302.00 Human Research Protections Program Policy

1.1 Scope

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 this plan. Throughout this document "Institution" refers to Pennington Biomedical Research Center.

1.2 Purpose

This Institution is committed to protecting the rights, safety, welfare, and wellbeing of subjects in human research. The purpose of this plan is to describe this Institution's plan to comply with ethical and legal requirements for the conduct and oversight of human research.

1.3 Definitions

1.3.1 Agent

An individual who is an employee is considered an **agent** of this Institution for purposes of engagement in human research when that individual is in any official capacity as an employee of this Institution.

An individual who is not an employee is considered an agent of this Institution for purposes of engagement in human research when that individual has been **specifically authorized** to conduct human research on behalf of this Institution.

1.3.2 Principal Investigator, Co-Investigator or Investigator

Principal Investigator ("PI"), Co-Investigator 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)

For the purposes of this Institution Principal Investigators must be a member of the regular faculty, 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 they have at least one regular Pennington faculty member, with the appropriate background and training to conduct the research, serve as a Sub-Investigator and, if applicable, permitted by their home institution policies.

1.3.3 Engaged in Human Research

This Institution is engaged in human research when its employees or agents are interacting or intervening with human subjects for the purpose of conducting research. This Institution follows the Office of Human Research Protections (OHRP) guidance on “Engagement of Institutions in Research” to apply this definition.

The Institution defines all research according to the DHHS definition, unless the clinical trial is subject to FDA oversight.

1.3.4 Human Research

Any activity that either:

- Is “research” as defined by DHHS and involves “human subjects” as defined by DHHS (“DHHS Human Research”); or DHHS 45 CFR 46.102
- Is “research” as defined by FDA and involves “human subjects” as defined by FDA (“FDA Human Research”). FDA 21 CFR 56.102.22(c); 21 CFR 50.3.25 (c)

1.3.5 Research as Defined by DHHS

Research as defined by DHHS is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

The institution defines all research according the DHHS definition, unless the clinical trial is subject to FDA oversight. 45 CFR 46.102(d)

Research activities that are specifically deemed not to be research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Generalizable Knowledge means information from which one may infer a general conclusion: knowledge brought into general use or that can be applied to a wider or different range of circumstances. For example, publication and presentation are typical methods used to disseminate research findings, thereby contributing to generalizable knowledge. However, not all information that is published or presented represents generalizable knowledge. Generalizable knowledge is also interpreted to include data intended for general use, regardless of its eventual distribution or acceptance.

1.3.6 Research as Defined by FDA

Clinical investigation or research as defined by FDA means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this

chapter, regarding nonclinical studies. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous.

[21 CFR 50.3(c) and 21 CFR 56.102(c)]

1.3.7 Human Subject as Defined by DHHS

A **human subject** as defined by DHHS is a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:

1.3.8 Definitions of Human Subject as Defined by DHHS

- **Intervention** means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

- **Interaction** means communication or interpersonal contact between investigator and subject.

- **Private Information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

- **Identifiable private Information** means private information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

- **An identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

When following DHHS regulations policies, a reexamination of the meaning of "private identifiable information" and "identifiable biospecimen" shall take place at least every four years, or when updated in the Federal Register per CRF46.102 (e)(7)

DHHS 45 CFR §46.102(b), 102(e)(7)

1.3.9 Human Subject as Defined by FDA

A **human subject** as defined by the FDA is an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects. FDA 21 CFR 56.23(e)

1.3.10 Clinical Trial Definitions as Defined by NIH & OHRP

A **clinical trial** is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

- The term *"prospectively assigned"* refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

- An *"intervention"* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

- A *"health-related biomedical or behavioral outcome"* is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

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1.4 Mission

The mission of this Institution's human research protection program plan is to protect the rights, safety, welfare and wellbeing of subjects involved in human research overseen by this Institution. Concern for the interests of the subject should prevail over the interests of science and society. All human subject research is subject to the human research protection program plans policies and procedures.

