



<b>Policy #</b>	<b>Policy Title</b>
6400	Human Research Protection Program
6401	Institutional Authority and the Scope of Piedmont Healthcare IRB Authority
6403	IRB Membership
6404	IRB Meetings
6405	Federalwide Assurance (FWA)
6406	IRB Administration, Staffing, and Registration
6407	IRB Records and Documentation
6408	Activities Requiring IRB Review
6409	IRB Submission Requirements
6410	Initial Review
6411	Expedited Review
6412	Continuing Review
6413	Amendments
6414	Non-local IRB Review
6415	Exempt Review
6416	Noncompliance with Human Research Protection Program
6417	Emergency Use of a Drug or Biologic
6418	IRB Meeting Minutes
6419	Informed Consent
6420	Study Closures
6421	Reporting of Unanticipated Problems
6422	Protocol Deviations and Violations
6423	Human Subjects Training – Investigator and Key Research Personnel
6425	Medical Devices – Significant Risk / Non-Significant Risk Determinations
6426	Reporting and Handling of Complaints
6427	Administrative Suspension and/or Termination of Research

<b>6429</b>	Requirements for PHCIRB Board Approval of Research
<b>6430</b>	Humanitarian Use Devices
<b>6431</b>	IRB Determinations on Research
<b>6432</b>	Observation and Monitoring of the Informed Consent Process
<b>6433</b>	Health Insurance Portability and Accountability Act (HIPAA)
<b>6434</b>	Investigator Reporting Responsibilities
<b>6435</b>	Quality Improvement / Quality Assurance Program for PHCIRB Operations
<b>6436</b>	IRB Reporting Responsibilities
<b>6440</b>	Expanded Access to Investigational New Drugs



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## Human Research Protection Program Policy, 6400

### **POLICY:**

Piedmont Healthcare, Inc. has established and maintains a comprehensive multi-tiered Human Research Protection Program (HRPP) inclusive of the Piedmont Healthcare Institutional Review Board (PHCIRB), Office of Research Services (ORS), the Institutional Official (IO), and other regulatory committees. The HRPP is implemented through the administration and oversight of the PHCIRB Manager. The program is charged with the responsibility of ensuring that all human research studies conducted by components of the Piedmont entity are conducted ethically and in a manner that promotes the protection of participants in research. In accordance with institutional policy, all such research must be in compliance with state and regulations, the Belmont Report, and the Common Rule (45 CFR 46), and 21 CFR 50 & 56.

### **PURPOSE:**

To protect human subjects research and to establish guidelines consistent with the ethical principals set forth in the Belmont Report and all applicable laws, including the Health and Human Services (HHS) Regulations and the Food and Drug Administration (FDA) Regulations, and all other applicable state and local laws and regulations.

### **HRPP Mission Statement:**

To facilitate research through the establishment of a researcher support mechanism that provides timely, high quality review and monitoring of human subjects research proposals. The HRPP will facilitate research excellence through education, researcher guidance, and compliance with all regulations that define proper conduct of human subjects research.

The Piedmont Healthcare IRB (PHCIRB) is established under the authority of the Belmont Report and Common Rule for the purpose of protecting the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Piedmont Healthcare.

The Piedmont Healthcare HRPP is composed of all entities, offices, and individuals engaged in and/or responsible for the review and conduct of human research at Piedmont Athens Regional, Piedmont Atlanta, Piedmont Columbus Regional Mid-town, Piedmont Columbus Regional-Northside, Piedmont Fayette, Piedmont Henry, Piedmont Mountainside, Piedmont Newnan, Piedmont Newton, Piedmont Rockdale, Piedmont Walton, Piedmont Physicians Group, Piedmont Heart Institute, Piedmont Cancer Center, and Piedmont-Georgia Lung Associates.

To facilitate management, review, and oversight of its research enterprise, the PHCIRB utilizes an electronic protocol tracking database called IRBNet. This secure web-based system provides a high level of accountability for all research protocols, as it allows for tracking of research and IRB reviews and determinations.

The Piedmont research enterprise currently includes biomedical, behavioral, and epidemiological research, as well as studies in the area of health services. Subjects may include healthy volunteers, as well as patients, and other individuals who may be considered vulnerable due to medical, cognitive, emotional, economical, educational, age, or other factors. In addition, researchers under the auspices of Piedmont Healthcare collaborate on projects with investigators at other institutions.

## **HRPP Governance:**

The regard to research conducted by or under its auspices, the Piedmont HRPP is established pursuant to and in accordance with the laws, regulations and principles specified below:

**The Common Rule:** the Department of Health and Human Services (HHS) policy and regulations of 45 CFR 46.

**FDA Regulations:** Food and Drug Administration (FDA) regulations of 21 CFR parts 51 and 56.

**The Belmont Report:** ethical principles that define 'respect for persons', 'beneficence', and 'justice' as they relate to human subjects in research.

## **HRPP Leadership:**

The Piedmont Healthcare HRPP reports to the Executive Director of Research (EDR) and the Institutional Official (IO).

The EDR and IO provide leadership and support for Piedmont Healthcare's HRPP program. It is the shared responsibility of the EDR, IO, IRB Chair and

IRB Manager to work towards supporting a culture of research integrity and to ensure all research under the PHCIRB FederalWide Assurance is conducted ethically and in compliance with all regulatory standards.

## HRPP Components:

The Piedmont HRPP is multi-tiered to include the PHCIRB, the Office of Research Services (ORS), the Institutional Official (IO), other regulatory committees, research investigators and key research personnel.

**Piedmont Healthcare Institutional Review Board (PHCIRB):** the committee formally designated to approve the initiation of, and to conduct periodic reviews of clinical research studies involving human subjects. The PHCIRB is responsible for reviewing clinical research studies involving human subjects conducted by or under the auspices of Piedmont. The PHCIRB has established written IRB procedures for each HHS and FDA regulatory requirement as applicable. These policies and procedures are available to investigators, research personnel, and administration via the Piedmont Village Intranet.

The mission of the PHCIRB is to enhance and facilitate the ethical conduct of human subjects research conducted by the Piedmont entity. The PHCIRB will perform this mission through its review of human subjects research, its educational and training initiatives, and its compliance oversight and quality improvement programs.

The PHCIRB is governed by the principles of the Belmont Report and the federal regulations for the protection of human subjects in research as codified by: 1) the U.S. Department of Health and Human Services regulations, 45 CFR Part 46, Subparts A (Common Rule), B, C, D and E; 2) the U.S. Food and Drug Administration (FDA) Regulations, 21 CFR Parts 50, 56, 600, and 812; and 3) PHCIRB Policies and Procedures.

The PHCIRB charged with the responsibility of providing review, approval, and oversight monitoring to ensure that all human research under the auspices of the Piedmont Healthcare HRPP is conducted: 1) ethically; 2) in a manner that protects human subjects, and 3) in accordance with the above mentioned regulations, laws, policies, and standards.

While approval from other Piedmont Healthcare offices or committees may be necessary per institutional policy, the decision of whether to approve or disapprove a submission is made autonomously and is not influenced by potential funding, prestige, or other benefit that may accrue to the Institution.

Additional IRBs may be added as necessary to ensure adequate and timely review of research proposals submitted for consideration.

**Office of Research Services (ORS):** this department is an integral part of the Piedmont Healthcare HRPP and serves as the entry portal to the research approval process through the assessment of financial feasibility. In addition, the ORS educates researchers on educational requirements and facilitates the use of the IRBNet (electronic submission system used to facilitate the management of research proposals. The ORS has established written policies and procedures that are available via the Piedmont Village Intranet.

**Institutional Official (IO):** the individual authorized to act for the institution and assume overall responsibility for compliance with the federal regulations, provide sufficient resources for the HRPP, and to ensure the integrity and functionality of institution's program for the protection of human subjects.

**Other regulatory committees:** are entities charged with reviewing other aspects of research proposals. The PHCIRB will coordinate its review processes with these bodies to ensure final PHCIRB approval is granted inclusive of documentation of approval from all relevant regulatory committees.

**Central IRBs:** The PHCIRB establishes Institutional Authorization Agreements (IAAs) with several AAHRPP accredited central IRBs and relies on their IRBs for certain types of research projects. Details regarding each agreement are provided in the PHCIRB Policies and Procedures. The decision to enter into an agreement with another institution for reliance of both institutions on one of the IRBs is made after: a) evaluation of the non-Piedmont institution's IRB policies and procedures; b) consideration of whether regulatory compliance and Piedmont standards may be upheld through the relationship, and c) analysis of whether an efficient process may be implemented to conduct the reviews.

**Department Chairs, Faculty, Research Investigators, and Staff:** The Department Chairs and Faculty are responsible for ensuring that all research involving human subjects is conducted in accordance with ethical principles, institutional policies, and federal and state regulations. The leadership provided by the Department Chairs, Faculty, and Administrators helps ensure that research at Piedmont is conducted with high quality and in an ethical manner. The research investigators and staff are at the forefront of human research protections, as they are best positioned to directly ensure that research is conducted ethically. Research investigators are the main contact persons who conduct the research projects and under whom immediate direction is established. Research staff (key research personnel) are individuals with significant roles in assisting the researcher in carrying out the research. These individuals are those that have direct contact with study participants and/or their research data and identifiers for purposes of conducting the research study.

## Reference:

**Regulatory Reference:** 45 CFR 46; 21 CFR 50 & 56

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## **Institutional Authority and the Scope of Piedmont Healthcare IRB Authority Policy, 6401**

### **POLICY:**

Piedmont Hospital designates the Medical Executive Committee as the body appointed to establish the Piedmont Healthcare Institutional Review Board. The Piedmont Healthcare IRB (PHCIRB) is responsible for reviewing human subjects research conducted by or under the auspices of Piedmont.

### **PURPOSE:**

This policy defines the scope of authority of both the PHCIRB and the body charged with ensuring its sufficient resources for successful operation.

### **Institutional Authority:**

Piedmont Hospital maintains the authority to designate a governing body (the Medical Executive Committee) to accomplish the following:

- a. Appointment of an Institutional Official (IO) that is authorized to act for the institution and assume overall responsibility for compliance with the federal regulations, provide sufficient resources for the Human Research Protections Program (HRPP), and to ensure the integrity and functionality of the institution's program for the protection of human subjects.
  1. The IO shall serve in this position, until the earlier of:
    - a. Departure from Piedmont Healthcare;

- b. The individual no longer has the ability or capacity to fulfill the role;
- c. The individual's resignation is requested by the Medical Executive Committee, or
- d. The individual tenders a resignation from the position.

NOTE: Resignation is required at any time in which the IO does not meet the qualifications of the position.

Research that has been reviewed and approved by the PHCIRB may be subject to review and disapproval by officials of Piedmont. However, those officials may not approve research if it has been disapproved by the PHCIRB.

- b. Establish the PHCIRB to oversee all research activities conducted at all entities within Piedmont Healthcare, Inc.

## **PHCIRB Authority:**

The PHCIRB is designated as the body within Piedmont Healthcare, Inc. that has jurisdiction over all human subjects research conducted under the auspices of Piedmont Healthcare, Inc. Pursuant to its duty to protect the rights and welfare of human subjects participating in research, the PHCIRB will conduct comprehensive initial and periodic reviews. In addition, the PHCIRB will ensure: an acceptable risk/benefit ratio, equitable subject selection, and an appropriate consent process.

The PHCIRB maintains the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy.

