



INSTITUTIONAL REVIEW BOARD CHARTER

March 2019



INTRODUCTION

The Piedmont Healthcare Institutional Review Board (PHCIRB) reviews federally funded, unfunded projects, industry-sponsored and other sponsored proposals that involve human subjects. The role of the PHCIRB is to promote and safeguard the health and welfare of human subjects participating in research by ensuring that rights are protected. In so doing, the PHCIRB considers a protocol's scientific soundness, study design, privacy and confidentiality concerns, and subject safety and selection.

INSTITUTIONAL AUTHORITY

This Charter and Standard Operating Procedures establishes and empowers the PHCIRB. Additionally, the PHCIRB is established pursuant to and in accordance with all laws and regulations governing the protection of human subjects. Currently, Piedmont Healthcare has one local committee that is in compliance with both the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP) under:

- Institution / Organization number: IORG0000487
- IRB Registration number: IRB00000809
- Federalwide Assurance number: FWA00000662

AUTHORITY AND SCOPE OF THE IRB

The PHCIRB is an administrative body established to protect the rights and welfare of subjects recruited to participate in research activities conducted under the auspices of Piedmont Healthcare and its affiliations through business and other agreements. The PHCIRB provides continuing advice and counsel related to research involving human subjects and is the body at Piedmont Healthcare that has the authority to:

- Approve, require modifications in, or disapprove all human subjects research activities conducted under the auspices of Piedmont Healthcare and its affiliations through business and other agreements. This is inclusive of exempt research activities under §46.104 for which limited IRB review is a condition of exemption (under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).
- Suspend, place restrictions on, or terminate approval of human subjects research activities that fall within its jurisdiction and that are not being conducted in accordance with PHCIRB requirements or that have been associated with unexpected serious harm to subjects.
- Require progress reports from the investigators and oversee the conduct of the study.
- Observe the informed consent process as practiced by any investigator or authorized person in any approved project. See PHCIRB policy #6432.

IRB PURPOSE

The primary purpose of the PHCIRB is to protect the rights and welfare of human subjects participating in research. To do this the PHCIRB has established guidelines consistent with the ethical principles set forth in the Belmont Report and all applicable laws, including the Department of Health and Human Services (DHHS) Regulations, FDA regulations, and all other state and local laws and regulations.

See PHCIRB policy # 6400.

MANAGEMENT OF THE IRB

The PHCIRB Office is managed by the IRB Manager. The IRB Manager has reporting responsibility to the IRB Chair for IRB business concerns and to the Director of Research Operations for administrative issues. This structure allows the PHCIRB to be independent and operate without perceived influences from the Office of Research Services (ORS) while ensuring full support of the administrative needs of the office.

- The PHCIRB Chair is appointed by the Medical Executive Committee and has accountability for (non-exhaustive):
 - Professional and administrative duties of the PHCIRB
 - Overseeing convened meeting conduct
 - Maintaining surveillance of the professional activities and performance of the PHCIRB
 - Enforcement of the PHCIRB policies, standards, and all applicable state and federal regulations
- The PHCIRB Vice-Chair is selected by the PHCIRB Chair and has accountability for (non-exhaustive):
 - Assisting the Chair with completion of duties
 - Performing Chair duties in the absence of the Chair.
- The PHCIRB Manager is a Piedmont entity hire and is responsible for (non-exhaustive):
 - All day-to-day IRB administrative functions
 - Maintenance of policies and operating procedures
 - Meeting preparation, facilitation, and dissemination of determinations.

See PHCIRB policy #6403.

THE IRB'S FUNCTIONAL RELATIONSHIPS

The PHCIRB is supported by the Institutional Official (IO) and functions administratively through the Office of Research Services (ORS). This structure provides for administrative coordination of the PHCIRB with various other departments involved in the research process. Direct oversight of the PHCIRB determinations process is under the purview of the PHCIRB Chair to avoid perceived influences of the IO or ORS. The PHCIRB advises and makes recommendations entity wide on all matters related to the use of human subjects in research and applies regulations to both federally funded and federally unfunded research.

OPERATIONS OF THE IRB

The PHCIRB, though independent of 'outside' influence, must function with the understanding that the protection of human subjects in research is a shared responsibility. As such, the PHCIRB will complete administrative reviews in consideration of the input from other departments such as Regulatory Affairs, Legal Counsel, and Compliance. Protocols requiring full board review are presented for review and discussion by the PHCIRB membership.

