2.0 Institutional Review Board

2.1 Policy

Pennington Biomedical Research Center has one IRB to ensure the protection of human subjects in research.

- IRB – Biomedical (IRB 00000708) (IORG00006218)
  The IRB is delegated to review human subject research for the following areas:
  - clinical trials such as drug studies;
  - research involving the social sciences
  - prevention, treatment, or understanding of diseases
  - research involving medical interventions

Pennington Biomedical Research Center also utilizes the services of two off-site IRBs (Baton Rouge General Medical Center – FWA00001821, Louisiana State University and Agriculture and Mechanical College Baton Rouge – FWA00003892) on a protocol-by-protocol basis. All non-exempt human research subjects must be reviewed and approved by Pennington Biomedical Research Center IRB prior to initiation of research activities.

Regulations & Guidance: DHHS 45 CFR 46.103

2.2 IRB Authority

Pennington Biomedical Research Center policy authorizes the IRB to:

a) Approve, conditionally approve (minor modifications required), withhold approval (major modifications required or major clarifications) or disapprove all research activities overseen and conducted at this Institution;
b) Suspend or terminate approval of research not being conducted in accordance with the IRB requirements or has been associated with unexpected serious harm to subjects; and
c) Observe, or have a third party observe, the consent process and the conduct of the research.
d) Request a directed audit; or otherwise investigate, address, remedy and, when required or appropriate, report on incidences of noncompliance with legal, regulatory, or IRB requirements or determinations; and
e) Conduct reviews and inquiries regarding human-subjects research as needed to obtain information necessary for the fulfillment of human research protection responsibilities and, for federally funded research, the institutional responsibilities outlined in the institutions' Office for Human Research Protections (OHRP)-approved Federal Wide Assurance (FWAs).

The IRB is responsible for reviewing research to ensure the protection of rights and welfare of human research subjects. It discharges this duty by complying with the requirements of the Common Rule and other applicable federal regulations; state laws and regulations; the terms of institutions' FWA; and institutional policies. Research that has been reviewed and approved by the IRB may be subject to further review and suspension and disapproval by the Institutional Officials consistent with Pennington Biomedical Research Center policy (see HRPP Policy 3 – IRB Review Process). However, such officials may not approve research that has not been approved by the IRB.

The IRB has the authority within the institution to determine:

- whether a research activity involves human subjects within the meaning of the DHHS, FDA, or other applicable federal regulations
- whether a research activity involving human subjects is exempt from 45 CFR 46 and 21 CFR 56.

Investigators or others within the organization may not independently make exemption determinations.

Regulations & Guidance: DHHS 45 CFR 46.112; FDA 21 CFR 56.103; 21 CFR 56.109; 21 CFR 56.112; and 21 CFR 56.113.

2.3 Roles and Responsibilities

2.3.1 IRB Chair

The Executive Director of Pennington Biomedical Research Center appoints an IRB Chair to serve for unlimited terms on the IRB. Any change in appointment, including re-appointment or removal, requires written notification from the Executive Director.

The IRB Chair should be a highly respected individual, fully capable of managing the IRB, and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the Institution will fall primarily on the shoulders of the IRB Chair. The IRB must be perceived to be fair, impartial and immune to pressure by the Institution's administration, the Investigator whose protocols are brought before it, and other professional and nonprofessional sources.

The criteria used to select an IRB Chair include experience with, and knowledge of, applicable federal and state laws and regulations, and Institutional policies. This individual must be willing to commit to the IRB; must have past experience as an IRB member; and must demonstrate excellent communication skills, along with an

understanding of clinical research. The IRB Chair must also be flexible and demonstrate a thorough understanding of ethical issues involved in clinical research.

The IRB Chair convenes and chairs the meetings of the IRB and is required to attend a majority of the convened meetings of the IRB. The IRB Chair may conduct or delegate expedited review of research that qualifies for such review; review the responses of Investigators to contingencies of the IRB (to secure IRB approval); and to review and approve minor changes in previously approved research during the period covered by the original approval. The IRB Chair may delegate such authority to another experienced IRB member.

The IRB Chair is a voting member and is the signatory for correspondence generated by the IRB and may delegate signatory authority to another experienced IRB member.

The performance of the IRB Chair will be reviewed on an annual basis by the Executive Director or designee. If the IRB Chair is not functioning in accordance with the IRB's mission, policies and procedures; has an undue number of absences; or is not fulfilling the responsibilities of IRB Chair, then he/she will be removed by the Executive Director and replaced by a suitable alternative.