The PHCIRB reviews all non-industry sponsored research involving human subjects that occurs at Piedmont. Industry sponsored research is managed through the Western Institutional Review Board (WIRB). In instances where a sponsor of an industry sponsored study does not wish to use WIRB the PHCIRB may serve as the IRB of record.

The PHCIRB shall have authority over all research under its purview not limited to:

- a. Establish education standards for individuals conducting research at sites under the auspices of Piedmont Healthcare;
- b. Approve, require modifications (to secure approval), or disapprove all research activities based on a consideration of human subjects protection;
- c. Suspend, place restrictions on or terminate activities that are not being conducted in accordance with PHCIRB requirements or that may cause unexpected serious risks to participants;
- d. Oversee the conduct of the study;



- e. Review and accept or not accept progress reports from researchers. The PHCIRB will permit continuing the study, require modifications to, suspend, or discontinue the research based on these reports;
- f. Investigate complaints or reports of noncompliance or protocol deviations/violations;
- g. Evaluate the risk:benefit ratio of a study;
- h. Ensure the adequacy of the Informed Consent process and all consent form documents;
- i. Observe the consent process;
- j. Monitor the Informed Consent process; and
- k. Ensure that the research has in place adequate mechanisms to protect human subjects, including the auditing of sites and monitoring the informed consent process including the use of in-house or third party monitors/QA monitors or auditors.

## Reference:

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# IRB Membership Policy, 6403

## **POLICY:**

In accordance with 45 CFR 46.107 and 21 CFR 56.107, the Piedmont Healthcare IRB (PHCIRB) membership consists of appointed individuals who are qualified through varying backgrounds to provide appropriate expertise to promote complete and adequate review of research activities conducted at Piedmont.

## **PURPOSE:**

This policy describes PHCIRB's adherence to and execution of the regulations as required for membership on an IRB (Institutional Review Board).

## **Membership Composition:**

The PHCIRB shall:

1. Be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote complete and adequate review of research activities commonly conducted at Piedmont;
2. Practice every nondiscriminatory effort to ensure that the IRB does not consist entirely of men or entirely of women so long as no selection of IRB members is made on the basis of gender;
3. Be able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law, and standards of professional conduct and practice;
4. When reviewing research involving a vulnerable population, such as children, prisoners, pregnant women, handicapped or mentally disabled persons, the IRB shall include one or more members who are knowledgeable about and experienced in working with these subjects (i.e., Subject Representative).
5. Include at least five members with varying backgrounds
6. Include at least one scientist member and at least one non-scientific member;
7. Include at least one member who is not otherwise affiliated with Piedmont Healthcare and who is not part of the immediate family of a person who is affiliated with Piedmont Healthcare (i.e., Non-Piedmont Affiliated Member);

8. Not consist entirely of members of one profession.

## **Ensuring Compositional Requirements:**

The PHCIRB Chair, with the assistance of the IRB Manager, shall periodically, but no less than annually, review and adjust the membership of the PHCIRB to ensure that the composition meets all regulatory and organizational requirements.

## **PHCIRB Members Selection and Tenure:**

1. Names and qualifications of prospective members of the PHCIRB are submitted to the PHCIRB Chair and/or PHCIRB Manager for appointment to the Committee.
2. The PHCIRB Chair will review the nomination of a prospective IRB member in consultation with the PHCIRB Manager.
3. PHCIRB members are selected based on the qualifications required of an IRB member and the current needs of the PHCIRB membership composition.
4. PHCIRB members can serve an indefinite term. If a member resigns from the PHCIRB, a 60-day notice will be given to the PHCIRB Chair to allow time for member replacement.

## **Member duties:**

1. Complete the committee member learning requirement as administered through the WIRB Copernicus-Group (WCG) Academy in order to be considered a member in good standing to count towards quorum at the convened meetings. Members not compliant with these requirements will be suspended from full participation until such time the certifications are made current. The IRB staff will monitor the PHCIRB members' progress and maintenance of qualification.
2. Become knowledgeable of:
  - a. the Federal Regulations at 45 CFR 46 and 21 CFR 50 and 56.
  - b. PHCIRB Policies and Procedures
  - c. The Belmont Report
3. Attend fifty (50) percent of the scheduled meetings and engage in discussions. If a member is unable to attend a scheduled meeting or complete designated assignments, it is the expectation that as much advance notice as possible will be given to the IRB staff so that other arrangements can

be made. If attendance falls below fifty (50) percent, it is at the discretion of the Chair and/or PHCIRB Manager to remove the PHCIRB member if appropriate inquiries indicate that the member is no longer interested in or available for membership.

4. Complete review assignments using IRBNet. Members are expected to obtain proper training needed to utilize the electronic protocol tracking system and to refresh their skills as needed.

## Documentation of Membership:

1. The PHCIRB Manager is responsible for filing and maintaining IRB Registration with OHRP and FDA. The IRB Registration shall serve as the official record of the primary members for whom alternate members may substitute.
2. The PHCIRB Manager shall notify OHRP/FDA of changes to IRB membership. Copies of the modified IRB Registration will be retained by the PHCIRB.
3. The IRB staff is responsible for maintaining a record for each current member, including but not limited to the member's *curriculum vitae*, any letters of appointment, and the member's signed confidentiality agreement.
  - a. Records relating to past members shall be stored according to Federal regulations regarding storage of IRB records.
4. The PHCIRB Manager is responsible for maintaining a roster of members. The roster will contain information to describe:
  - a. Name and earned degrees;
  - b. Representative capacity;
  - c. Indication of experience to describe contribution to committee deliberations
  - d. Any employment or other relationship with the institution.
5. The membership roster shall be made available to the research community.

## Member Orientation and Training:

1. All continuing education articles, sessions, etc. are available within IRBNet as reference materials for any PHCIRB members. In addition, the text *Institutional Review Board Management and Function (Bankert & Amdur)* is available in the IRB office as reference.
2. New guidance documents, articles, rulings, etc., pertinent to Human Subjects Research will be sent to PHCIRB members as appropriate.
3. PHCIRB members will be invited to relevant educational research programs, webinars, seminars, etc., held at Piedmont.

## **PHCIRB Chair:**

The PHCIRB Chair shall be a member of the PHCIRB who is qualified by training, experience and demonstrated ability for the position. The Chair shall be appointed by the Medical Executive Committee for a two-year minimum term and shall perform functions including; but not limited to:

1. Accountability for all professional and administrative activities of the PHCIRB;
2. Maintain continuing surveillance of the professional activities and performance of the PHCIRB;
3. Responsibility for enforcement of the PHCIRB policies, standards, and all applicable state and federal rules, regulations, and statutes, including enforcement of sanctions for violations;
4. Maintain training related to fulfilling the role of an IRB Chair.

## **PHCIRB Vice-Chair:**

The Vice-Chair shall be a member of the PHCIRB and qualified by training experience, and demonstrated ability. The Vice-Chair shall be selected by the PHCRB Chair for a two-year minimum term and shall perform the following functions, including, but not limited to:

1. Assistance of the PHCIRB Chair in the completion of duties;
2. In the absence of the Chair, the Vice-Chair assumes the responsibilities of the Chairman.

## **Absence of the Chair:**

Whenever the Chair is not available to perform his or her duties, the Chair may designate the IRB Vice-Chair or another IRB member to assume his or her responsibilities during his or her absence.

## **Alternate Members:**

Alternates are designated for specific members. If both the alternate and primary member attend a meeting, only one of these two may vote. When an alternate member substitutes for a primary member, the alternate member will receive and review the same material that the primary member received or would have received. Alternate members should have equivalent expertise, including the same scientific or nonscientific status, as the primary member for whom they are substituting.

## **Consultants:**

Either before or during review of a protocol, the PHCIRB may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that routinely available on the PHCIRB. Consultants may be asked to provide their expertise regarding a specific issue, or provide general comments regarding a project. Consultants may not vote with the PHCIRB.

## **Confidentiality Agreement:**

PHCIRB members are required to sign a Confidentiality Agreement, and must agree not to discuss, disclose, or reproduce any confidential PHCIRB information, except as necessary to carry out IRB membership responsibilities or as required by law.

## **Compensation and Liability:**

PHCIRB members do not receive any compensation for participation above that received for their normal Institutional duties and responsibilities. Community members are also non-paid volunteers. Liability coverage for PHCIRB members is included as part of the Institution's liability insurance policy.

## **Reference:**

**Regulatory Reference:** 45 CFR 46.103,.107, and .115; 21 CFR 56.107 and .115.

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## IRB Meetings Policy, 6404

### **POLICY:**

The Piedmont Healthcare IRB (PHCIRB) will hold regularly scheduled meetings for the purpose of providing initial and continuing review for and modifications to human subjects research protocols that the PHCIRB has authority to review. The meetings serve to conduct official PHCIRB business. A quorum must be present in order to conduct an IRB meeting.

### **PURPOSE:**

To define the PHCIRB's scheduling and execution of official IRB committee meetings.

### **Definitions:**

Quorum: the minimum number of members that must be present to conduct official PHCIRB business. A quorum shall be established when the following criteria are met: (a) a majority of the voting IRB members are present (e.g., quorum for an IRB Committee of sixteen (16) voting members would be nine (9); (b) one of the voting members present is a non-scientist; and (c) if a protocol involving an FDA-regulated article is reviewed, then a licensed physician (MD) must be present.

### **Convened Meetings:**

Per 45 CFR 46.108(b) and 21 CFR 56.108(c), except when an expedited or exempt review procedure is used, the PHCIRB will review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in non-scientific areas. The attendance of a non-scientist shall be recorded in the meeting minutes. Without such a member in attendance, the meeting may not commence with business. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

Meetings of the PHCIRB will be held on a monthly basis on the third (3<sup>rd</sup>) Friday of each month at 12:30 PM. Meetings will be held via WebEx and/or in an appropriate space that allows the committee to conduct official business. The meeting space will include electronic and computer equipment that allows the utilization of the IRB software system during meetings. The meeting space will also have a telephone system equipped with conference calling capabilities.

The PHCIRB Chair, Manager and/or members can request additional meetings at anytime if deemed necessary in order to complete the review or monitoring process.

The PHCIRB Chair, or designee, will establish that a quorum is present before starting the meeting.

The PHCIRB Chair and IRB staff will monitor that quorum is maintained throughout the entire meeting. If quorum is lost, the meeting will stop until quorum is regained. The minutes will reflect when quorum was met; minutes will also reflect anytime quorum is lost, and when it is regained.

## **Pre-Meeting Distribution to PHCIRB Members:**

The IRB staff will:

1. Send a schedule of the year's meeting dates, times, and locations at the beginning of each year;
2. Send a reminder notice via e-mail two (2) weeks before each meeting as a reminder of the next scheduled IRB meeting;
3. Send an agenda for the next meeting via e-mail at least one (1) week prior to the next scheduled IRB meeting;
4. Via IRBNet, utilizing the Primary/Secondary Reviewer system, send each member selected to review items the study materials to be reviewed at least two (2) weeks prior to the next scheduled IRB meeting, these include, but are not limited to:
  - a. Complete IRB application form for the protocol;
  - b. Protocol
  - c. Proposed consent form(s);
  - d. Recruitment materials/subject information;
  - e. Surveys and questionnaires;



f. Investigator's brochure;

All meeting materials required for review will be available to all members via the IRBNet electronic IRB system for review and reference. ***Members who have a conflict of interest related to any study will not have access to it via IRBNet as an IRB member.***

Any member may request additional information to complete his/her review by contacting the IRB office and/or contacting the Principal Investigator directly.