The HRPP includes mechanisms to:

- Establish a formal process to monitor, evaluate and continually improve the protection of human research participants;
- Exercise oversight of research protection;
- Educate IRB members, IRB support staff, investigators and research staff about their ethical responsibility to protect research participants;
- When appropriate, intervene in research and respond directly to concerns of research participants;
- Educate research participants and the community.
- Ensure sufficient coordination among the components of the HRPP and dedicate resources sufficient to carry out the above tasks.

1.4.1 Ethical Requirements

In the oversight of all human research, this Institution (including its investigators, research staff, students involved with the conduct of human research, the Institution's Institutional Review Board (IRB), IRB members and chair, IRB staff, the Institutional official, and employees) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," also known as "The Belmont Report", which includes:

- Respect for Persons
- Beneficence
- Justice

1.4.2 Legal and Regulatory Requirements

The HRPP is responsible for ensuring compliance by the institution and its investigators with applicable federal, state, and local laws and regulations (including 45 CFR 46 and 21 CFR 50 and 56) and institutional policies governing human subject research under its auspices.

All human research must undergo review by the Institution's IRB. Activities that do not meet the definition of human research (e.g., most classroom activities, quality improvement activities, program evaluation, and surveillance activities that do not meet the definition of human research) do not require review and approval by the Institution IRB and do not need to be submitted to the Institution IRB unless there is a question regarding whether the activity is human research.

When this Institution is engaged in DHHS human research that is conducted, funded, or otherwise subject to regulations by a federal department or agency who is a signatory of the Common Rule, the Institution commits to apply the regulations of that agency relevant to the protection of human subjects.

When this Institution is engaged in FDA human research, it commits to apply the FDA regulations relevant to the protection of human subjects.

Any questions about whether an activity meets the regulatory definitions of human research should be referred to the IRB Office who will provide a determination.

1.4.3 Other Requirements

- This Institution commits to apply its ethical standards to all human research regardless of funding.
- For clinical trials, this Institution commits to apply the "International Council on Harmonization – Good Clinical Practice E6." International Research studies must adhere to recognized ethics codes such as: The Common Rule and the Declaration of Helsinki. (World Medical Association Declaration of Helsinki, A1,2)
- This Institution prohibits payments to professionals, meaning individuals and not entities, in exchange for referrals of potential subjects ("finder's fees") and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments.") FDA Guidance "Payment to Research Subjects"
- When Human Research is conducted or funded by the Department of Defense (DOD), this Institution commits to apply the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46

Subparts B, C, and D[1]. This Institution will comply with the terms of the DFARS clause or comparable language used in the agreement with the Department of Defense (DOD) component supporting the research involving human subjects. See HRPP Policy 15.0 for Research Funded by the Department of Defense.

- When Human Research is conducted or funded by the Department of Education (ED), this Institution commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99. See HRPP Policy 16.0 for Research Funded by the Department of Education

1.4.3.1 Research in Other Countries

- All policies and procedures that are applied to Human Research conducted domestically are applied to Human Research conducted in other countries.
    - For research conducted in other countries the PI must ensure the following:
        - Knowledge of local law and cultural context is sufficient to inform decisions about how the research is conducted.
        - qualifications of the researchers and research staff for conducting research in that country.
        - The consent process is appropriate to the population, coordination and communication with local IRBs when appropriate.
    - When research is conducted outside the United States, the IRB will:
        - Ensure activities are consistent with the ethical principles in the HRPP policies and that the participants are afforded protections that are at least equivalent to the ethical standards outlined in the Belmont Report.
        - Ensure appropriate expertise and knowledge of the country(ies) either through IRB members or consultants.
        - Ensure knowledge of local laws.