2.3.2 IRB Co-Chair

The responsibilities of the Co-Chair mirror those of the Chair with the extent of responsibilities outside the meeting dependent on the activities delegated by the Chair and ability of the Chair to perform those duties (e.g., due to vacation, illness, leave of absence), including:

- Preside over meetings of the fully convened IRB and ensure that the IRB carries out its duly authorized responsibilities as required by federal regulations, ethical principles, state laws and HRPP policy.
- Review and approve protocol submissions that qualify for expedited review pursuant to federal regulations, ethical principles, state laws and University policies.
- Ensure that membership of the IRB is recruited, appointed and oriented such that the IRB is duly qualified to fulfill its obligations to review, require modifications to, approve (or disapprove) research protocols that represent the breadth of research submitted to the IRB by Pennington researchers.
- Maintain a working knowledge of federal human subject's regulations through continued education and training
- Attend Institutional meeting that involve the IRB
- Participate in Subcommittees
- Represent the IRB at national and local meetings related to institutional review board activities and human subject protections

The performance of the IRB Co-Chair will be reviewed on an annual basis by the Executive Director or designee. If the IRB Co-Chair is not functioning in accordance with the IRB's mission, policies and procedures; has an undue number of absences; or is not fulfilling the responsibilities of IRB Co-Chair, then he/she will be removed by the Executive Director and replaced by a suitable alternative.

2.3.3 HRPP/IRB Staff

2.3.3.1 HRPP Director

The HRPP Director supervises the Human Research Protections Program. The HRPP Director is the primary contact and liaison at the Institution for communications with Federal, State and local regulatory agencies with respect to Human Subjects (e.g., OHRP or the FDA). The HRPP Director responds to faculty and staff questions about Human Subjects Research as well as organizing and documenting the IRB review process. The HRPP Director works closely with the IRB Chair and others within the HRPP in the development, management and implementation of IRB policy and procedures to ensure compliance with all local, state, and federal regulations governing human research protections. This includes monitoring changes in regulations and external policies and emerging ethical and scientific issues that relate to human research protection. The HRPP Director is not a voting member of the IRB.

2.3.3.2 IRB Manager

The IRB Manager manages all day to day operations of the IRB office. Assesses minutes for quality, completeness, and regulatory compliance and IRB member reviews for quality, completeness, and regulatory compliance. The IRB Manager analyzes overall findings for trends and key process failures, providing input for team training regarding identified quality trends. Participates in and provide support during preparation for and conduct of internal and external quality audits of PBRC. Contributes in making not human subject or exempt determinations and approving minor expedited submissions as allowed by HRPP policy and authorized by the IRB Chair. The IRB Manager provides guidance to researchers on IRB policies and assist investigators and research staff with protocol and consent requirements for IRB submission. Works in partnership with the HRPP Director, the IRB Chair and others to develop written guidelines to improve communication and understanding of human research requirements. Assist in the maintenance of the HRPP website as needed. The IRB Manager is a voting member of the IRB.

2.3.3.3 IRB Coordinator

The IRB Coordinator organizes IRB meetings and review activities: prepares relevant materials and necessary correspondence, including agendas and reports. Reviews project submissions for completeness; communicates with investigators and coordinators for any additional information or materials. Prepares and enters information into database for new submissions. Prepares appropriate paperwork and approval correspondence in conjunction with submissions to the IRB; communicates with investigators and coordinators for additional information or materials. Updates and maintains records related to IRB membership, maintains various tracking logs and files related to IRB activities. The IRB Coordinator maintains records of IRB approvals and oversees the archiving of terminated IRB files and responds to general information queries from investigators and study coordinators regarding IRB procedures. Assists HRPP Director and IRB Manager with administrative tasks as needed and maintains a good working relationship with IRB members, Principal Investigators, Project Managers, and Study Coordinators

2.4 IRB Membership

IRB members are selected based on appropriate diversity, including consideration of race, gender, and cultural backgrounds; varied community involvement and affiliations; knowledge and experience with vulnerable populations; and with multiple, diverse professions or specialties, including both scientific members and non-scientific members. The structure and composition of the IRB must be appropriate to the nature of the research that is reviewed. Every effort is made to have member representation that has an understanding of the areas of specialty that encompasses the types of research performed at the Institution. Pennington Biomedical Research Center has procedures (see section 2.7, Use of Guests & Consultants and Scientific Merit section in Policy 3) that specifically outline the requirements for protocol review by individuals with appropriate scientific or scholarly expertise beyond or in addition to that available through the IRB members.