## **Attendance:**

PHCIRB Members are expected to attend all IRB meetings and arrive at the meeting start time. Attendance will be recorded in the IRB minutes. If a PHCIRB member is unable to attend a scheduled IRB meeting, it is his/her responsibility to notify the IRB staff in advance of the scheduled meeting. PHCIRB members are expected to attend at least fifty (50%) percent of the meetings. Continual attendance problems may be cause for removal by the PHIRB Chair and/or Manager.

Attendance in person or via teleconference and/or WebEx is acceptable and counts toward quorum. The following is effective for teleconference and/or WebEx meeting attendance:

1. The member utilizes a phone that is secure and in a private setting so the meeting proceedings cannot be overheard.
2. The PHCIRB staff will connect the member to a speaker-phone that can be heard by both the committee members and other members on the conference line.

## **IRB Staff Attendance:**

IRB staff will be in attendance at each IRB meeting and will coordinate the electronic IRB software system by setting it up and logging in to each submission discussed at the meeting. IRB Staff will record meeting minutes and in conjunction with the PHCIRB Chair, will assist the committee in resolving questions regarding the federal regulations related to the review of human subjects research.

## **Guests Attending Meetings:**

At its discretion, the PHCIRB may invite: Investigators, research personnel and/or advisors for the purpose of additional clarification or discussion regarding their study. These individuals are required to leave the meeting before the final deliberation and vote on the study. The IRB meeting minutes reflect the presence of all guests. Guests will sign an IRB confidentiality agreement that will be kept on file in the IRB office.

Guests can include members of medical or administrative staff of Piedmont, regulatory or other agencies or the community. Guests and the reason(s) for attendance are stated at the beginning of the meeting and in the minutes.

When other guests are invited to the meeting, they may observe only and may not participate in the meeting except to provide information requested by the board. Guests are not included in determining or establishing a quorum at the meetings. Guests may remain present to observe during the discussion, the final deliberation and vote for research under review, but may not make recommendations to the board or participate in the vote.

## **Duration of Meetings:**

Thorough discussion of all items on the agenda will be permitted to all PHCIRB members. An IRB meeting will continue from the time quorum is established until the time (a.) quorum is lost or (b.) all items of business shown on the agenda have been discussed or (c.) the PHCIRB Chair calls the meeting to an end.

In general, IRB members shall refrain from leaving IRB meetings before all items of business are discussed and shall advise the IRB staff in advance of any need to leave before the IRB meeting's conclusion.

## **Member Review Assignments:**

IRB Reviewers – Primary and Secondary: Each item for discussion will be assigned designated primary and secondary reviewers who will present the item and lead the discussion on that topic. Consultants will be assigned on an as needed basis.

Reviewers shall thoroughly review all research protocol submissions assigned to him/her in advance of the IRB meeting. Additionally, prior to the meeting, members should solicit the assistance of the IRB staff to resolve potential pending issues if possible.

## **Committee Discussions:**

After the reviewer presentation is complete, the committee will discuss any issues related to the review of the research protocol submission(s). After discussion, the committee will vote on the research protocol submission(s) that were reviewed and discussed.

All PHCIRB members that do not have a conflict-of-interest with a study are encouraged to actively participate in the review and discussion of research protocol submissions reviewed at convened meetings.

## **Voting:**

Each PHCIRB member has one (1) vote. Voting by proxy is not permitted.

Any PHCIRB member can call a motion to vote. Motions shall carry by a majority of the persons voting, and in the event of a tie, the recommendation/motion will not carry and the matter will be deferred until the next PHCIRB called meeting.

Votes will be sought and counted as follows: a. In Favor; b. Opposed; c. Abstained.

No PHCIRB member may participate in deliberations or voting of the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. These members must be recused from the meeting prior to the deliberation and voting processes.

## Reference:

### Regulatory Reference:

45 CFR §§ 46.107, .108, .109, .115

21 CFR §§ 56.107, .108, 109; .111 & .115

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## Federalwide Assurance (FWA) Policy, 6405

## **POLICY:**

It is the policy of Piedmont Healthcare, Inc. to hold a Federalwide Assurance (FWA) # 00000662, approved by the Office for Human Research Protections (OHRP). Piedmont Healthcare, Inc. and its entities (collectively "Piedmont") are covered by this FWA. The terms of the FWA apply whenever Piedmont becomes engaged in human subjects research (not otherwise exempt) that is conducted or supported by any agency of the U.S. Department of Health and Human Services (HHS) as outlined in 45 CFR Part 46 (the "Common Rule") unless the federal department or agency conducting or supporting the Research determines that the Research shall be conducted under a separate assurance.

Piedmont Healthcare IRB activities in relation to any human subjects research that is conducted or supported by any agency of the U.S. Department of Health and Human Services (HHS) are governed by and subject to the terms and conditions of the FWA. With regard to human subjects research that is not conducted or supported by any agency of the U.S. Department of Health and Human Services (HHS), Piedmont applies the policies and procedures of its internal Human Research Protections Program.

## **PURPOSE:**

To describe the Federalwide Assurance held by Piedmont and the activities which meet the regulatory definition of human research that are governed by the FWA as outlined in 45 CFR 46, the Common Rule.

## **Definition:**

Federalwide Assurance (FWA): An assurance of compliance is a written document submitted by an institution that is [engaged](#) in non-exempt human subjects research conducted or supported by HHS. Through the assurance, an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects per 45 CFR 46.

## **Procedures:**

1. The Piedmont Healthcare FWA shall be executed by the Institutional Official (IO). Any changes made to the FWA shall be executed by the IO.
2. Piedmont FWA: FWA #00000662 is held by Piedmont Healthcare, Inc. The Institutional Official (IO) is the Chief Medical Officer, Executive Vice President and Chief Quality Officer.
3. Piedmont Healthcare, including the Piedmont Healthcare IRB, is subject to and agrees to abide by the Terms of Assurance required by the OHRP. For human subjects research under the jurisdiction of the Piedmont Healthcare IRB (PHCIRB), the PHCIRB provides oversight to human subjects research conducted or supported by any agency of the U.S. Department of Health and Human Services (HHS) that has adopted the Common Rule. This oversight is conducted in accordance with the Terms of Assurance outlined in the Piedmont Healthcare FWA.

4. The entities of Piedmont Healthcare that are covered by the Piedmont Healthcare FWA are: Piedmont Athens Regional Medical Center, Piedmont Newton Hospital, Piedmont Mountainside Hospital, Piedmont Walton Hospital, Piedmont Columbus Regional - Northside Hospital, Piedmont Columbus Regional-Midtown Hospital, Piedmont Fayette Hospital, Piedmont Henry Hospital, Piedmont Newnan Hospital, Piedmont Atlanta Hospital, Piedmont Rockdale Hospital, Piedmont Heart Institute Physicians, Piedmont Physicians Group, Piedmont Cancer Institute, and Piedmont-Georgia Lung Associates. The IO is required to grant approval to any additions or withdrawals of the components covered by the Piedmont Healthcare FWA.
5. The PHCIRB Manager is responsible for filing any required documentation with the Office of Human Research Protections (OHRP) in regards to the FWA held by Piedmont Healthcare, Inc., including updates and revisions.
6. Any external institution that relies on the Piedmont Healthcare FWA is subject to the terms of its Policies and Procedures.
7. Renewal of the Piedmont Healthcare FWA is required every five years. The PHCIRB Manager is responsible for ensuring that the Piedmont Healthcare FWA is renewed. A copy of the complete current Piedmont Healthcare FWA is kept in the PHCIRB office. Verification of Piedmont Healthcare's FWA can be viewed at the OHRP web-site at <http://ohrp.cit.nih.gov/search/> by searching Piedmont Healthcare in the Assurances (FWA) section.
8. All Investigators at Piedmont are expected to conduct research in accordance with the provisions of the Federalwide Assurance. Primary responsibility for assuring that the rights and welfare of the individuals involved are protected rests with Principal Investigator (PI) conducting the research. PIs who delegate responsibilities to other physicians and/or research staff have an obligation to consider carefully whether those individuals are qualified to safeguard adequately the rights and welfare of subjects.

## Reference:

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## IRB Administration, Staffing, and Registration Policy, 6406

### **POLICY:**

It is the policy of the Piedmont Healthcare IRB (PHCIRB) to maintain adequate resources and promote an environment that supports the IRB in making independent decisions related to the protection of research subjects.

### **PURPOSE:**

This policy outlines PHCIRB's policy and procedures related to adequate staffing and appropriate resources to support the IRB's mission to protect human subjects involved in research.

### **Reporting Structure:**

The Piedmont Healthcare IRB (PHCIRB) is administratively housed within the Office of Research Services of Piedmont Healthcare.

The Chief Medical Officer, Executive Vice President and Chief Quality Officer of Piedmont Healthcare serves as the Institutional Official.

The PHCIRB reporting structure will be organized so that no real or perceived conflict of interest compromises PHCIRB function or credibility. The PHCIRB will be administratively independent from Piedmont offices that have any direct responsibility for the recruitment of subjects or research dollars.

The PHCIRB Manager reports to Director of Research Operations, Office of Research Services for matters unrelated to IRB business. IRB specific issues are discussed and agreed upon with the IRB Chair and/or Vice-Chair.

The Piedmont Hospital Medical Executive Committee of Piedmont Hospital charges the PHCIRB committee with making independent and sound decisions related to the protection of research subjects.

## **Lines of Authority:**

The PHCIRB shall have an IRB Chair and an IRB Vice-Chair.

The IRB Chair acts on behalf of the IRB.

The Institutional Official, by definition, acts on behalf of the institution.

## **Staff, Space, and Supplies:**

Per 45 CFR 46.103(b)(2), Piedmont Healthcare shall provide the IRB with sufficient meeting space to conduct convened IRB meetings and staff to support the IRB's review and record keeping duties. Per PHCIRB policy and procedure # 6400, the Institutional Official is the individual charged with the provision of sufficient resources as well as ensuring the integrity and functionality of the institution's program for the protection of human subjects.

## **IRB Registration:**

The Piedmont Healthcare IRB must be registered with OHRP and FDA. Any other institution's IRB upon which Piedmont may rely for review of research with human subjects pursuant to a duly executed IRB Authorization Agreement must also be registered with OHRP and FDA.

The IRB registration must be renewed every 5 years, whether or not any changes to the IRB has occurred, in order to maintain an active OHRP and FDA registration. The IRB Manger is responsible for ensuring that the IRB registration is renewed in a timely fashion and is not permitted to expire. Copies of all documentation regarding PHCIRB registration shall be kept in the IRB offices.

## **Reference:**

**Regulatory Reference:** 45 CFR 46 and 21 CFR 56

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## IRB Records and Documentation Policy, 6407

### **POLICY:**

It is the policy of the Piedmont Healthcare IRB (PHCIRB) to maintain adequate records that meet regulatory requirements and provide clear documentation of PHCIRB findings and determinations.

### **PURPOSE:**

This policy outlines PHCIRB's records requirements and documentation of findings and determinations procedures.

### **Record and Documentation Requirements:**

The PHCIRB shall prepare and maintain adequate documentation of IRB records and activities, including the following:

1. A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, or consultant.



Changes in IRB membership shall be reported to the department or agency heads, unless in accord with 45 CFR 46.103(a), the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.