[1] Quick applicability table for DHHS Subparts:

	DHHS	DOD	ED
Subpart B	X	X	
Subpart C	X	X	
Subpart D	X	X	X

- Ensure knowledge of cultural context.
- Confirm the qualifications of the researchers and research staff for conducting research in that country.
- Ensure Initial review, continuing review, and review of modifications to previously approved research.
- Ensure post-approval monitoring.
- Handle of complaints, noncompliance, and unanticipated problems involving risk to subjects or others.
- Ensure procedures for Consent process and document and other language issues.
- Ensure coordination and communication with local IRBs when appropriate. Some examples of ways of ensuring knowledge of the laws of other countries might include:
    - Rely upon an IRB or EC in the country.
    - Using a consultant with expertise in the country.
    - Partnering with an organization such as a nonprofit that regularly works in the country.

1.4.4 Scope of Human Research Protection Program

The categories of human research overseen by the IRB include:

- Research conducted or funded by the Department of Defense (DOD). For additional requirements of research conducted by the Department of Defense, see Guidance G-003: Additional Requirements Conducted by the Department of Defense
- Federally funded research
- Research involving fetuses.
- FDA-regulated research.
- Research involving drugs that require an IND.
- Research involving devices that require an IDE issued by FDA.
- Research involving pregnant women as subjects.
- Research involving non-viable neonates.
- Research involving neonates of uncertain viability.
- Research involving children as subjects.

- International research
- Research conducted or funded by the Department of Education (ED)
- Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approvable of an agency secretary or director.
- Investigator held IND or IDE.
- Research involving devices that require an abbreviated IDE.
- Investigator held abbreviated IDE.

The categories of human research not overseen include:

- Research conducted or funded by the Veteran Administration (VA)
- Research conducted or funded by the Department of Justice (DOJ)
- Research conducted or funded by the Department of Energy (DOE)
- Research conducted, funded, or subject to oversight by the Environmental Protection Agency (EPA)
- Research involving *in vitro* fertilization.
- Research that plans to or is likely to involve prisoners as subjects.
- Research involving a waiver of consent for planned emergency research.
- Emergency use of a test article in a life threatening situation.
- Activities involving humanitarian use devices.
- Research using the short form of consent documentation.
- Classified Research

1.4.5 Human Research Protection Program Policies and Procedures

Pennington Biomedical Research Center Policies and procedures are made available for all Pennington Biomedical investigators and research staff at the following web site: http://pbrc.edu/HRPP. Pennington Biomedical uses the HRPP website to communicate policies and procedures, guidance to investigators and staff, required forms, and contact information for the HRPP office.

1.5 Human Research Protection Program Components

The components comprising the HRPP and their responsibilities, ethical obligations, and authorities for carrying out the mission of the program are described below.

1.5.1 Institutional Official

The Executive Director of Pennington Biomedical Research Center is designated as the Institutional Official. The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Federal-wide Assurance.

The general administrative obligations of the Institutional Official are including but not limited to:

- Designating one or more Institutional Review Boards (IRBs) that will review research covered by the institution's FWA;
- Providing sufficient resources, meeting space, and staff to support the IRB's review and record keeping duties;
- Ensuring that adequate resources, including funds, meeting space, and personnel are provided to support the operation of the HRPP;
- Providing training and educational opportunities for the IRB and investigators;
- "Setting the tone" by promoting an institutional culture of respect and conscience, so that the ethical conduct of human subjects research is supported at the highest levels of the organization;
- Ensuring effective institution-wide communication and guidance on human subjects research;
- Ensuring that investigators fulfill their responsibilities;
- Encouraging that all staff engaged in the conduct or oversight of human subject research participate in education activities;
- Serving as a knowledgeable point of contact for OHRP and other federal agencies, or delegating the responsibility to another appropriate individual;
- Granting the IRB authority to act independently to bind the entire organization, including but not limited to the Institutional Official with regards to human subjects protections.

Regulations: Federalwide Assurance (FWA) for the Protection of Human Subjects

The Institutional Official may delegate the performance of certain oversight and operational duties (listed below) to one or more individuals. Any delegation of duty must be in writing. Upon designation of a new Institutional Official, all delegation letters must be reviewed and renewed by the new Institutional Official if the new Institutional Official chooses to maintain delegation.