In addition, the IRB will include members who are knowledgeable about and experienced in working with vulnerable populations (e.g., children, pregnant women, or handicapped or cognitively-disabled persons) that typically participate in research.

The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects and possess the professional competence necessary to review specific research activities. Ideally, a single member of the IRB could exhibit a profile that fulfills multiple specific requirements for IRB composition.

Regulations & Guidance: DHHS 45 CFR 46.107; FDA 21 CFR 56.107

A. Definitions

Affiliated IRB Member: is an employee or agent of Pennington Biomedical Research Center or affiliated with Pennington Biomedical Research Center (faculty or medical staff). If a member of that person's immediate family is affiliated with Pennington Biomedical Research Center then the IRB member must disclose this information. Affiliated members include, but are not limited to individuals who are: full or part-time employees; members of any governing panel or board of the Institution; paid or unpaid consultants; and volunteers working at the Institution on business unrelated to the IRB.

Experienced Member: is an IRB member determined by the IRB Chair to be qualified to perform reviews using expedited procedures. The following criteria are considered when determining whether an IRB member is experienced: length of IRB service, training regarding expedited review procedures, research experience/expertise, and/or work with the research participants being studied.

Non-Affiliated Member: is an IRB member with no affiliation to the Institution, nor can any immediate family member be affiliated with the Institution. The non-affiliated member is drawn from the community and must be willing to discuss issues and research from that perspective.

Alternate Member: is an individual who has the experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member(s) whom the alternate would replace.

Non-scientific Member: is any IRB member who has formal education and training in a discipline generally considered to be non-scientific (e.g. humanities, law, business) and/or is engaged in an occupation or role that is generally considered to be non-scientific (e.g. law enforcement, minister).

Scientific Member: is an individual who has formal education and training as a physician or other medical professional, and M.S. and/or Ph.D. level physical, biological, or social behavioral scientists.

B. Composition of the IRB

a. The IRB will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the Institution.

b. The IRB will be sufficiently qualified through the experience, expertise, and diversity of its members, including consideration of race, gender, cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
c. In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to ascertain the acceptability of proposed research in terms of Institutional policies and regulations, applicable law, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas.
d. If the IRB regularly reviews research that involves a vulnerable category of subjects, consideration will be given to the inclusion of one or more individuals on the IRB, who are knowledgeable about and experienced in working with these subjects. When protocols involve vulnerable populations, the review process will include one or more individuals who are knowledgeable about or experienced in working with these subjects, either as members of the IRB or as consultants (see Consultant - Vulnerable Populations section in Policy 3 and Policy 6 - Vulnerable Subjects in Research).
e. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the Institution's consideration of qualified persons of both sexes. The IRB shall not consist entirely of members of one profession.
f. The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.
g. At least one member who is not otherwise affiliated with Pennington Biomedical Research Center and who is not part of the immediate family of a person who is affiliated with Pennington Biomedical Research Center.
h. One member may satisfy more than one membership category.

Regulations & Guidance: DHHS 45 CFR 46.107; FDA 21 CFR 56.107

C. Appointment of New IRB Members

The IRB Chair is responsible for selecting individuals to serve as a new IRB member (and indicate whether regular or alternate). However, the Institutional Official makes the final determination and appointment regarding new IRB members.

Initial appointments are made for a year service term and IRB members are evaluated annually for extension of appointment. Any change in appointment or

removal by the IRB Chair, requires written notification. Members may resign by written notification to the IRB Chair.

D. Documentation and Information for New IRB Members

The following items are required from each member of the IRB at initial appointment and as directed and will be made available as appropriate, upon request [DHHS 45 CFR 46.107]:

- Current curriculum vitae ("CV") annually.
- Participation in the required initial education (section 2.10 B) and new IRB member orientation (section 2.10 A) must occur prior to review of any research.
- Documentation of current Institutional certification in compliance education (e.g., CITI Training). The IRB office documents and files compliance training for IRB members.
- Members must make every effort to attend all meetings for which the member is scheduled. (see section 2.8 - Duties of IRB Members)
- All members must sign a Confidentiality Agreement upon assignment as a member which is effective for the duration of the term served regardless of the length of the term. A Conflict of Interest Disclosure must be completed and signed annually.
- Documents supporting final appointments along with records of continuing education will become part of the permanent membership records maintained by IRB office. The IRB membership is indefinite pending annual IRB evaluation. Required changes will be reported to the OHRP.