2. Written IRB Policies, Procedures, and Guidelines as outlined in 21 CFR 56.108.
3. Minutes of IRB meetings, including:
  - a. Members present, i.e. attendance, (any consultants/ guests/others shown separately);
  - b. Record of vote on all IRB actions, including the number of members voting for, against, and abstaining. Members who recuse themselves from deliberations and voting will be recorded;
  - c. Separate deliberations, actions taken, and votes for each protocol undergoing initial or continuing review by the convened IRB;
  - d. The basis for requiring changes in or disapproving research;
  - e. A written summary of the discussion of controverted issues and their resolution (more information regarding IRB minutes can be found in the PHCIRB policy # 6418: IRB Minutes);
4. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;
5. Records of continuing review activities;
6. Communications to and from the PHCIRB, including copies of all correspondence between the IRB and the investigators;
7. Adverse reactions reports that require reporting;
8. Statements of significant new findings provided to subjects, as required by 45 CFR 46.116(b)(5) and 21 CFR 50.25;
9. IRB records shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of HHS departments or agencies, including the Office of Human Research Protections and the Food and Drug Administration, at reasonable times and in a reasonable manner;
10. Emergency Use Reports (more information related to emergency use reports can be found in PHIRB policy #6417: Emergency Use).

## Reference:

Regulatory Reference: 45 CFR 46.115; 21 CFR 56.115

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## Activities Requiring IRB Review Policy, 6408

### **POLICY:**

Piedmont Healthcare conducts biomedical human subjects research, social science and behavioral research involving human subjects. No intervention or interaction with human subjects in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol.

All research involving human subjects, and all other activities which even in part, involve such research, regardless of sponsorship, must be reviewed and approved by the Piedmont Healthcare IRB.

### **PURPOSE:**

This policy describes specific activities that require IRB review and those that do not. It also describes activities that do not require IRB review.

## Definitions:

**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.

**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. **NOTE:** If it isn't identifiable, it doesn't involve human subjects, and is not under the Common Rule.

**Identifiable private information** is private information for which the identify of the subject is or may readily be ascertained by the investigator or associated with the information. **NOTE:** If it isn't identifiable, it doesn't involve human subjects, and is not under the Common Rule.

**Intervention** includes physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

**Interaction** includes communication or interpersonal contact between investigator and subject.

**Private information** includes 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 (ie., a medical record). Private information must be individually identifiable in order for obtaining of the information to constitute research involving human subjects.

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

**A Systematic Investigation** is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question.

## Determination of Human Subjects Research:

Investigators should contact the PHCIRB for assistance in determining if a project qualifies as human subjects research. When a project for review is received, the PHCIRB staff conducts an initial review of the proposal to verify if the activity does or does not meet the regulatory definition of human subjects research. The IRB determination is documented and communicated to the researcher in writing.

## Activities Requiring IRB Review:

Specific activities that require IRB Review include, but are not limited to:

- Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Food, Drug, and Cosmetic Act, or need not meet the 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 later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.
- Collection and use of data about a series of standard procedures or treatments for dissemination or generalization if the activity meets the definition of "human research."
- Patient care or the assignment of normal participants to any intervention that is altered for research purposes in any way.
- A diagnostic procedure for research purposes that is added to a standard treatment.
- "Systematic investigations" involving innovative procedures or treatments. For example, if an investigator plans to collect information about an innovative procedure for scientific purposes or will repeat the innovation with other participants in order to compare it to the accepted standard.
- Emergency Use of an Investigational Drug or Device. One time emergency uses of an investigational drug or device may proceed without prospective IRB review. When emergency medical care involving an investigational article, the research does not require prospective IRB review and approval, the patient is a research subject as defined by FDA regulations, but may not be considered a research subject as defined by HHS regulations, and data generated from such care cannot be included in any prospectively conceived report of an HHS regulated research activity.
- Emergency Medicine Research. Prospectively planned emergency medicine research with investigational drugs, devices, or biologics requires IRB approval. If the researcher intends to waive the requirement for informed consent, additional requirements must be met including community consultation and public disclosure.
- Data, Human Cell or Tissue Repository. Human cell or tissue (genetic tissue) research typically involves repositories that collect, store, and distribute human tissue materials for research purposes.
- Investigator Research. A Piedmont investigator who both initiates and conducts, alone or with others, a research project or clinical trial regardless of source of funding or support.
- Student Research. Directed or independent human research projects which employ systematic data collection with the intent to contribute to generalizable knowledge.
- Access to protected health information. Investigators conducting research with protected health information maintained within any of the covered entities of Piedmont Healthcare, Inc. must provide the IRB with appropriate information to obtain approval of the activity prior to access of the protected health information.
- Collaborative Research. Collaborative research requires IRB review by each performance site unless an IRB authorization or Independent Investigator Agreement is in place or carried out under the terms of a cooperative agreement.

## **Activities that generally do not require IRB Review:**

- Research that does not meet the regulatory definition of human research or clinical investigations does not require IRB approval.
- Proposals that lack definite plans for involvement of human subjects will not require IRB review.

- Activities such as quality assurance or quality control, program and fiscal audits generally do not qualify as research that requires IRB review.
- Certain disease monitoring as prescribed by the Public Health Department generally does not qualify as research that requires IRB review.
- Case Studies. A single retrospective case study that reports the observation of a single subject receiving the normal standard of care (no new or novel procedures) is generally not considered research. There is no intent to test a hypothesis via systematic analysis, or add to a body of knowledge.

However, when a series (more than one) of subject observations is compiled in such a manner that would allow possible extrapolation of the results to a larger population, this would likely represent research.

## Failure to Submit Project for IRB Review

Engaging in activities that qualify as research that is subject to IRB review without obtaining such review and approval is a major violation of the federal regulations for human subjects research. If an investigator begins a project without prospective IRB review and approval and later learns of the review requirement, the investigator should promptly notify the IRB. The IRB may allow or deny use of the data. The investigators should also notify FDA, if applicable. The IRB will report the violation to FDA and OHRP, if required.

If an investigator begins a project and later finds that the data gathered could contribute to generalizable knowledge, has changed in some fashion as to now require IRB review, or that he or she may wish to publish the results, the investigator should submit a proposal to the IRB for review as soon as possible. If the IRB does not approve the research, the IRB may determine that the research cannot be used as part of a study, thesis or dissertation nor may the results of the research be published.

## Reliance on an Outside (Independent) IRB:

Under certain conditions, the PHCIRB may rely on another organization's IRB. The reliance on another IRB will be outlined in an approved IRB Authorization agreement or under the conditions of an approved cooperative agreement.

## Reference:

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## IRB Submission Requirements Policy, 6409

### **POLICY:**

Piedmont Healthcare IRB (PHCIRB) requires investigators to provide sufficient documentation to fulfill its role in providing initial and continuing review of human subjects research under the authority of the PHCIRB. A submitted proposal will be scheduled for IRB review only when the IRB staff determines that the information and materials submitted present an adequate description of the proposed research and/or changes to previously approved research.

### **PURPOSE:**

This policy outlines the required documents and supporting information required from investigators for IRB review and determination of Initial Review, including Informed Consent documents, Continuing Review, Amendments and Revisions, Protocol Deviations and Violations, and Serious Adverse Events and Unanticipated Problems.

### **Procedures:**

A Principal Investigator requesting PHCIRB to review a research project must submit the required documents outlined in this policy to the IRB prior to or on the Office of Research Services (ORS) submission deadline date via the IRBNet electronic submission system.

### **Submission Requirements for Initial Review of a New Protocol**

Investigators applying for initial approval of proposed research are required to submit the following:

- A. Completed New Protocol Application form;
- B. Full final grant application(if applicable)
- C. Final study protocol with elements not limited to the following:
  - a. Full protocol title, sponsor name (if applicable), researcher name(s), date of document, contact information.
  - b. Abstract/synopsis to include a description of the study objectives, target population, study design, and outcome measure.
  - c. Introduction and background with a summary of the primary hypothesis, purpose, rationale and prior literature support with results of previous related research.
  - d. Study objectives with primary and secondary aims and outcome measures.
  - e. Study design and methods. This section should include full descriptions of the procedures to be performed, risks and discomforts, potential benefits (if any), information and/or specimens to be collected. Participant selection and expectations for inclusion and exclusion with respective rationales.
  - f. Provisions for managing adverse reactions and plans for notifying the IRB of reportable events.
- D. Consent document(s) and translated document(s) (when necessary) to include all relevant basic and additional elements. A comprehensive list of these elements will be found in the regulations at 45 CFR 46.116, in IRBNet Library Manager 'Elements of Informed Consent' and further described in detail in PHCIRB policy # 6419.
- E. Lay summary to give a brief succinct synopsis of the research to include:
  - a. A statement of the problem of interest;
  - b. General statement of how the problem will be studied;
  - c. A statement of how the research will advance scientific knowledge and/or human health;
  - d. A statement of what the standard of care is, if any.
- F. Investigator's Assurances Document. This is a list of affirmations from the principal investigator verifying that the research will be conducted in compliance with PHCIRB policies.
- G. All supplemental materials as required by the study sponsor, if any. These items can include study diaries, recruitment materials, questionnaires, quality of life measures, etc...
- H. Ancillary Review Committee approval(s), if applicable. These committees are inclusive of:

- a. Radiation Safety Committee
- b. Conflict of Interest Committee
- c. Biosafety Committee
- d. Scientific Review Committees
- I. Investigator Drug Brochures or Package Inserts.
- J. Device Manual/Manual of Operations
- K. FDA Correspondence to reference IND, IDE, or conditional approval statements.
- L. Request for Waiver of Documentation of Informed Consents form
- M. Request for Alteration of Waiver of Informed Consent form
- N. HIPAA Waiver form.

## **Submission Requirements for Continuing Review:**

Investigators applying for continuing review of approved research are required to submit the following:

- A. Completed Continuing Renewal & Final Closure Request Form;
- B. Current PHCIRB approved informed consent document(s);
- C. Research Authorization(s);
- D. Itemized log of any protocol deviations, unanticipated problems, adverse events, non-compliance issues, etc not required to be promptly reported to the PHCIRB or if not previously reported to the PHCIRB;
- E. Medical Device Reporting, if study involves an HDE;
- F. Recent reports, if not previously submitted, to include but not limited to:
  - a. DSMB, DSMC, DMC, etc...
  - b. FDA, OHRP, NIH, audits (internal and external) and/or progress reports, complaints, etc...
  - c. Sponsor monitoring visit reports
  - d. Sponsor annual reports



- e. Etc. / other
- f. Reports in recent literature, publications, or abstracts resulting from the conduct of the research.

### **Submission Requirements for Amendments / Revisions:**

Investigators applying for modification to approved research are required to submit the following:

- A. Completed Request for Modification form;
- B. All revised study documents to be accompanied by a summary of proposed changes or a tracked version of the documents is required. These documents can be but are not limited to:
  - a. Study protocol
  - b. Consent(s)
  - c. Recruitment materials
  - d. Questionnaires, surveys, measures, etc...
  - e. Drug brochures and device manuals
- C. FDA correspondence regarding INDs or IDE, when applicable.