- Appointing IRB members. Suspending or terminating the IRB membership of any individual for whom it has been determined that he/she is not fulfilling membership responsibilities and or obligations;
- Appointing the IRB chair or co-chairs. Suspending or terminating the appointment of any chair or co-chair who is not fulfilling his/her responsibilities and or obligations;
- Performing periodic evaluation of the performance of the IRB chairs and co-chairs and administrative staff;

- Managing and administering funds. Ensuring that adequate personnel, space and other resources are allocated to the HRPP;
- Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organizations, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements);
- Being the point of contact for correspondence addressing human subjects research with the OHRP, FDA and other agencies as applicable, including reports to federal agencies;
- Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- Developing and implementing an educational plan for IRB members, staff and investigators;
- Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- Performing periodic evaluation of the performance of the IRB members and administrative staff;
- Recruiting qualified members to include expert, non-scientific and unaffiliated representation on the IRB;
- Reviewing and approving Standard Operating Procedures (SOPs) for the IRB and HRPP;
- Overseeing daily operations of the IRB and HRPP in accordance with the SOPs.
- Assessing this plan periodically to determine whether it is providing the desired results and recommending amendments as needed.
- Establishing policies and procedures designed to increase the likelihood that human research will be conducted in accordance with ethical and legal requirements.

The following responsibilities of the Institutional Official should not be delegated to a designee:

- Signatory authority for the FWA;
- Ensuring that the IRB functions independently and that its chair or chairs and members have direct access to the Institutional Official for appeal if they experience undue influence or if they have concerns about the function of the IRB;
- Ensuring that adequate resources, including funds, space, and personnel are provided to support the operation of the HRPP.
- The Institutional Official or the designee cannot approve research that has been disapproved (or not yet approved) by the IRB.
- HHS CFR 46.112 and the terms of the institution’s FWA

1.5.2 All members of the Institution

All individuals within the Institution have the responsibility to:

- Be aware of the definition of human research (see section 1.3.4).
- Consult the IRB when there is uncertainty about whether an activity is human research.
- Ensure all human subjects research is approved by the IRB.
- Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the Institutional Official.
- Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB.
- Research involving human participants must not commence until the research has received all approvals required by the organization.

1.5.3 IRB

The IRB designated by the Institutional Official is to be the IRB relied upon by the Human Research Protection Program and the scope of review of this IRB is listed in the IRB roster available from the IRB Office.

Competing business interests can influence the review process when individuals responsible for business development serve on the IRB are involved in the day to day operations of the IRB. Therefore, no individual responsible for raising funds or garnering support for research should serve as an IRB member or be involved in the day to day operations of the IRB.

Individuals who are responsible for business development are prohibited from:

- Serving as members or ex-officio members on the IRB.
- IRB members are prohibited from owning equity in the organization, if appropriate.

The IRB functions independently of, but in coordination with, other institutional departments. The IRB, however, makes its independent determination whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected. The IRB has review jurisdiction over all research involving human subjects, conducted, supported or otherwise subject to regulation by any federal department or agency that has adopted the human subject regulations.

Consistent with federal regulations, no one within the institution may approve human subjects research that has not been approved by the IRB. However, research

approved by the IRB may be subject to further institutional review, approval or disapproval.

Consistent with the federal regulations, the IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities constituting non-exempt human subjects research under the regulations. Furthermore, the IRB shall conduct continuing review of research as appropriate to the degree of risk (in federally-funded research, no less than annually). The IRB shall also suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

IRB approval notwithstanding, research involving human participants must not commence until all institutional requirements are met and institutional approval to proceed has been obtained.

This Institution may rely upon IRBs of another Institution provided one of the following is true:

- The IRBs are part of an AAHRPP accredited Institution.
- This Institution’s investigator is a collaborator on Human Research that is primarily conducted at another Institution and the investigator’s role does not include interaction or intervention with subjects.
- The Institution is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)

Reliance on an external IRB requires an Institutional Agreement for IRB review (IAIR) and a local review for compliance with local policies of the Institution. These requirements must be formalized and in place before the Institution will accept any human research proposals from the other institution or rely on the review of the other institution.

