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Louisiana State University System

HUMAN RESEARCH PROTECTIONS PROGRAM EDUCATION AND TRAINING

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Why Are You Here?

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Because you are…

- **A Pennington Biomedical Researcher**
- **Research Staff**
- **You have a role(s) in the Human Research Protection Program**

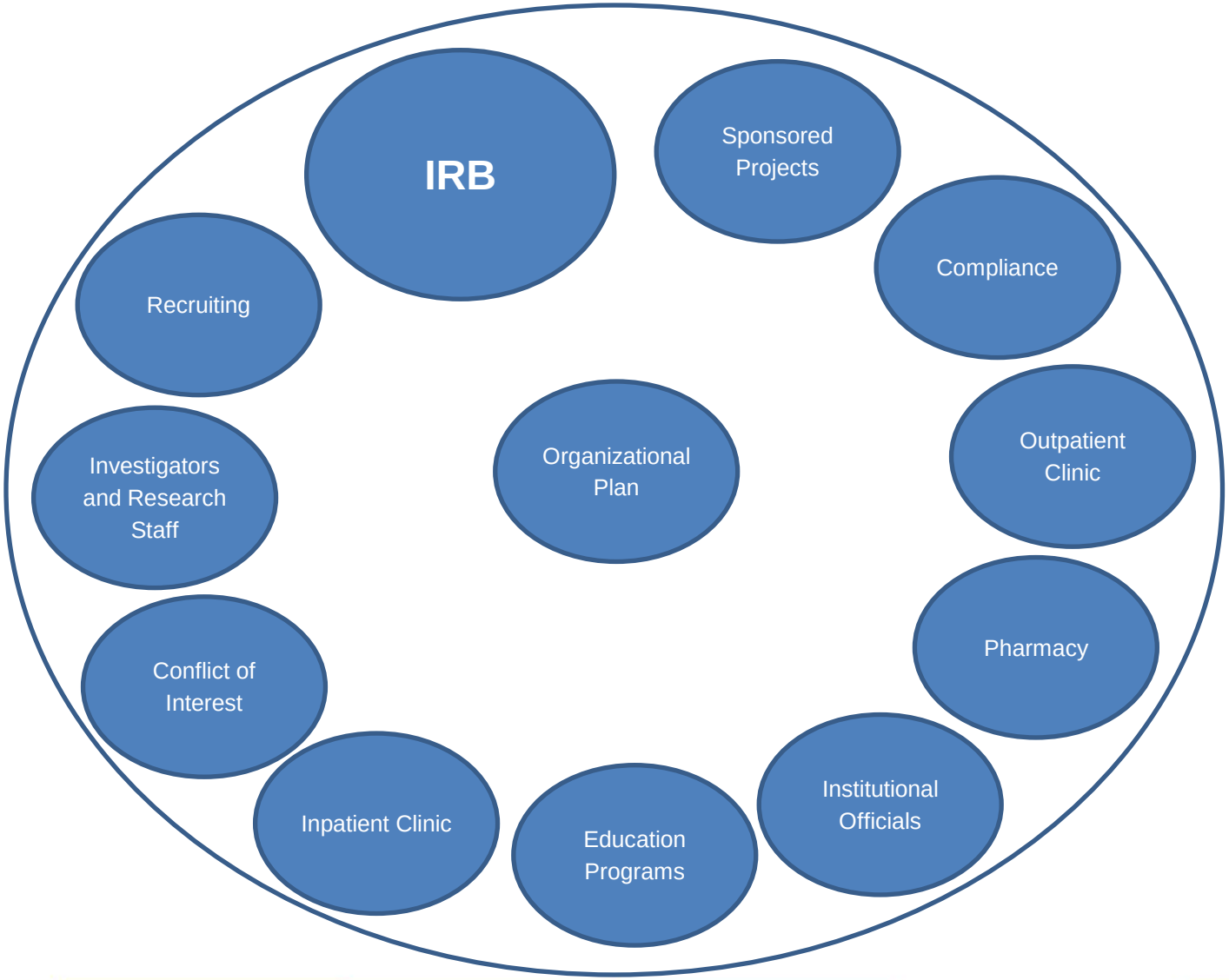
Pennington Biomedical HRPP

What is a Human Research Protections Program?

It's not the IRB

- Ensures balance of the welfare, safety and rights and interests of human subjects vs. the medical and scientific benefits to individuals and society.
- Governs all human research activities conducted by investigators and research staff.
- Aligns Pennington Biomedical's research policies and procedures with existing regulatory framework

Pennington Biomedical HRPP



Pennington Biomedical HRPP

Pennington Biomedical developed the HRPP:

- To strive to adhere to the highest ethical standards in the protection of human research participants
- To establish a formal process to monitor, evaluate and continually improve the protection of human research participants.
- To exercise oversight of research protection.
- To educate investigators and research staff about their ethical responsibility to protect research participants.
- To meet accreditation standards for the Association for Accreditation of Human Research Protection Programs

AAHRPP

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AAHRPP accredits high-quality human research protections programs in order to promote excellent, ethically sound research.

- **Done through a voluntary, peer-driven, educationally focused program which aims to foster a culture of conscience and responsibility**

AAHRPP Advantages

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Why is Pennington Biomedical seeking accreditation?

- **Improves human research protections programs**
- **Improves research quality**
- **Builds public trust**
- **Assures regulatory compliance**
- **Reduces burden from government and industry inspection**

AAHRPP Advantages, cont.