### **Submission Requirements for Protocol Deviations & Violations:**

Investigators reporting protocol deviations and violations are required to submit the following:

- A. Completed Protocol Deviation/Violation Report form;
- B. Supporting documentation, as applicable. This can include but is not limited to redacted laboratory reports, redacted discharge reports, redacted progress notes, etc...
- C. Correct actions, if applicable, as well as a plan for preventing a recurrence of the deviation/violation.
- D. Sponsor letters, if applicable.

### **Submission Requirements for Serious Adverse Events (SAEs) and Unanticipated Problems (UPs):**

Investigators reporting serious adverse events and unanticipated problems are required to submit the following:

- A. Completed Report of an Internal Serious Adverse Event (SAE) or Unanticipated Problem (UP) or Report of External Unanticipated Problems form, as appropriate.
- B. Supporting documentation, as applicable. This can include but is not limited to redacted laboratory reports, redacted discharge reports, redacted progress notes, etc...
- C. Sponsor letters, if applicable.

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## Initial Review Policy, 6410

## POLICY:

It is the policy of the Piedmont Healthcare IRB to review all research proposals that intend to involve human subjects. The research proposals must meet certain criteria before study related procedures can be initiated. The criteria are based on the principles of justice, beneficence and autonomy as discussed in the Belmont Report and are specified below. In addition, federal regulations as related to human subjects research and certain other criteria that are specific to Piedmont Healthcare and its entities, collectively "Piedmont", may apply and must be met before any involvement of human subjects can start.

## **PURPOSE:**

To state the requirements and procedures that all initial, i.e. new, research proposals that involve human subject participation must meet in order to be approved by the Piedmont Healthcare IRB (PHCIRB).

## **Procedures:**

### **Minimal Criteria for Approval of Research:**

In order for a research project to be approved, the IRB must find that:

1. Risks to subjects are minimized:

By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.

In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies those subjects would receive even if not participating in the research).

The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable.

In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

4. When applicable, informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations.
5. Informed consent will be appropriately documented as required by local, state and federal regulations.
6. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. Where appropriate, there is adequate provision to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or international sites are used, additional safeguards have been included in the study, and in the IRB review process to protect the rights and welfare of these subjects.
9. The IRB determines that the provisions are adequate to protect the privacy interests of subjects.
10. The IRB determines that the provisions are adequate to protect the confidentiality of data.
11. For repository activities, the IRB makes determinations concerning the regulatory status and appropriate use of stored biologic samples.

### **Additional Criteria for Studies Involving Protected Health Information:**

Studies proposing access to or collection of protected health information within the covered entities of Piedmont Healthcare require consideration of additional items to protect the privacy of the protected health information. Therefore the IRB must find that:

1. Appropriate authorization is obtained from human subjects or their effective representative for the use or disclosure of their protected health information;
2. The IRB has approved a waiver of such authorization, if applicable;
3. The protected health information will be contained in a limited data set with appropriate safeguards to maintain privacy; or,
4. The protected health information will be de-identified.

### **Other Criteria**

The IRB may require verification of information submitted by an investigator. The need to verify any information will be determined during the review by the Primary and/or Secondary Reviewer or by the IRB at a convened meeting. The purpose of the verification will be to provide necessary protection to subjects when deemed appropriate by the IRB.

# Responsibility:

## Full Board (Convened) Meeting / Expedited Review -

The IRB can review Initial protocols via a convened full board meeting or via expedited review, based on federal regulations. The majority of research conducted at Piedmont requires initial review by a convened full board meeting. It is at the discretion of the IRB to send any new protocol, regardless of risk criteria, to a convened full board IRB meeting, even if it meets criteria for expedited review.

## Primary / Secondary Reviewers –

a. The IRB Manager is responsible for:

1. Ensuring that IRB reviewers have all the tools and resources needed to complete their research reviews.

The tools include access to Reviewer Checklists; all items requiring submission outlined in the PHCIRB policy 6409: IRB Submission Requirements.

2. For selecting Primary and Secondary Reviewers with the relevant expertise to perform reviews;
3. Provide guidance regarding federal regulations and guidance documents to aid IRB reviewers.

b. The IRB Chair and IRB Manager are responsible for providing IRB members adequate submission review training and ongoing guidance;

c. IRB Reviewers are responsible for conducting thorough reviews and making appropriate recommendations for approvals or modifications to research;

d. The Primary Reviewer is responsible for conducting an in-depth initial review and presentation to the committee; the Secondary Reviewer is responsible for supplementing the review and should provide adequate review to complement the Primary Reviewer.

## IRB Members Assigned Reviews:

Duties of IRB members, both primary and secondary, when assigned reviews include:

1. Conduct an in-depth review of the protocol submission focusing the review on the criteria for IRB approval.
2. Ascertain whether third party verification of submitted information is necessary.
3. Prepare summary of findings and recommendations for presentation at the next convened IRB meeting.

4. Present to the convened IRB a summary of findings along with stipulations required for approval, as needed.

## **Protocol Expiration Date:**

For initial review of research protocols, the expiration date will be the earlier of:

- a. one year from the date on which the committee granted approval; or
- b. any shorter period prescribed by the committee.

Unless specifically waived by the IRB, research that meets any of the following criteria will require review more often than annually (*this list is not inclusive*):

1. Carries significant risk of harm to research subjects (e.g., death, permanent or long lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the subjects;
2. Involves especially vulnerable populations likely to be subject to undue influence or coercion (e.g., pregnant women); or
3. Having a history of serious or continuing non-compliance on the part of the Principal Investigator.

The following factors also will be considered when determining which studies require review more frequently than once a year:

1. The probability and magnitude of anticipated risks to subjects;
2. The likely medical condition of the proposed subjects;
3. The overall qualifications of the PI and other members of the research team;
4. The specific experience of the PI and other members of the research team in conducting similar research;
5. The nature and frequency of adverse events observed in similar research at this and other institutions;
6. The novelty of the research and the likelihood of unanticipated events;
7. Any other factors that the IRB deems relevant.

In specifying an approval period of less than annually, the IRB may define the period with either a time interval or a maximum number of subjects either studied or enrolled.

If a maximum number of subjects studied or enrolled is used to define the approval period, it is understood that the approval period in no case can exceed one year and that the number of subjects studied or enrolled determine the approval period only when the number of subjects is studied or enrolled in less than one year.

The meeting minutes will reflect the approval period specified.

## Reference:

**Regulatory Reference:** 21 CFR812, 45 CFR 46.111, 21 CFR 56.111

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<b>Applicability:</b>	<i>Piedmont Healthcare System</i>

## Expedited Review Policy, 6411

## POLICY:

The Piedmont Healthcare Institutional Review Board (PHCIRB) may utilize the expedited review process for initial or continuing review of research that is no more than minimal risk and falls within a category approved for expedited review per 45 CFR 46 and 21 CFR 56. The expedited review procedure consists of review of research involving human subjects by the PHCIRB Chair or designee(s).

## **PURPOSE:**

To explain the expedited review procedures for certain kinds of research involving no more than minimal risk; and for minor changes in previous PHCIRB approved research.

## **Definitions:**

**Designated / Expedited Reviewer:** A member of the PHCIRB who has been designated to perform expedited reviews, preferably in writing. To be eligible for consideration as a Designated Reviewer, the person must be a PHCIRB member who meets current training requirements.

**Minor Change:** A minor change is one which, in the judgment of the PHCIRB Designated Reviewer, makes no substantial alteration in (i) the level of risks to subjects; (ii) the research design or methodology (e.g., an addition of a procedure which would increase risk to subjects); (iii) the number of subjects enrolled in the research (increasing the approved number of subjects by greater than 20% of the currently approved number of subjects); (iv) the qualifications of the research team; or (v) the facilities available to support safe conduct of the research.

A minor change does NOT include the addition of any procedure that involves more than minimal risk or does not fall into categories (1)-(7) of research that can be reviewed using expedited review.

## **Determining if a Submission Qualifies for Expedited Review:**

The IRB Manager, in consultation with the PHCIRB Chair (when needed) is initially responsible for identifying submissions that qualify for expedited review and assigning the review to a qualified reviewer. A PHCIRB member may also identify submissions that qualify for expedited review.

## **Designated / Expedited Reviewer:**

The PHCIRB Chair or designee may carry out an Expedited Review. In conducting expedited review, the reviewers may exercise all of the authorities of the full IRB except that they may not disapprove the research. A research proposal may be disapproved only after review by a convened IRB meeting.

The IRB Manager may conduct expedited reviews, is a member of the full board IRB, is an experienced IRB member, and designated by the PHCIRB Chair.



Consultants may assist the PHCIRB in the review of issues that require expertise beyond that available on the committee; but may not carry out the expedited review itself. Individuals conducting expedited review will contact the PHCIRB Chair and/or the PHCIRB Manager to provide notification that review by a consultant is needed or requested. The IRB Manager will document the use of consultants in the PHCIRB minutes.

## **Notification and Documentation of Expedited Review to the PHCIRB:**

The reviewer for an expedited review will receive the same information that the primary reviewer receives for review at a convened IRB meeting.

The reviewer may recommend approval of the research or require modifications to secure approval. If the study qualifies for review via expedited review, the designated reviewer will document his/her determination of the applicable expedited review category.

Consistent with review by a convened IRB, the expedited reviewer will consider:

- all the criteria for review found at 45 CFR 46.111 and 21 CFR 56.111;
- all requirements found at Subparts B, C, and D, when applicable;
- the requirements for informed consent including altering or waiving the requirement for consent.

The PHCIRB's agenda and minutes will include documentation of the studies that were reviewed via expedited review including a brief description of the research, the designated IRB reviewer who approved the research and the approval date. Any IRB member may request that an expedited review noted on the agenda and/or minutes be discussed at a convened IRB meeting.

## **Additional Items that May be Reviewed by the PHCIRB Chair or Designee:**

- Conditional Approval Pending Minor Revisions or Conditional Re-approvals
- Minor revisions to consent documents
- Documentation submitted as a result of a convened PHCIRB review and as a condition to final approval

When the PHCIRB requests **minor** clarifications or modifications at a convened meeting that are directly relevant to the determinations required by the PHCIRB, the protocol may be approved by the PHCIRB Chair or member on behalf of the convened IRB via Expedited Review procedures, based on the regulations.

**NOTE:** However, when the PHCIRB requests **substantive** clarifications or modifications at a convened meeting that were directly relevant to the determinations required by the PHCIRB, the protocol will go back to a convened PHCIRB meeting and not be approved by the PHCIRB Chair or member on behalf of the convened IRB via Expedited Review.

## **Continuing Review:**

The PHCIRB Chair or his/her designee may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized.

Any protocol revision that entails more than a minimal risk to the subject(s) as determined by PHCIRB Chair or his/her designee must be reviewed by the IRB at a convened meeting.

Addition of procedures that involve increased risk or discomfort may not be considered minor changes.

## **Examples:**

*Minor modification or amendment of previously approved research may be reviewed using an expedited review mechanism.*

The following are examples of the kinds of research modifications requiring either expedited or full board review. Specific decisions on the level of review are made on a case-by-case basis.

- Adding research activities that qualify for exemption or fall under an expedited review category
- Narrowing of inclusion
- Broadening of exclusion criteria
- An increase in the number of safety visits for the purpose of increased safety monitoring
- A decrease in the number of visits, provided the decrease does not affect the collection of information related to safety evaluations
- Changes in remuneration
- Changes to improve clarity of statement or correct typographical errors provided the change does not significantly alter the content or intent of the statement
- The deletion of investigators study staff, the addition of qualified investigators or study staff
- The addition or deletion of study sites

## **Revisions to Informed Consent Documents:**

Minor changes to informed consent documents that do not affect the rights and welfare of study subjects, or do not involve increased risk or significant changes in study procedures may be reviewed and approved by the PHCIRB Chair or his/her designee.

