

## **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 three off-site IRBs (Baton Rouge General Medical Center – FWA00001821, Louisiana State University and Agriculture and Mechanical College Baton Rouge – FWA00003892, Louisiana State University Health Care Services Division Baton Rouge – FWA00010253) 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), withheld 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 that 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.

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 section 3.11.1 – IRB Review Process). However, such officials may not approve research that has not been approved by the IRB. Pennington Biomedical Research Center officials may strengthen requirements and/or conditions, or add other modifications to secure approval or approval by another committee. Previously approved research proposals and/or

consent forms must be re-approved by the IRB before initiating the changes or modifications. The IRB Chair (or designee) makes the determination whether the changes require convened IRB re-review or expedited review.

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, employed by Pennington Biomedical Research Center, 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. The IRB Chair self-assessment will be used to assist in this evaluation. 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 HRPP/IRB Staff**

### **2.3.2.1 HRPP Manager**

The HRPP Manager supervises the Human Research Protections Program. The HRPP Manager 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 Manager responds to faculty and staff questions about Human Subjects Research as well as organizing and documenting the IRB review process. The HRPP Manager works closely with the IRB Chair in the development of policy and procedures and is not a voting member of the IRB.

### **2.3.2.2 IRB Coordinator**

The IRB Coordinator is responsible for all aspects of the IRB during the review process of a research proposal involving human subjects. This responsibility includes the review and screening of documents for research proposals prior to review by the IRB. The IRB Coordinator reviews the IRB minutes for accuracy and ensures proper documentation of discussions including discussions and actions taken by the IRB during convened meetings. The IRB Coordinator is responsible for providing administrative and clerical support to the IRB and the IRB Chair and maintaining complete IRB records.

## **2.4 IRB Membership<sup>1</sup>**

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 2.6, Use of Consultants, 3.7.1.1, Scientific Merit) 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.

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<sup>1</sup> The membership of the IRB is based upon Federal policy requirements as described in 45 CFR 46.107 and 21 CFR 56.107.

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:** 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 Members:** 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 section 3.6.7 Consultant Advice on Vulnerable Populations and Section 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. Nomination & Appointment of IRB Members

The IRB Chair identifies a need for a new and/or replacement IRB member who may be either a regular or alternate member of the IRB.

D. 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).

Appointments are made indefinitely. Any change in appointment, including reappointment or removal by the IRB Chair, requires written notification. Members may resign by written notification to the IRB Chair.

E. 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”) initially;
- Participation in the required initial training and new IRB member orientation must occur prior to review of any research; and
- Documentation of current Institutional certification in compliance education in the conduct of human subjects research (e.g., NIH Training). The IRB office documents and files compliance training for IRB members not affiliated with Pennington Biomedical Institution. Compliance training for all affiliated members (employees of Pennington Biomedical) is documented and filed in the Director of Legal and Regulatory Compliance Office.
- Attend at minimum of 75% of IRB meetings. (see 2.7, 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. Required changes will be reported to the OHRP.

F. 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.

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 discussion 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 Consultants**

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.

IRB Chair will review the COI policy for IRB members (see section IRB Member Conflict of Interest) with consultants. Consultants must verbally confirm to the IRB Chair that they do not have a COI prior to review. 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 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 at least 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.

Attendance at 75% (at minimum) of the regularly scheduled IRB meetings during the course of a year is required. The member is to contact the IRB office of any potential absence as far in advance as possible; a member who repeatedly misses meetings (>25% unless excused) will either be asked to step down or have an alternate assigned who can act in his/her stead. Pennington Biomedical employees who serve on the IRB are not subject to term limits, but serve at the discretion of the IRB Chair.

## **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 two weeks 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 Section 2.3.A and 2.4), the alternate can serve during the regular member's absence, provided the IRB has been notified in advance.

## 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. NIH human subject training is required annually for all IRB members ([www.nihtraining.com](http://www.nihtraining.com)).

### 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 a handbook that includes copies of the following:

- Pennington Biomedical Research Center FWA
- Pennington Biomedical Research Center IRB policies and procedures
- IRB member Reviewer forms
- IRB member handbook
- 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 NIH web-based initial education requirement, which consists of the training for the protection of Human Subjects involved in Research for both biomedical and social behavioral research.

### 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 IRB Chair 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 members performance will be reviewed on an annual basis by the IRB Chair, which feedback from such review shall be provided to the IRB member under review. Annually IRB members will be asked to fill out an IRB self-assessment and the IRB will use the assessment to evaluate IRB members. 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.