The IRBs relied upon by this Institution have the authority to:

- Approve, require modifications to secure approval, and disapprove all human research overseen and conducted by the Institution. All human research must be approved by the IRB designated by the Institutional Official. Officials of this Institution may not approve human research that has not been approved by one of the Institution’s IRBs.

- Suspend or terminate approval of human research not being conducted in accordance with a IRBs' requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the human research.
- Determine whether an activity is human research as described in HRPP Policy 3.0. 45 CFR 46.102(d)
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the human research to be approved. PBRC Policy 401.00

IRB member and IRB staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to IRB members and staff.

1.5.4 Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program policies and procedures that apply to IRB members and staff.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the Institutional Official.
- Oversee the review and conduct of Human Research in their department or laboratory.
- Forward complaints and allegations regarding the Human Research Protection Program to the Institutional Official or designee.
- Ensure that each Human Research study conducted in their department or laboratory has adequate resources.

1.5.5 Director of Legal and Regulatory Compliance

The Director of Legal and Regulatory Compliance has the responsibility to:

- Provide advice upon request to the Institutional Official, IRB, and other individuals involved with the Human Research Protection Program regarding the interpretation and application of federal and Louisiana state law relevant to human subject research and as an initial point of contact about the laws of other jurisdictions where research is conducted as they may apply to human subject research.
- Determine who meets the definition of "legally authorized representative" and "children" when human research is conducted in jurisdictions not covered by policies and procedures in accordance with applicable law.
    - Resolve conflicts among applicable laws

1.5.6 Sponsored Project Services

The Sponsored Project Services (SPS) has the responsibility to review contracts and funding agreements for compliance with Human Research Protection Program policies and procedures.

For both sponsored and non-sponsored human research this Institution abides by its ethical principles, applicable regulatory requirements, and its policies and procedures.

SPS reviews all research funding agreements with federal, foundation, non-profit, and industry sponsors. This institutional review ensures that all terms of an award or a contract are in compliance with institutional policies, including the policies of the HRPP. Only designated senior level individuals within the institution have the authority to approve sponsored research proposals and to execute research agreements on behalf of the institution.

When the grant or contract or other agreement includes human subject research activities that will be conducted by investigators who are not employees or agents of the institution, a subcontract is executed between this institution and the collaborating institution. The collaborating institution must also ensure that key personnel involved in human subject research are in compliance with the NIH policy on education in the protection of human research subjects and provide documentation of education of key personnel to the institution.

SPS, License and Technology Officer, the IRB and the Director of Legal and Regulatory Compliance meet on a regular basis to ensure consistency and communication about key issues in the protection of human subjects as they may impact the work, and specifically the research agreements, negotiated by Sponsored Human Research.

1.5.7 Pharmacy

The Pharmacy is available to provide guidance to investigators in relation to the management of the study drugs. The Pharmacist assures that information about all studies involving the use of drugs in the research is shared with the Pharmacy Staff as appropriate. Generally, responsibility for drug/biologic control and accountability is delegated to the Pharmacy by the investigator. Research involving administration of a test article that is not being stored, dispensed and managed by the Pharmacy requires protocol specific approval of the investigator’s plan to control the test article by IRB.

1.5.8 Research Computing Group (RCG)

The Research Computing Group (RCG) is a unit within the department of Computing Services. RCG's primary responsibility is the continuing development of a proprietary web-based portal to the clinical research database. The clinical research database is a Microsoft SQL Server database secured on the Pennington Biomedical network. Direct access to this database is restricted to authorized personnel within the RCG and Computing Services. Security is managed by the Pennington Biomedical Computing Services Infrastructure Security Group and is administered in accordance with established standard operating procedures. Active Directory (AD) credentials serve to authenticate, authorize and facilitate accountability for a user's access to PBRC information systems. The RCG team interfaces with researchers to ensure the efficient and accurate transfer of data from observation to electronic files for storage and analysis; monitors the data processing throughout each study's duration; and provides investigators with study specific data sets via web-based desktop data access. The team has developed custom applications for expedited creation of study specific data sets that may contain both PBRC data and Non-PBRC data. This development and data storage paradigm allows the team to work with both intramural and extramural researchers.