## **Advertisements/Recruitment Materials:**

The PHCIRB Chair or his/her designee may approve new or revised advertisements, recruitment materials, including audio and video recruitment materials.

## Deferral to Full Board:

At any time during an Expedited Review, the PHCIRB Chair, or his/her designee, may defer a review to Full Board for review if he/she feels that discussion and deliberation by the committee is necessary.

## Reference:

### Regulatory Reference:

45 CFR 46.110; 21 CFR 56.110

21 CFR 812

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## Continuing Review Policy, 6412

## **POLICY:**

The Piedmont Healthcare Institutional Review Board (PHCIRB) maintains written procedures for conducting substantive and meaningful continuing review of research and for reporting its findings and actions to investigators and the institution per applicable regulations

Continuing review of research will take place at intervals appropriate to the degree of risk, but not less often than once a year. There is no provision for a grace period if a lapse in approval occurs.

## **PURPOSE:**

This policy outlines the requirements of the PHCIRB regarding continuing review and re-approval of research.

### **Criteria for Approving Research During Continuing Review:**

Continuing review must be substantive and meaningful. The IRB must determine that:

- a. Risks to subjects continue to be minimized;
- b. Risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result;
- c. Selection of subjects is equitable;
- d. Informed consent continues to be sought and appropriately documented (when applicable)
- e. Where appropriate, the research plan adequately provides for monitoring the data collected to ensure the safety of subjects;
- f. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
- g. Appropriate additional safeguards are included to protect vulnerable subjects;
- h. There are no issue of noncompliance or conflict of interest that have not been appropriately addressed;
- i. Any other issues that the IRB committee thinks appropriate to the study and information reviewed.

Because it may be only after research has begun that the real risks can be evaluated and the preliminary results used to compute the actual risk/benefit ratio; the IRB can then determine whether or not the study can be renewed at the same risk/benefit, or if new information has changed that determination.

The IRB makes its continuing review determination by considering whether any new information is available that would affect the IRB's prior finding that the research meets the criteria in 45 CFR 46.111 and 21 CFR 56.111.

The Piedmont Healthcare IRB has authority to disapprove or require modifications in (to secure re-approval of) a research activity that does not meet any of the above criteria (e.g. full study or any part thereof, such as changes to the protocol, advertisements, etc.)

## **Process for Conducting Continuing Review:**

Continuing Review shall take place at a convened meeting of the IRB, unless it meets the criteria for expedited review under 45 CFR 46.110 and 21 CFR 56.110 (More information related to Expedited Review can be found in this policy in the Expedited Review section and in PHCIRB policy # 6411: Expedited Review).

The IRB is required to conduct continuing review of research per 45 CFR 46.109(e) and 21 CFR 56.109(f) and shall maintain records of continuing review activities (45 CFR 46.115(a)(3) and 21 CFR 46.115(a)(3)), including minutes of meetings at which such activities are undertaken.

The minutes shall be in sufficient detail to show actions taken by the IRB and the vote on these actions, and to summarize the discussion of controverted issues and their resolution (45 CFR 46.115(a)(2) and 21 CFR 56.115(a)(2)).

For research to be approved, a majority of IRB members present at a meeting must approve it (45 CFR 46.108(b) and 21 CFR 56.108(c)).

The PHCIRB may ask the PI or his/her designee to be available to answer questions concerning the continuing review.

During the review of Continuing Review submissions, the following will be considered by the PHCIRB:

- a. Current status of the study, e.g. open to enrollment, open to follow-up, in data analysis, etc.;
- b. Currently approved informed consent(s);
- c. Changes to the risk/benefit assessment based on study results, reports, new information, adverse events and/or unanticipated problems;
- d. Protocol violations and/or deviations;
- e. Investigator non-compliance;
- f. Subject complaints;
- g. Reports from employees, staff and/or physicians;
- h. Lapsed protocol approval period and appropriate management;
- i. Consideration of any audit report(s);
- j. Reviewing the PI's monitoring plan to assure it is adequate;

- k. Consideration if the research has been terminated or suspended by another IRB;
- l. Current recruitment status;
- m. Updates to any conflict of interest;
- n. Review period required, i.e. annually or more frequently;
- o. Other information provided by the site.

## **Possible Outcomes of Continuing Review:**

As an outcome of continuing review, the IRB may:

- a. Authorize continuation of the research;
- b. Require modifications to the research and/or require more information;
- c. Reassess the approval period based on study risk information;
- d. Require termination of the research.

The IRB may need to impose special precautions or lessen special requirements it had previously imposed on the research protocol, such as the requirement of interim reports or duration of IRB approval period, so long as the approval period does not exceed one year.

Any determination, including approval or changes required to obtain continued renewal approval, shall be provided to the investigators in writing by the IRB. The IRB decision letter will state the review date and expiration date, as well as any pertinent information required by the IRB and/or federal regulations.

## **Lapse in Continuing Review:**

- a. As noted in the Submission Deadline section of this policy, investigators must plan ahead to meet required continuing review dates. If an investigator fails to provide continuing review information to the IRB by the submission deadline date and the study expires, **the research must stop.**

There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. If an investigator fails to provide continuing review information to the IRB, or the IRB has not reviewed and approved a research study before the expiration date specified by the IRB, no research related activities may occur after the protocol expiration date.

*NOTE: If the PI thinks that it is in the best interest of individual subjects to continue study interventions or interactions after approval has lapsed, he or she must contact the IRB Chair, who will determine if the IRB will approve the continuation of interactions or interventions.*

*This must be documented in writing by the IRB. The IRB would generally only grant this request if subjects would be harmed or their safety put in jeopardy if study interventions or interactions ceased.*

*The IRB Chair may consult with the committee, consultants, study sponsor, the Institutional Official, or other persons with an expertise in the research protocol to make this determination.*

- b. Enrollment of new subjects cannot occur after the expiration date of IRB approval.
- c. When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically.

*(NOTE: This type of expiration of IRB approval does not require reporting to OHRP as a suspension of IRB approval under HHS regulations).*

- d. A study within 90-days after the expiration date may be submitted for renewal via a Continuing Review submission. The reason for allowing the study to lapse must be clearly explained and an action plan put in place to avoid further lapse in approval. Data collected during the time the study lapsed in approval may not be able to be used for the research study and must be decided upon by the IRB on a case-by-case basis.

## **Expedited Review:**

When conducting Continuing Review of research under an expedited review procedure, the IRB Chair, or his/her designee, shall receive and review all of the above-reference documentation, including the complete protocol.

*More information related to Expedited Review can be found at PHCIRB policy # 6411: Expedited Review*

## **Submission Items Required:**

In conducting continuing review of research, the IRB shall receive and consider all requested information per the Continuing Renewal & Permanent Closure Request Form. Items for consideration include but are not limited to:

- a. The number of subjects accrued;
- b. A summary of any unanticipated problems and available information regarding adverse events .
- c. A summary of any withdrawal of subjects from the research since the last IRB review;
- d. A summary of any complaints about the research since the last IRB review;

- e. Any relevant multi-center trial reports;
- f. Any other relevant information, especially information about risks associated with the research.

## **Submission Deadline:**

A Continuing Review IRB submission is due by the IRB submission deadline date (a copy of the IRB meeting and submission schedule is available from the IRB office).

**It is the PI's responsibility to ensure that Continuing Review applications are submitted to the IRB in a timely manner to avoid a lapse in approval.**

The IRBNet system will send courtesy e-mails to PIs as a reminder that their studies will expire in 60-days. PIs should not rely only on reminders from the IRB. Failure to submit a Continuing Review by the IRB deadline will delay the review.

The IRB Manager will review all continuing review submissions. Any incomplete submissions will be sent back to the PI for corrections. Failure to have a complete and thorough Continuing Review application submitted to the IRB by the deadline date may result in a delay in the review.

## **Primary and Secondary Reviewers:**

The Piedmont Healthcare IRB works under the Reviewer system.

The Primary and Secondary reviewers will have access to this information at least two weeks prior to the scheduled IRB meeting. Committee members without a conflict of interest (COI) on study will also have access to this information via IRBNet.

Committee members will have access to the complete IRB protocol file, including relevant minutes, via IRBNet, as long as a COI on the study does not exist.

## **Verification from Other Sources:**

The IRB may require verification from other sources that no material changes have occurred since the previous review by the IRB. This might include, but is not limited to:

- a. Contacting the Sponsor and/or Clinical Research Organization;
- b. IRB audit of the site;
- c. Randomly select projects to ensure Quality Assurance standards;



- d. Projects conducted by investigators who have previously failed to comply with the requirements of the IRB, HHS, and/or FDA;
- e. Projects where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports and/or other sources;
- f. When it appears that the IRB is not receiving sufficient information as outlined in the federal regulations and/or PHCIRB policy.

## Reference:

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45 CFR 46 21 CFR 56  
21 CFR 812

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## Amendments Policy, 6413

## **POLICY:**

In accordance with 45 CFR 46 requested changes to an approved research proposal must first be reviewed and approved by the IRB prior to initiation except is necessary to eliminate immediate hazard to a subject, in which case the IRB must be immediately notified of the change. The Piedmont Healthcare Institutional Review Board (PHCIRB) shall review all proposed changes to previously approved research by either full committee or expedited review as appropriate and in accordance with applicable regulations.

## **PURPOSE:**

This policy describes the PHCIRB's requirements for the submission, review and approval of changes made to approved research.

## **Definitions:**

**Amendment:** any change made by correction, addition, or deletion to the previously approved research proposal.

**Minor change:** a change that does not materially affect an assessment of the risks and benefits of the study and do not substantially change the specific aims/design of the study. A minor change that makes no substantial alteration in:

- a. The level of risks to subjects
- b. The research design or methodology
  - a. Example: the addition of a procedure that does not increase risks to subjects
- c. The number of subjects enrolled in the research
  - a. Increase in sample size by 20% or less (both single and multisite studies). Sponsored studies require the approval of the study sponsor to be included in the request for modification submission.
- d. The qualifications of the research team
- e. The facilities available to support safe conduct of the research

Minor changes do not include the addition of any procedure that involves more than minimal risk. Minor changes may include the addition of any procedure that poses minimal risk and falls into expedited review categories. Expedited review is appropriate for such changes.

Examples of minor changes include, but are not limited to:

- a. Scientific and/or therapeutic changes that leave the research population at the same or lower risk than currently approved risks

- b. Consent form changes reflecting the changes above
- c. Increasing the number of subjects in the currently approved target population
- d. Decreases in sample size that do not affect the risk-benefit ratio
- e. Add new procedures that are minimal risk and fall into expedite review categories
- f. Study team member additions to assist with study conduct
- g. Study team member deletions so long as they do not affect the conduct of the study. The deletion of a pivotal study team member role may negatively affect the conduct of the study
- h. Changes in contact information.

**Non-minor change:** inclusive of all changes having the potential to substantially affect the assessment of the risks and benefits of the study. Non-minor changes that are greater than minimal risk require full board review.