E. Periodic Review of IRB Composition and Membership

On an annual basis, the IRB Chair shall review the membership and composition of the IRB to determine if they continue to meet regulatory and Institutional requirements. Required changes in IRB members will be reported to the OHRP.

2.5 Alternate IRB Members

The appointment and function of alternate members is the same as that of regular IRB members; and the alternate's expertise and perspective are comparable to those of the regular member. The area of expertise of the alternates should match that of the regular member such that the federal policy requirements are met if a regular member cannot attend an IRB meeting. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will

receive and review the same materials prior to the IRB meeting that the regular member received or would have received.

The IRB roster identifies the regular member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the regular member is absent. The IRB minutes will document when an alternate member has replaced a regular member.

2.6 IRB Member Conflict of Interest

No IRB member may participate in the review (initial, continuing review, modification, unanticipated problem or non-compliance) of any research project in which the member has a conflict of interest ("COI"), except to provide information as requested. Matters involving financial COI involving IRB members are governed by the Institution's policy detailed in Pennington Biomedical Research Center Policy 401.00 Individual Financial Conflicts of Interest Policy, IRB members may find themselves in any of the following COI when reviewing research:

1. Where the member or consultant is involved in the design, conduct, and reporting of the research;
2. Where an immediate family member of the member or consultant is involved in the design, conduct, and reporting of the research;
3. Where the member holds significant financial interests related to the research being reviewed; and
4. Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol. For expedited reviews all reviewers must attest on the expedited reviewer form whether a COI exists. If a COI exists, a member is asked to notify the IRB immediately, so the review can be re-assigned.

It is the responsibility of each IRB member to disclose any COI with a study submitted for review, and recuse him/herself from the deliberations and vote by leaving the room, which departure is noted in the minutes.

The IRB Chair, will poll IRB members at each convened meeting to determine if a COI exists regarding any protocols to be considered during the meeting and reminds the committee that members with conflicts should recuse themselves by leaving the room during the deliberation and vote of a specific protocol. IRB members with a conflicting interest are excluded from being counted towards quorum. All recusals by members with COI are recorded in the minutes.

If the conflict of interest status of an IRB member changes during the course of a study, the IRB member is required to declare this to the IRB Chair.

Regulations & Guidance: DHHS 45 CFR 46.107(e); FDA 21 CFR 54; 21 CFR 56.107(e)

2.7 Use of Guests and Consultants

At the discretion of the IRB, the Principal Investigator may be invited to the IRB meeting to answer questions about their proposed or ongoing research. The Principal Investigator may not be present for the discussion or vote on their research.

A consultant is an individual with competence in a special area that the IRB has invited to assist in the review of issues which require expertise beyond or in addition to the availability on the IRB. These individuals do not count for IRB quorum purposes and cannot vote on any issue before the IRB [45 CFR 46.107(f)].

When necessary, the IRB Chair may solicit advice or otherwise engage individuals to assist the IRB in its review of issues or IRB proposals, which require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB.

The need for an outside reviewer is determined in advance of the IRB meeting by the IRB Chair by reviewing the IRB proposals scheduled to be reviewed at the convened meeting. The IRB staff will ensure that all relevant materials are provided to the outside reviewer prior to the convened IRB meeting.

Outside reviewers or consultants can be obtained either within or outside the Pennington Biomedical Research Center. In the event that additional scientific or scholarly expertise cannot be obtained for a research proposal the IRB Chair will defer the proposal to the next IRB meeting in order that appropriate review may be obtained.

Consultants are subject to the policy on conflicts of interest for IRB members and will sign a Financial Disclosure form. Consultants must remain in compliance with the COI policy. Individuals who have a COI or whose spouse or family members have a COI in the research will not be invited to provide consultation.

The consultant’s findings will be presented to the convened IRB for consideration either in person or in writing. If in attendance, these individuals will provide consultation but may not participate in or observe the vote.

Ad hoc or informal consultations requested by individual IRB members (rather than for convened IRB review) will be requested in a manner that protects the researcher’s confidentiality and is in compliance with the IRB COI policy.

To the extent that written statements or recommendations are provided by a consultant, a copy will be kept in IRB records. Key information provided by consultants at meetings will be documented in the minutes. Written reviews provided by the outside reviewer will be filed with the protocol. If a consultant is obtained, the consultant will be required to complete the same review documentation required by IRB members for appropriate review of a submission.