Per OHRP and FDA guidelines, the PHCIRB maintains a membership consistent with the appropriate expertise needed to make relevant determinations on research proposals.

The PHCIRB conducts monthly meetings in person with both WebEx and audio conference options per the following:

- Members are provided all review materials at least two weeks in advance of the convened meeting via the electronic protocol tracking database known as IRBNet.

- Expertise appropriate members are designated primary and secondary reviewers responsible for presentation to the committee. The entire attending membership is expected to review materials in order to contribute to a robust discussion and confident vote on all agenda items.
- A majority vote of the quorum is required in order to vote on a submission and make committee determinations to approve, disapprove, require modifications, or terminate.
- Allow for direct physician input relating to clarification or appeal issues. Researchers are provided written documentation for all determinations.
- Ensure the solicitation of an expertise appropriate consultant is secured, when appropriate.

See PHCIRB policy #6404, 45 CFR 46.108(b), and 21 CFR 56.108(c).

MEMBERSHIP OF THE IRB

The PHCIRB is duly constituted through its Federalwide Assurance and registration with the Office for Human Research Protections (OHRP) and has the appropriate expertise to give complete and robust review of research. The IRB may consult with specialists to review proposals for which additional expertise is needed, but the specialists may not vote. The combined membership expertise as follows: Transplant/Nephrology, Endocrinology, IRB Administration, Jurisprudence, Community Representation, Cardiovascular, Pharmacy, Pathology, Pulmonology, Chaplaincy, Cardiology, Nursing, Hematology/Oncology, and Gastroenterology/Transplant/Hepatology, Cardiac Electrophysiology, Cardiac Critical Care.

- All IRB members are required to undergo formal training at the time of their initial appointment and complete the research training requirement administered through the WIRB Copernicus Group (WCG) Academy. Trainings are valid for a three year period, after which the member is required to become recertified through the same program in order to maintain ‘member in good standing’ status.
- IRB members do not receive compensation for their service.

See PHCIRB policy # 6403.

PROCEDURE FOR SELECTING/ APPOINTING IRB MEMBERS

Recruitment of new members is largely handled by the PHCIRB Manager with advisement from the Chair. Members may serve an indefinite term with a minimum of three years requested. If a member finds that s/he is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the committee before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately.

See PHCIRB policy #6403.

CONFLICTS OF INTEREST POLICY AND PROCEDURE

It is the responsibility of each PHCIRB member to identify and avoid any situations in which s/he either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before the PHCIRB of which they are a member. For any such scenario the IRB member must notify the PHCIRB Manager immediately so the matter may be reassigned to another reviewer. In order not to delay the review process, it is essential that designated reviewers peruse the matters to which they are assigned immediately upon receipt to determine whether they have a conflict.

A financial conflict of interest (COI) exists/occurs:

- When there is a financial interest in the sponsor, product or service being tested, or competitor of the sponsor or product or service being tested.

A professional conflict of interest (COI) exists/occurs:

- When a member is a key member of the research team for the protocol under review. This includes the Principal Investigator, Co-investigator, and Study / Project coordinator and any individual that is listed on a grant application or FDA 1572 form,
- When there is professional interest in a competing protocol,
- When employment or job performance is contingent on successful approval of grants and contracts,
- For those who have an employment supervisory or reporting role to the person whose work the PHCIRB is examining,
- For those who have a relationship with an entity that grants the member a non-financial benefit, such as a voluntary professional leadership role,
- When a PHCIRB member's immediate family has either a financial or a professional COI.

*Immediate family includes a spouse along with you and your spouse's parents, siblings, children, grandparents, and grandchildren.

PHCIRB member(s) who have a real or perceived conflict of interest may remain in the meeting room during the discussion of the matter at the discretion of the Chair in order to provide answers to questions and to clarify research. However, said member(s) must leave the meeting room for deliberations and actions/votes on the matter. Minutes of IRB meetings will reflect the conflicted member's abstinence from voting on that particular protocol.

See PHCIRB policy # 6404.

BASIC PRINCIPLES FOR RESEARCH INVOLVING HUMAN SUBJECTS

The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained in Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The Belmont Report). As such, Piedmont Healthcare applies the following principles to all research involving human subjects at Piedmont Healthcare to ensure that adequate safeguards are provided:

- Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.
- Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.
- Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified.
- Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.
- Participation of a human subject in research must be voluntary, and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.