Examples of non-minor changes include, but are not limited to:

- a. Study design changes
- b. Addition of a subject population different from what is currently approved
- c. Increases of greater than 20% in the number of subjects enrolled. NOTE: this is specific to single-site (local/investigator-initiated) studies. Sponsored studies require the approval of the study sponsor to be included in the request for modification submission.
- d. Adding questions to a questionnaire that opens new avenues of inquiry that may create a new risk of stigmatization if confidentiality were breached.

## Procedure:

1. Change requests for IRB consideration must be submitted by completion of the Request for Modification form within the protocol tracking database (IRBNet).
2. Upon receipt of the change request the submission will be administratively assessed to determine the appropriate level of review and either:
  - a. Reviewed and approved administratively [expedited],
  - b. Assigned to an expedited committee member with sufficient level of expertise, or
  - c. Assigned for full committee review.

3. The IRB determination will be communicated via correspondence to the study team. Determination letters may include additional instructions or notices to the study to alert them to re-consent and/or other requirements.

## Reference:

**Regulatory Reference:** 45 CFR 46.103(b)(4)

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## Non-Local IRB Review Policy, 6414

### POLICY:

The Piedmont Healthcare IRB (PHCIRB), on a case-by-case basis, may opt to enter into a written agreement per which it: (a) agrees to provide Human Subjects Research protection oversight (IRB Review) for another institution; or (b) agrees to defer to the review of another IRB located at another institution or a central (independent) IRB that is registered with OHRP and has its own FWA.

## **PURPOSE:**

To define the PHCIRB's relationship to other institutions in regard to providing IRB oversight for another institution or deferring IRB review to another institution or independent IRB.

## **Definitions:**

**Engaged in Research:** An institution is considered to be engaged in research whenever its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through Intervention or Interaction with them; or (2) identifiable private information about the subjects of the research.

## **Determination of the IRB of Record:**

1. **Non-Local IRB Review.** In the conduct of cooperative research projects, Piedmont acknowledges that each institution that is engaged in research is responsible for safeguarding the rights and welfare of human subjects and for adhering to applicable federal regulations. With regard to such cooperative research projects, the PHCIRB may: (1) enter into a written agreement per which the PHCIRB relies on the review of another qualified IRB that holds a Federal Wide Assurance (FWA).

With regard to any cooperative research projects that fall within the jurisdiction of the PHCIRB, i.e. human subjects research conducted under the auspices of Piedmont Healthcare, Inc., the PHCIRB reserves the right to defer or subjugate to another appropriately constituted IRB for the review of the research. The non-local IRB's institution must hold an (FWA) and maintain an accredited Human Subjects Research Protection Program through AAHRPP for the PHCIRB to consider relying on its IRB. The process of subjugation occurs through the establishment of a master IRB working agreement and completion of the central IRB's jurisdiction waiver form requirements.

**Authorization Agreement with the other IRB:** The authorization agreement must set forth the FWAs of each institution involved; describe the Human Subjects Research that the agreement covers; and provide that the IRB to which the PHCIRB is deferring will provide the PHCIRB with documentation or correspondence regarding that IRB's reviews of the deferred research protocol(s), including copies of those portions of the reviewing IRB's minutes that document review or other action by the reviewing IRB.

The Institutional Official (IO) shall have the final decision with regard to any decision as to whether to defer to another IRB. The IRB Manager shall take responsibility for ensuring that any required agreements are appropriately signed by the signatory officials for both institutions involved and when required, that OHRP and any other appropriate governmental agencies are appropriately notified of deferral arrangements.

## Community Attitudes:

The non-local IRB should have adequate knowledge of community attitudes and applicable state and local laws governing the conduct of the research for the Piedmont entity.

When the decision is made to defer to another IRB for review the PHCIRB Manager or other administrative IRB staff shall make a confirmatory review of the other IRB's actions to ensure compliance with PHCIRB standards.

## Reference:

**Regulatory Reference:** 45 CFR 46, 102(f), .114;

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## Exempt Review Policy, 6415

## POLICY:

Research activities in which the only involvement of human subjects will be in one or more specific categories outlined in the federal regulations and guidance may be exempt from IRB review. Determination of exemption must be based on federal regulations and guidance, as well as institutional criteria. Investigators are not permitted to make a determination that a research project is exempt and must obtain a verification of exempt status determination from the Piedmont Healthcare Institutional Review Board (PHCIRB).

## **PURPOSE:**

The purpose of this policy is to describe the process for determining whether a research proposal qualifies for exemption from IRB review and approval.

## **Procedure for evaluation of research proposals to determine exempt status:**

### **Submission Request:**

Investigators must provide sufficient information about proposed research to allow the PHCIRB to make a determination whether it is exempt and, when appropriate, that protections are provided to participants.

### **Request Review:**

Exempt determinations are made by the IRB Chair, IRB Vice-Chair, designated IRB Member, or IRB staff. The criteria for exemption specified in DHHS regulations are applied unless the research is Food and Drug Administration (FDA)-regulated. For research subject to FDA regulations, only FDA exemption categories apply.

Exempt determinations are not appropriate for:

- Prisoners
- Survey research involving children
- Observation of a minor's public behavior (unless the investigator does not participate in the activities being observed)

### **Submission Determinations:**

1. The proposed research activity **IS** exempt from compliance with federal regulations for the protection of human subjects and has no statutory requirement for IRB review and approval.

2. The research is **NOT** exempt, and before the study starts, it must undergo the IRB review and approval process.

## **Notification of Determination:**

Exempt research activities may not begin until the principal investigator receives notification of the exempt determination from the IRB. Notification will include the exempt category under which the determination was made.

## **Modification:**

Investigators are required to report modifications that may change the eligibility of the protocol's exempt status. It is the investigator's responsibility to notify the IRB of any changes or modifications that are made to the study's design or procedures. Modifications may not be made to exempt research without prior IRB review because of the possibility that proposed changes may modify the research in a way that it no longer meets the criteria for exemption.

A modification request must be submitted and reviewed prior to changing the research activity, unless the investigator believes that the change must be made to prevent harm to participants. All such changes must be reported to the IRB.

## **Categories of research that are be exempt from IRB review and approval:**

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
  - (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
  - (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
  - (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
  - (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained,



directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not

limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

## **FDA regulated research:**

The FDA does not have categories of research that qualify for exempt status except in emergency and taste and food quality studies.

## **Reference:**

**Regulatory Reference:** 45 CFR 46.101(b); 21 CFR 56.104

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## Noncompliance with Human Research Protection Program Policy, 6416

### POLICY:

The Piedmont Healthcare Institutional Review Board (PHCIRB) shall promptly report to the Office of Human Research Protection (OHRP) and the US Food and Drug Administration (FDA) any serious or continuing noncompliance with institutional or federal policies or determinations made by the PHCIRB.

### PURPOSE:

This policy describes how the PHCIRB will comply with regulations establishing the authority of the Institutional Review Board (IRB), the protection of human research participants, and how the PHCIRB will investigate and report instances of serious or continuing noncompliance. This policy applies to principal investigators, sub-investigators, the investigator's research staff, or any member of the human research protection program, including the PHCIRB and the PHCIRB administrative staff.

### Definitions:

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

**Serious Noncompliance:** Failure to act or willful violation of policies or regulations which create increased risks to research participants, adversely affects the rights, welfare and safety of research participants or adversely affects the scientific integrity of the study.

**Continuing Noncompliance:** A pattern of repeated non-compliance that indicates a lack of ability or willingness to adhere to policies or regulations; or repeated noncompliance that if allowed to continue is likely to increase risk, adversely affect the rights, welfare and safety of research participants, or adversely affect the scientific integrity of the study.

## Procedures:

- **Reporting allegations of noncompliance.** Investigators and research staff are required to report any observed, suspected, or apparent noncompliance to the PHCIRB. All institutional members, research participants and others are encouraged to report any observed, suspected, or apparent noncompliance. All allegations of noncompliance should be referred to the Chairman of the IRB or designee. The Chairman or designee may assign members of the board or engage the Office of Research Services to help review the allegations and determine if they have merit. If it is determined that there is no merit to the allegations, there will be no further action under this policy. However, if the conclusion is that there is merit to the allegations, the process will move forward as outlined below.
- **Determination of the allegations.** The Chairman of the IRB and a designee will review all noncompliance and determine whether it is not serious or continuing or that it may be serious or continuing noncompliance as defined in this policy. If the noncompliance is determined not to be serious or continuing noncompliance, the Chairman or designee will decide whether any corrective actions are needed, and if so communicate those to the involved individual(s) and ensure all corrective actions are completed. The Chairman or designee will work with the involved individuals to implement the correction action plan. If the Chairman or designee is unable to work with the involved individuals to implement the corrective active plan, the matter will be considered to be continuing noncompliance. Noncompliance that is not considered serious continuing will be reported to the full board and the corrective actions will be recorded in the meeting minutes.
- **Preliminary findings of serious or continuing noncompliance.** If it is determined that the noncompliance may be serious or continuing noncompliance, then the Chairman or designee will prepare a written report describing the review, documenting the allegation evaluated, explaining why the allegation had merit, explaining why the noncompliance was found to represent serious or continuing noncompliance, and any recommended corrective actions. This report will be sent to the Institutional Official (IO), the Office of Research Services and the noncompliance will be referred to a convened IRB for review and action.
- **IRB review of serious or continuing noncompliance.** Official determination of serious or continuing noncompliance occurs at a convened meeting of the full board. All materials that were gathered as a part of the review will be provided to all board members attending the meeting. In addition, all board members will be provided with a copy of the IRB application, the currently approved protocol summary, and current approved

consent documents. The Chairman and the designee will serve as primary/secondary reviewers, but all members will be expected to review these materials.

- **IRB Actions.** The convened IRB will confirm by vote whether the noncompliance is serious or continuing. If the IRB finds that the noncompliance is not serious or continuing, the noncompliance along with any recommendations will be handled in accordance with the noncompliance provisions outlined in the 'determination of allegations' section above. If the convened IRB confirms that the noncompliance is serious or continuing, it may immediately suspend the research if it finds that doing so is necessary to eliminate any immediate hazards to the research participant(s). Or, the IRB may consider the following actions:
  - Termination of research
  - Modification of continuing review schedule
  - Modification of the research protocol
  - Modification of the information disclosed during the consenting process or modification of the consent document
  - Require additional information to be provided to past participants
  - Monitoring of the consent process of enrollees
  - Notification of current research participants (necessary when such information might impact willingness to continue in research)
  - Defer final decisions pending additional information
  - Refer the matter to compliance, legal or risk management
  - Require additional education or training for the investigator or his/her team
  - Require re-consenting of current research participants
  - Suspension or termination of investigator research privileges
  - Develop other corrective actions as appropriate.
- **Final determination and reporting to regulatory agencies.** The IO or his/her designee based upon the findings of the IRB, has the final authority to make the determination of serious or continuing noncompliance. The IO or designee, with the assistance of the Chairman of the IRB, will report findings to the appropriate internal offices and regulatory agencies (OHRP and FDA) and in accordance with this policy and published guidance.

## Reference:

**Regulatory Reference:** 45CFR46.103(b)(5): 21 CFR 56.108(b)(2)

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## Emergency Use of a Drug or Biologic Policy, 6417

### **POLICY:**

Piedmont Healthcare IRB (PHCIRB) review and approval is required prior to the use of a non-FDA approved drug with limited exception being the instance of a subject in a life-threatening situation. In such cases, and where prior IRB approval is not feasible, emergency use of the test drug may commence so long as the IRB is notified within five working days of the use and any subsequent use of the item.