Guidelines for Good Clinical Practices as they relate to data handling have been documented and implemented in daily tasks. The group maintains current HIPAA Security Rule training and works closely with the Director of Legal and Regulatory Compliance.

1.5.9 Recruiting

Recruitment services for clinical trials conducted at The Pennington Biomedical Research Center (PBRC) are coordinated by the Recruitment Core. The Recruitment Core manages all incoming calls to determine study eligibility. Incoming calls are directed to a call center that is operated by 3 full time recruiters and is equipped with a Uniform Call Distributor (UCD) system. A UCD system expands the capability of a traditional phone system and allows multiple individuals to call simultaneously and be directed to the next available recruiter. The core utilizes an electronic message tracking application that tracks the outgoing phone call activity and a "smart" electronic phone screen system that screens potential participants upon initial phone contact and seamlessly matches them to alternative studies when deemed ineligible for the original study that the participant called. In 2012 the core launched a new web-screener for participants to be able to go on-line, choose a study that are interested in and complete a preliminary screening. The system is able to tell the participant upon completion whether they are eligible to that point in the screening

process and if they are ineligible the screener will alert them to other studies that they might be eligible for and at that point could continue to screen for those studies. If the participant is eligible they are then contacted by a live recruiter to complete the screening process and schedule their first screening appointment. All the information provided to the recruiter by the participant or the parent/guardian is protected in the Clinical Trials Database. The information is HIPAA protected and monitored by IT systems to assure no data breach occurs.

1.5.10 License and Technology

The Office of Intellectual Property and Technology Transfer is responsible for managing the intellectual property assets of the institution. Of particular relevance to human subject research protections are:

- Material Transfer Agreements (MTA's) – these are contracts that govern the transfer of tangible research materials between institutions for use in research. The Protocol Application asks whether tissues are to be distributed as part of such an agreement.

1.5.11 Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) ensures that research involving biological agents of humans, animals and plants, and/or recombinant DNA technology is conducted within existing Federal and State laws and guidelines. The IBC is obligated to require information from the Principal Investigator for a thorough review of proposed research. Reciprocal communication between the IRB and the IBC is essential in order to fulfill its functions relative to human research. The IRB shall not grant final approval of human participant research for those projects under purview of IBC, for example research involving recombinant DNA, gene transfer, microorganisms, viruses or biological toxins, until the project has been reviewed and approved by the IBC.

1.5.12 Radiation Committee

The Radiation Safety Committee (RSC) oversees the use of radioactive materials and radiation-producing devices at the institution. In collaboration with LSU, the committee promotes radiological safety through safety training, professional guidance, and technical support, in accordance with federal and state regulations and institutional policies. All human subject research involving radiation must have RSC approval before research activities may commence. Examples of uses of these sources include (but are not limited to) chest x-rays, DXA scans, CT scans, fluoroscopy, and nuclear medicine procedures. If radioactive isotopes are

administered to humans, the RSC and the RDRC (radioactive drug research committee) must provide approval before research activities may begin.

1.5.13 Clinics (Outpatient, Inpatient, TREC)

The Clinical Trials Unit (CTU) includes the inpatient, outpatient, pediatric and interventional research functions. Under the direction of the Principal Investigator, the CTU completes all clinical, medical and interventional procedures and processes as defined by the study protocol in compliance with all Institutional policies and procedures. The CTU works with the Principal Investigators to ensure the required resources necessary for study implementation and ongoing operation are available and meet specified study criteria.

The Clinical Trials Unit works closely with the Principal Investigators to ensure effective, accurate, and timely communication is maintained with the HRPP office to include, but not limited to, approval and modification of protocols and informed consents, reporting of Serious Adverse Effects (SAE), reporting of protocol deviations, changes in study status, changes in study personnel, and all other reports defined by the Institutional policies and procedures.