- All research that involve human subjects must be reviewed by and must receive approval of a formally constituted review prior to their initiation or prior to initiating any changes to the project. Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

COOPERATIVE ACTIVITIES

Cooperative activities relating to human subjects are those involving PHCIRB and another institution. Each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with all applicable laws that govern human subjects research. On a case-by-case basis the institutions can enter into joint review arrangements or rely upon the review of another IRB using an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties.

See PHCIRB policy # 6414.

RECORD REQUIREMENTS

The IRB prepares and maintains adequate documentation of IRB activities via the protocol tracking database (IRBNet), including the following (non-exhaustive):

- Copies of all research proposals reviewed and accompanying documents including: scientific evaluations, approved sample consent documents, progress reports and reports of injuries to subjects.
- Detailed minutes of IRB meetings that show the following: members present (any consultants/ guests/others shown separately). Results of discussions on debated issues and record of IRB decisions, including the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution.
- Record of voting (showing votes for, against, and abstentions).
- Documentation on all required findings when approving an informed consent modification/ waiver.
- Records of continuing review activities.
- Copies of all correspondence between IRB and the investigators.

Other documents maintained by the PHCIRB office include: Federalwide Assurance, membership logs, Policies & Procedures, and Standard Operating Procedures (SOPs).

See PHCIRB policy # 6407.

RESEARCH MISCONDUCT

The PHCIRB will promptly report any serious or continuing noncompliance with institutional or federal policies or determinations made by the PHCIRB. All allegations of non-compliance will be investigated by the PHCIRB to determine handling and if further actions are required. The following is a non-exhaustive list of actions the PHCIRB can take upon a finding of non-compliance/misconduct:

- Termination of research
- Require a corrective action plan
- Referral to compliance
- Monitoring of the consent process, etc...

See PHCIRB policy #6416

IRB REVIEW

The PHCIRB has jurisdiction over human subjects research only. Other project types such as: case series, program evaluation, public health practice, quality assurance, quality improvement, humanitarian and/or emergency uses, etc... though not meeting the definitions of 'human subjects' and 'research' must still be sent to the PHCIRB for a formal determination of project type and/or further processing. The main categories of project requiring IRB review are projects that are exempt, expedited or requiring full board review. All determinations are provided in written form and forwarded to the principal investigator (PI). Any determinations not providing full approval will be duly noted in the correspondence to the PI along with suggestions that will make the submission approvable. The PI is invited to respond in writing or may request to speak with the designated committee member or committee in person.

The PHCIRB will conduct continuing review of research at intervals appropriate to the degree of risk but not less than once per year. Researchers are asked to provide updates on the process and conduct of the study well in advance of the study's expiration date. If an investigator fails to provide continuing review information to the PHCIRB or the PHCIRB has not reviewed and approved a research study by the continuing review date specified by the PHCIRB, the research must stop, unless the Chair or Vice Chair find that it is in the best interests of individual subjects to continue participating in the research interventions or interactions and unless this finding is ratified at the next convened IRB meeting. However, after the expiration of IRB approval, the project will be considered closed. Enrollment of new subjects cannot occur, nor can any data collected be used for research purposes.

Reportable events reporting:

Events meeting the definitions needed for reporting and 'prompt' reporting are spelled out in the applicable submission forms. Events requiring full board review will be placed on the next available agenda for review and determination.

See PHCIRB policies # 6408, # 6421, and # 6422.

DEFINITIONS

FDA: The Food and Drug Administration is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments.

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) 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.

Institutional Official (IO): The IO is the hospital official responsible for ensuring that the Piedmont Human Research Protections Program has sufficient resources and support needed to comply with federal regulations and guidelines that govern human subjects research. This individual is authorized to represent the hospital and is the signatory official for all assurances. The individual authorized to act for the institution and assume overall responsibility for compliance with the federal regulations, provide sufficient resources for Piedmont Human Research Protections Program, and to ensure the integrity and functionality of institution's program for the protection of human subjects.

Non-compliance: Failure to act in accordance with institutional policies and/or regulations, governing human participant research, and/or the requirements or determination of the PHCIRB.

Office for Human Research Protection (OHRP): An office within the United States Department of Health and Human Services (DHHS) that is responsible for implementing ethical oversight for clinical research.

Research: (1 – as defined by the DHHS): A clinical investigation or systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research whether or not they are conducted or supported under a program which is considered research for other purposes.(2 – as defined by the FDA): Any experiment that involves a test article and one or more human subjects, and meets any one of the following: a. must meet the requirements for prior submission to the FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice; b. must meet the requirements for prior submission to the FDA under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR c. any activity the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research marketing permit. A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.