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- Leads to better risk management
- Makes the research program more competitive
- Helps in recruiting participants and sponsors
- Fosters alliances with accredited organizations

AAHRPP Accreditation Standards

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- Based on U.S. federal regulations for conducting human research
- Department of Health and Human Services
  - 45 CFR 46
- Food and Drug Administration
  - 21 CFR 50, 56
- ICH Good Clinical Practice Guidelines (International)
- Department of Defense Regulations
- Department of Education Regulations
- Common Sense

AAHRPP Accreditation Standards

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REGULATIONS

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Ethical Principles

- What is the Belmont Report?
- What is the “Common Rule”? OHRP? FDA? HIPAA?
- How does your research protect human subjects?

What Do Standards Evaluate?

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Structure of our institution

- **What we have**

Process

- **How we do it**

Outcome

- **What we achieve**

AAHRPP Does Not…

- Audit decisions made by the IRB
- Critique researcher's proposals
- Report findings to regulatory agencies

The entire process is confidential!

AAHRPP Site Visit

- **In order to achieve AAHRPP accreditation, AAHRPP will spend 2-3 days at Pennington Biomedical.**
- **AAHRPP site visitors will interview the following:**
  - **IRB Members**
  - **Investigators**
  - **Research Staff**
  - **Administration**
  - **Institutional Officials and Institutional Designees**

Know What Policies Pertain to You?

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- Vulnerable Populations
- DOD Research
- DOE Research
- Recruiting/Advertising
- Consent Process
- Deviations/Violation
- Unanticipated Problems
- Investigational Drugs
- Institutional Policies affecting the HRPP

Know Your Role

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Principal Investigator

- Provides continuous and appropriate oversight of their study and staff
- Assume ultimate responsibility for all study related activities and are directly responsible for the protection of human subjects
- Maintain mandated education requirements
- Report to the IRB the progress of your study annually or more if mandated by the IRB
- Proper tissue banking
- Maintain adequate resources for the study

Know Your Role

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Principal Investigator, cont.

- Consistent sound research study design
- Minimize risk to subjects
- Maintain an equitable selection
- Informed Consent Process according to Federal Regulations

Know Your Role

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Research Staff

- First impact with subjects (screening)
- Informed Consent Process according to Federal Regulations
- Maintain education requirements
- Minimize risk to subjects
- Follow the protocol
- Report problems to the PI and the IRB if applicable

Know Your Role

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Institutional Staff supporting the HRPP

- Recruiting
- In-Patient Unit
- Out-Patient Clinic
- Institutional Officials
- Imaging
- Sponsored Projects
- Others…

HRPP Website

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WWW.PBRC.EDU/HRPP

- Policies and Procedures
- Guidance for investigators and staff
- Forms and applications
  - Applications for Initial, Continuing Review, Modifications and Subject Materials
- Study Procedures with Associated Risk for the Consent
- Consent Templates
- Protocol Template

AAHRPP Questions for Investigators and Staff

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Training and Responsibilities

- What do you consider your primary responsibility in conducting a human research study?
- What kind of training did you receive in conducting human research?
- To whom do you go for help on issues, regulatory or ethical?
- What type of training do you require for your staff?

AAHRPP Questions for Investigators and Staff

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Training and Responsibilities, cont.

- **Describe your oversight of the study and the communication that occurs regarding the study, i.e. do you have weekly meetings?**
- **Who is responsible for preparing and submitting IRB correspondence?**
- **Do you maintain a regulatory file for this study and where is it stored?**

AAHRPP Questions for Investigators and Staff

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Research

- **What is your research topic(s)?**
- **Describe what mechanism you have in place to ensure that each subject meets the stated inclusion/exclusion criteria and that all study procedures are implemented as written.**
- **What mechanisms do you have in place to protect the confidentiality of your research participants?**
- **How frequently is the study data reviewed, i.e. per subject, per month, etc.?**

AAHRPP Questions for Investigators and Staff

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Research cont.

- **Do you have a DSMB (Data Safety Monitoring Board)? If not, why not?**
- **What are your recruitment measures?**
- **Where (in what setting) is the consent obtained?**
- **Is the prospective participant given a copy of the consent form to read prior to the discussion of the project?**

AAHRPP Questions for Investigators and Staff

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Research, cont.

- **What is the time interval between the presentation of the research study information and the actual signing of the consent form?**
- **Who addresses/answers questions presented by the participant or participant's family?**
- **What methods do you use to determine that the subject truly understands the project, especially the risks involved?**
- **Is the principal investigator usually/typically present for the informed consent process?**

AAHRPP Questions for Investigators and Staff

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Research, cont.

- **Are there additional regulations for studies with vulnerable populations? How do you find out? What do you do about it?**

AAHRPP Questions for Investigators and Staff

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PROTOCOL DEVIATIONS VS. VIOLATIONS

Protocol Deviation - any departure or inadvertent act in study activity from the currently approved protocol

- **Classified as serious (affecting subject safety, rights welfare and/or data integrity**
- **Non-Serious deviations do not affect subject safety, rights, welfare and/or data integrity**

Protocol Violation – intentional acts or continuous acts in which the IRB approved protocol is not followed

AAHRPP Questions for Investigators and Staff

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IRB

- **What does the IRB do?**
- **Do you have positive or negative feelings about the IRB?**
- **What is the IRB's reputation?**
- **What is the IRB's reputation regarding turn-around time?**

AAHRPP Questions for Investigators and Staff

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SESSION TWO TOPICS

- Consent Process
- Waiving the consent process
- Unanticipated Problems
- Conflict of Interest
- Privacy vs. Confidentiality