Interest Policy describes the institutional policy all investigators and staff must follow regarding COI.**
  - **Application for Initial Review ask if the investigator has a COI**
- **HRPP Continuing Review Report ask the investigator if there has been a change in COI.**
- **HRPP Modification of Approved Research Form states the modification is due to a change in investigator or key personnel they must attest to having no COI or contact the Director of Legal and Regulatory Compliance.**

Element III.1.C.

Element III.1.C. Researchers employ sound study design in accordance with the standards of their discipline. Researchers design studies in a manner that minimizes risks to participants.

- Protocol Template
- Application for Initial Review asks researchers to describe **how they employ sound research design in accordance with the standards of their discipline and minimizes risks to subjects.**
- HRPP Policy 3.0 IRB Review Process
    - Criteria for IRB Approval of Research (**determined by IRB or primary reviewer if greater than minimal risk**)
    - Safety Monitoring policy states the **IRB will determine** if the safety plan is adequate and may ask the investigator for additional safety considerations.
- HRPP Policy 6.0 Vulnerable Subjects in Research
    - Involvement of **Vulnerable Population** policy states the **investigator should include additional safeguards** to protect the rights and welfare of the subjects.
- HRPP Policy 15.0 Research Funded by the Department of Defense policy states a **research monitor will be appointed for minimal risk** study if IRB thinks necessary.
- Continuing Review Progress Report **ask investigators if the risks or benefits have changed** and if there is any relevant information new information.
- Modification of Approved Human Research asks the investigator if the **risks to subjects continue to be minimized**.
- PBRC Policy 301.00 ask researchers if they have **adequate resources and staff to complete the research**.

Element III.1.D.

Element III.1.D. Researchers determine that the resources necessary to protect participants are present before conducting each research study.

- HRPP Policy 12.0 Investigator Responsibilities
  - **Responsibilities policy states the investigator must have the sufficient resources necessary to protect human subjects and defines the responsibilities.**
- PBRC Policy 301.00 - Clinical Study Budget Facilitation Initiation Policy - **The budget system ask each core unit to assure that staffing and resources are adequate to complete the study. IRB receives notice of all studies after the budget is complete.**

Element III.1.E.

Element III.1.E. Researchers and Research Staff **recruit** participants in a fair and equitable manner.

- Application for Initial Review
  - Ask the following questions, purpose of the research, setting of the research and to provide the plan for recruitment of subjects
  - Research Involving Department of Defense ask investigators questions about recruitment (DOD requirements)
- HRPP Policy 3.0 IRB Review Process
  - Equitable Selection of Subjects defines the IRB's evaluation of equitable selection of subjects.
- HRPP Policy 12.0 Investigator Responsibilities
  - Policy addresses recruiting in a fair and equitable manner.

Element III.1.F.

Element III.1.F. Researchers employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of comprehension and voluntary participation to foster informed decision-making by participants.

- HRPP Policy 12.0 Investigator Responsibilities
  - Policy states **investigators must 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**
- HRPP Initial Review Application
  - Application for Initial Review asks the investigator questions about who will provide consent, type of research, study population
- Additional Responsibilities
  - HRPP Policy 15.0 Research Funded by the Department of Defense
  - HRPP Policy 16.0 Research Conducted by the Department of Education
    - Guidance on Conducting Research in Schools
    - School Permission to Conduct Research Template
- HRPP Templates
  - Consent Template for Adults, Consent Template for Minors &Assent Template – assent consent template for minors
  - Must tell a subject they do not have to participate and list other choices, if applicable.
  - Must tell subjects what information will be kept private.

Element III.1.G.

Element III.1.G. Researchers and Research Staff have a process to address participants' concerns, complaints, or requests for information.

- HRPP Policy 10.0 Complaints and Non-compliance. Pennington Biomedical Research Center **reviews all complaints and allegations of non-compliance and takes any necessary action to ensure the ethical conduct of research**.

- HRPP Policy 5.0 Obtaining Informed Consent from Research Subjects
  - Basic Elements of Informed Consent policy states the **consent must have an explanation of whom to contact on the research team for answers to pertinent questions or voice complaints or concerns**.
  - HRPP Template language Consent Template for Adults, Minors and Assent Document state who the subject can call if they have questions or problems.

Standard III-2

Standard III-2: Researchers and Research Staff meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the Organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.

Element III.2.A

Element III.2.A. Researchers and Research Staff are qualified by **training** and **experience** for their research roles, including **knowledge of applicable laws**, regulations, codes, and guidance; relevant professional standards; and the **Organization's policies and procedures** regarding the protection of research participants.

- PBRC 302.00 - Human Research Protection Program Policy (Knowledge)
  - Investigators and Research Staff Investigators and research staff have the responsibility to:
    - Know and comply with the Human Research Protection Program policies and procedures
    - Oversee the review and conduct of Human Research in their department or laboratory.
    - Ensure that each Human Research study conducted in their department or laboratory has adequate resources
- HRPP Policy 12.0 Investigator Responsibilities (Training)
  - Responsibilities policy states investigators must 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
  - Training / Ongoing Education of Investigators and Research Team policy describes the responsibilities for investigators and research staff to certify they are qualified through training and experience.
- PBRC Policy 106.00 policy defines CITI training for all investigators and research staff.

Element III.2.B.

Element III.2.B. Researchers **maintain appropriate oversight** of each research study, as well as Research Staff and trainees, and appropriately delegate research responsibilities and functions.

- HRPP Policy 2.0 Investigator Responsibilities
  - Policy states investigators must 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

- Clinic Policy and SOP
  - Clinic Policy 501 – Regulatory Binder Formation and Storage – policy establishes consistency and accuracy related to information stored in a protocol-specific regulatory master file binder, such as a CV.
  - Clinic SOP 203 Study Initiation policy dictates training of staff before study initiates.

Element III.2.C.

Element III.2.C. Researchers and Research Staff **follow** the requirements of the **research protocol** or plan and **adhere to the policies and procedures of the Organization** and to the requirements or determinations of the IRB or EC.

- Protocol Template assist investigators in writing a protocol.
    - How the study will comply with regulatory requirements
    - The specific events and activities that will be monitored during the study
    - The roles and responsibilities for everyone on the team who is involved in monitoring
    - Who has responsibility for reporting (and who they report to)
    - A schedule for monitoring
    - The timing or number of events that would lead to a stop in study accrual, an assessment of eligibility, monitoring, intervention, and under what conditions study accrual would resume
    - Follow what is written in the protocol.
- Adhere to any additional provisions for Vulnerable Subjects in Research (e.g., children, pregnant women, or handicapped or cognitively-disabled persons)

Element III.2.D.

Element III.2.D. Researchers and Research Staff follow reporting requirements in accordance with applicable laws, regulations, codes, and guidance; the Organization's policies and procedures; and the IRB's or EC's requirements.

- HRPP Policy 12.0 Investigator Responsibilities
  - Policy states 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 Investigators 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.**
  - Policy states investigators **must have plans to monitor the data collected for the safety of research subjects.**
  - Policy states investigators are to ensure that pertinent laws, regulations, and institutional procedures and guidelines are observed by participating investigators and research staff
  - Policy states investigators must **report unanticipated problems involving risk to subjects or other or any other reportable events to the IRB.**

ACCOUNTABILITY

Investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study. These may include warning, seizure, injunction, debarment, injunction, fines or criminal prosecution.

QUESTIONS
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.

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