Regulations & Guidance: DHHS 45 CFR 46.107(f); FDA 21 CFR 56.107(f)

2.8 Duties of IRB Members

Except for emergency IRB meetings, the agenda, submission materials, proposals, proposed informed consent forms and other appropriate documents are distributed to IRB members approximately one week prior to the convened meetings at which the research is scheduled to be discussed. For emergency IRB meetings, these written materials will be submitted as timely as possible in advance of the scheduled IRB meeting date and time. IRB members will treat the IRB proposals, protocols, and supporting data confidentially. All copies of the protocols and supporting data are returned to the IRB staff at the conclusion of review for document destruction.

Unaffiliated members must attend at least 60% of the IRB meetings (for which the member is scheduled) during the course of a calendar year. The member is to contact the IRB office of any potential absence as far in advance as possible; an unaffiliated member who repeatedly misses meetings (>60% without prior notice or excuse) may either be asked to step down or have an alternate assigned who can act in his/her stead.

2.9 Attendance Requirements

IRB members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, they should timely inform the IRB Chair or IRB staff member at least one week prior to the scheduled meeting. In the case of an emergency, members should provide notification as soon as possible. If an IRB member is unable to attend IRB meetings for a prolonged period, then such notice should be given so that the IRB Chair can determine whether an alternate member is needed and, if so, such alternate member should be temporary or permanent. If an IRB member is to be absent for an extended period of time, such as for a sabbatical, he or she must notify the IRB at least 30 days in advance so that an appropriate replacement can be obtained. The replacement can be temporary, for the period of absence, or permanent if the member is not returning to the IRB. If the member has a designated alternate (see sections 2.4 and 2.5), the alternate can serve during the regular member's absence, provided the IRB has been notified in advance.

Designated alternates (alternate voting members) shall be asked to attend meetings and vote when the primary voting member indicates that s/he does not plan to attend the meeting. Should both the primary voting member and alternate voting member attend the same meeting and be present for review of the same research activity, only one member shall vote on the specific research activity under review. The other shall be recorded in the minutes as attending, but not voting on the research activity.

The Chair of the IRB may recommend suspension or removal for cause of any member of the IRB; provided, however, that such member shall have been given reasonable notice of the grounds for the suspension or removal and an opportunity to be heard. For this purpose, cause (with respect to a voting member) shall include the failure to attend at least 60% of the convened meetings in a calendar year of the IRB panel of which he/she is a member without excuse or the failure to perform reviews when assigned as a primary or secondary reviewer without prior notice or excuse.

2.10 Training & Education

Pennington Biomedical Research Center is committed to providing initial and on-going training and education for the IRB Chair, IRB members, and IRB staff related to research ethics concerns. The IRB Chair, IRB members and IRB staff are subject to the Institutional Policy 106.00 for training and education requirements.

A. New IRB Members—Orientation

New IRB members, including alternate members, will meet with the IRB Chair for an informal orientation session. At the session, the new member will be given copies of the following:

- Pennington Biomedical Research Center IRB Policies and Procedures
- IRB member Reviewer forms
- The Belmont Report
- Applicable federal and state regulations including
    - 45 CFR Part 46 – The Common Rule
    - 21 CFR Part 50 – Protection of Human Subjects
    - 21 CFR Part 56 – Institutional Review Boards

B. New IRB Members—Initial Education

Before serving as a primary reviewer, a new IRB member must receive and successfully complete the education requirement.

C. IRB Members—Continuing Education

To ensure that oversight of research involving human subjects is ethically grounded and the decisions made by the IRB is consistent with current regulatory

and policy requirements, training is continuous for IRB members throughout their service on the IRB. Educational activities include, but are not limited to:

- In-service training at IRB meetings
- Distribution of appropriate publications; and
- Identification and dissemination by the HRPP Director of new information that might affect the IRB, including laws, regulations, policies, procedures, and emerging ethical and scientific issues to IRB members via e-mail, mail, or during IRB meetings.

2.11 Insurance Coverage for Research Oversight Activity

Non-Pennington employees are appointed adjunct gratis faculty members of the Pennington Biomedical Research Center, for the sole purpose of their activities as members of the IRB. In this way, they, along with Pennington Biomedical Research Center employees, are protected by the Louisiana State University System Office of Risk Management.

2.12 Review of IRB Member Performance

IRB member's performance will be reviewed on an annual basis. IRB members will be asked to fill out self-assessments and the HRPP Director will use the assessment to evaluate each member. IRB members who are not acting in accordance with the IRB mission or IRB policies and procedures, or who have an undue number of absences will be removed.