All staff completes the required initial and maintenance compliance training as defined by Institutional and Clinical Trials Unit policies and procedures. In-service training is provided to all staff as required based upon the development of new policies and procedures or changes in established policies and procedures.

1.6 Education and Training

IRB members, IRB staff, and others involved in the review of human research must complete CITI IRB Administration training. This training is valid for a three-year period, after which time CITI training must be completed again. IRB staff also train IRB members on the SOPs and forms applicable to IRB members including regulatory and guidance requirements noted in the section “Other Requirements (section 1.4.3).”

Investigators and research staff must complete CITI training relevant to the type of research being conducted.in accordance with PBRC policy 106. The IRB is notified electronically when CITI training is completed and notified by the Director of Legal and Regulatory Compliance of any investigator and research staff out of compliance with the policy.

1.7 Resources for the HRPP

Resources for the HRPP components are provided through the annual budget review processes in the administrative units in which the components reside.

The need for study-specific resources is evaluated at the local level. Investigators and sponsoring units are responsible to ensure that sufficient resources are allocated to all projects, whether sponsored or investigator-initiated. These include staffing and personnel (in terms of availability, number, expertise and experience); psychological, social and medical services (including counseling or social support services that may be required because of participation in a study); psychological, social, or medical monitoring, ancillary care, equipment needed to protect participants, and resources for participant communication. Study-specific resources are verified electronically as defined by Policy 301.00 Clinical Study Budget, Resource Facilitation and Initiation.

The need for incremental or off-cycle resources may emerge as a result of special or unusual demands on the offices, either as reported by the offices or by quality assurance/review activities, or through deliberations by the Executive Director.

Resources for the HRPP are allocated to the individual PBRC entities engaged in human-subjects research overseen by the HRPP. Such resources include, but are not limited to:

- Staffing commensurate with the size and complexity of the research program.
- Appropriate office space, equipment, material, and technology.
- Resources for the production, maintenance, and secure storage of HRPP and IRB records.
- Resources for auditing and other compliance activities and investigations of non-compliance.
- Access to legal counsel.
- Support for educational opportunities related to human research protections for IRB members, relevant administrative staff, and all members of the research team.
- Support for evaluation of Conflict of Interest; and
- Support for Community Outreach

1.8 Questions and Additional Information for the IRB

The IRB Office wants your questions, information, and feedback.

Contact and location information for the IRB Office is:
Human Research Protections Program Director
Pennington Biomedical Research Center
6400 Perkins Road

Baton Rouge, LA 70808
Email: irb@pbrc.edu
Phone: (225) 763-2693

1.9 Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, IRB Office, Institutional Official or Director of Legal and Regulatory Compliance.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The Institutional Official has the responsibility to investigate all other reports and take corrective actions as needed.

Employees who report in good faith possible compliance issues should not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Institutional Official or designee.

To make such reports, contact:
John P. Kirwan, Ph.D.
Executive Director
Pennington Biomedical Research Center
6400 Perkins Road
Baton Rouge, LA 70808
Email: John.Kirwan@pbrc.edu
Phone: (225) 763-2513

1.10 Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and Institutional requirements will conduct periodic audits. Audits may focus on areas of concern that have been identified by any entity, i.e., federal, state or Institutional. Random audits may also be conducted. See HRPP policy 13.0 – Quality Improvement in the HRPP Program

1.11 Disciplinary Actions

The Institutional Official may place limitations or conditions on an investigator's or research staff's privilege to conduct human research whenever, in the opinion of the

Institutional Official, such actions are required to maintain the Human Research Protection Program.

1.12 Approval and Revisions to the Plan

This Human Research Protection Program Policy is to be approved by the Policy Committee of Pennington Biomedical Research Center. This policy is intended to be flexible and readily adaptable to changes in regulatory requirements. The Institutional Official has the responsibility to review this plan to assess whether it is providing the desired results. At the request of the HRPP Office or the Institutional Official, the Policy Committee has the authority to amend this plan as deemed necessary.