### **PURPOSE:**

The policy addresses the establishment of a working process to allow for emergency use cases prior to full IRB review and the requirement for IRB review and approval for all prospective uses.

### **DEFINITIONS:**

**Emergency use:** the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval. [21 CFR 56.102(d)]

**Life-threatening:** means disease or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the

condition to be immediately life-threatening or to immediately result in death. Rather, the subject must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

**Severely debilitating:** means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

**Test article:** any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act (Food and Drug Act).

## PROCEDURES:

- To initiate the emergency use process, the researcher must establish that the situation fits the 'emergency use' or 'severely debilitating' definitions above.
- The researcher must notify the IRB by contacting the IRB Manager at 404.605.3638 or at [madeline.peyton@piedmont.org](mailto:madeline.peyton@piedmont.org).
- Within 5 business days of use of the drug the researcher must provide the following information via submission in IRBNet:
  - Protocol/proposal specific treatment plan
  - Principal investigator letter with rationale for emergency use
  - Second opinion letter from uninvolved physician concerning the emergency use
  - Consent
  - Subject clinical history summary with rationale for proposed treatment
- The submitted materials will be taken to a convened IRB meeting for review and approval.
- The researcher is required to report to the IRB any subsequent use of the drug which can be reviewed via the expedited review process. A follow up summary outcome of the emergency use must be reported to the IRB within four weeks of resolution of the emergency situation.

## Reference:

**Regulatory Reference:** 21 CFR 56.102(d) & .104(c)

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## IRB Meeting Minutes Policy, 6418

### **POLICY:**

In compliance with the federal regulations found at 45 CFR 46.115(2), the Piedmont Healthcare IRB (PHCIRB) shall maintain written minutes of IRB meetings in sufficient detail to meet the minimum requirements outlined in the regulations.

### **PURPOSE:**

This policy outlines the recording points needed to uniformly document all regulatory review requirements in a manner such that a non present reader can determine the justifications for how the committee arrived at its decisions on each research project.

### **Minutes contents (for projects discussed at a convened meeting):**

**Meeting time:** the minutes shall reflect the start and end times of each meeting.

**Attendance:** the minutes shall be a comprehensive record of attendance of all meeting attendees inclusive of regular members, alternating members (if any), and guests.

**Quorum:** each research project will contain a notation that documents the number of voting members present during the vote portion of the discussions to ensure that a proper quorum was maintained. Loss of quorum results in a halt of meeting proceedings until quorum is regained.



**Actions:** each research project will receive individual documentation of IRB discussion, determinations, and vote.

- IRB discussion will minimally include verification to establish that the research meets the criteria for approved in accordance with 45 CFR 116. A full discussion of the risk level and recommended approval period appropriate to the degree of risk will be clearly documented. In addition, minutes will document any controverted issues and resolutions.
- The minutes will appropriately reflect when the IRB reviewed additional safeguards to protect vulnerable populations.
- IRB determinations are reflective of the IRB's discussion of a specific proposal. In accordance with the regulations the PHCIRB shall notify investigators and the institution in writing of its decision to approve or disapprove research. Investigators are afforded the opportunity to respond to IRB decisions in person or in writing.
- PHCIRB determinations fall into the following categories (see PHCIRB policy # 6431 for full descriptions of the categories below):
  - Approve
  - Modification Required
  - Suspended
  - Tabled or Deferred
  - Disapproved
- IRB Vote notation will specify the number of votes for, against, and abstaining for a project. Actions will be reflected in the minutes per the regulations. No member shall participate in the vote on a protocol on which they have a conflict of interest. The only exception is to provide information requested by the IRB (see PHCIRB policy # 6404).
- The minutes will reflect the duration of effective approval granted to each protocol.

Notification of expedited review, exempt, closure, reportable events, and 'other' actions are provided to the IRB committee via inclusion in the meeting agendas and minutes documentation.

**Minutes approval:** The final draft of meeting minutes are prepared for inspection and approval at the next meeting of that deciding committee. During the business portion of the meeting, the committee submits the vote for acceptance of record of the meeting. At that time each member is able to request clarification of or recommend revision to the minutes record. Any recommendations for revision must be voted on and updated in the official meeting record.

In addition, all minutes shall be available for inspection and copying by OHRP or the FDA upon request.

**Retention of Minutes:** IRB records, including meeting Minutes, shall be retained for at least 3 years after completion of the research. See PHCIRB policy # 6407. Minutes are stored within the IRBNet platform and can be maintained indefinitely.

## Reference:

**Regulatory Reference:**

45CFR46.107(e), .109(d)(e),.115(2)  
21 CFR 56.107(e),.108(2),.109(a)(e)(f),.115(2)

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## Informed Consent Policy, 6419

### Policy

It is the policy of the Piedmont Healthcare IRB (PHCIRB) that prior to the conduct of any research involving a human subject, the Principal Investigator (or designee) must obtain legally effective informed consent from the human subject or the human subject’s legally authorized representative, unless the conditions for a waiver or alteration of informed consent are met as determined by the PHCIRB after review and approval. Informed consent (or an IRB approved waiver thereof) must be obtained before entering a subject into a research protocol and/or conducting any procedures required by the protocol. Informed consent may be either oral or written depending on the circumstances of the research.

### Purpose

This policy outlines the required elements of informed consent; the administration and documentation of providing informed consent; and the procedures related to the IRB's review and approval of consent forms.

## Definitions

**Enrolled:** When a subject gives written or oral informed consent to participate, he or she is considered to be enrolled in a research study.

**Informed Consent:** An individual's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research. Individuals capable of giving informed consent should be of sound mind, mentally unimpaired, conscious, and physically able to read and/or hear and understand the elements of informed consent. In addition, they must not have been declared to be legally incompetent.

**Informed Consent Prior to Screening Procedures:** the use of screening tests to assess whether prospective subjects are appropriate candidates for inclusion in studies is an appropriate pre-entry activity that requires consent prior to the conduct of any research procedures including withdrawal from medication (wash-out). When wash-out is done in anticipation of or in preparation for the research, it is part of the research.

Procedures that are to be performed as part of the practice of medicine and which would be done whether or not study entry was contemplated, such as for diagnosis or treatment of a disease or medical condition, may be performed and the results subsequently used for determining study eligibility without first obtaining consent.

**Legally Authorized Representative (LAR) is defined as** an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in the research. Such designation is necessary for cases of medical incapacitation and diminished competence.

Decision-making capacity is the ability to make one's own decisions. Incapable patients cannot give a valid consent, so someone else must make the decision on the patient's behalf.

**'Short Form'** is a written consent document stating that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative (LAR).

## Consent Elements

**Required elements of Informed Consent** (unless exceptions as approved by the IRB are instated)

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may be reasonably expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records, if applicable.
6. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject, if relevant. Typically, questions concerning a research project should be referred to the PI for that project, whereas questions concerning the rights of human subjects should be referred to the IRB.
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.
9. Research collecting identifiable private information and/or identifiable biospecimens MUST:
  - a. State that collected samples/data may be de-identified and used for future research or be given to another investigator for future research without additional informed consent, OR
  - b. State that collected samples/data will not be used or distributed for future research even if de-identified.

A statement that the subject may discontinue participation/ revoke permission at any time without penalty or loss of benefits to which the subject is otherwise entitled. To do this the participant is asked to complete the revocation form. Consent, whether oral or written, may not include any exculpatory language through which the subject or the subject's authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

## **Additional Elements of Informed Consent**

When appropriate, one or more of the following elements of information should be provided to each subject.

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject (particularly when potentially therapeutic experimental interventions are being administered and unscheduled cessation of the intervention may pose health risks to subjects);
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. The amount and schedule of payments, if any;
8. Provisions for protection of subject's privacy.
9. Statement that biospecimens, even if de-identified, may be used for commercial profit and whether/if that profit will be shared.
10. Statement regarding whether clinically relevant research results will be given to the subject and under what conditions.
11. For research involving biospecimens, whether the research will or might include (specifically) whole genome or exome sequencing.

## **IRB Authority, Duties, and Requirements**

### **Authority**

In evaluating the appropriateness of the informed consent process, the IRB will consider where the consent process will take place and if the setting and process are designed to minimize the possibility of undue influence or coercion. In addition to the circumstances surrounding the setting of the consent procedure, subject autonomy concerns, language difficulties, and vulnerable populations included in the research protocol will be considered by the IRB. Use of vulnerable populations may require additional informed consent requirements. Informed consent must be conducted by someone who is familiar with the informed consent process, trained on the protocol, and who has undergone the appropriate research education training modules (*see policy #6423: Human Subjects Training – Investigator and Key Research Personnel*). If someone other than the PI will obtain the informed consent, then the PI must formally delegate this responsibility and that person should sign the consent form as the “person who obtained consent.” In evaluating the consent process, the IRB also will consider the individual who will be obtaining the informed consent (e.g., PI, sub-investigator, clinical research coordinator or RN). The IRB will also evaluate the process to ensure that the human subject has adequate time to consider participation in the research protocol, and that someone is available to answer all of the human subject’s questions prior to enrolling him or her in the research protocol.

The IRB has the authority to observe or have a third party observe the consent process and the research, as allowed under 45 CFR 46.109(e).

The PHCIRB may require the PI to obtain informed consent for certain studies.

## **Duties**

The IRB is responsible for the review and approval of the informed consent form prepared by the Principal Investigator. The wording on the informed consent form must contain all of the required elements and meet all other requirements as described in this policy. No informed consent, whether written or oral, may contain any exculpatory language by which the participant or his/her legally authorized representative is made to waive or appear to waive any of the participant's legal rights, or which releases or appears to release the PI, sponsor, or Piedmont Healthcare, or any of their agents or employees from liability for negligence.

The IRB will review and approve all informed consent documents. No informed consent can take place without IRB approval of the consent form document, unless the IRB approves waivers.

## **Requirements**

Consent must be obtained from each subject who is legally, mentally, and physically able to provide it unless waived by the IRB. Consent should be in writing unless the IRB finds that written documentation of informed consent may be waived.

### **Documentation of Informed Consent:**

Informed consent must be documented in accordance with and the extent required by 45 CFR Section 46.117 or 21 CFR Section 50.27. Informed consent must be documented by the use of a written consent form that is approved by the IRB and signed and dated at the time of consent by the subject or the subject's Legally Authorized Representative.

The PI (or designee) is responsible for obtaining a signed and dated consent document prior to enrolling any person in a research protocol, except in circumstances in which the IRB has granted waiver of informed consent or a waiver of the documentation of informed consent.

The PI is responsible for maintaining a copy of each signed consent document and must be able to provide a copy of the documents to the PHCIRB upon request. A copy of the consent document must be given to the human subject or his/her legally authorized representative.

Study teams are strongly advised to adopt a practice utilizing a checklist/tool to ensure that all required and relevant consent process steps are consistently completed.

### **Exceptions to Informed Consent Requirements**

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of subjects;
3. The research could not practicably be carried out without the waiver or alteration;
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

### **Waiver of Informed Consent**

The IRB may waive the requirement for the investigator to obtain a signed consent form in cases where circumstances warrant such a waiver. Such a waiver is allowable if:

- The consent document is the only link between the subject and the research and the principal risk of harm would come from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or [45 CFR 46.117 (d)(1)]
- The research presents no more than a minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context. [45 CFR 46.117 (d)(2)]
- In lieu of a signed consent form the IRB may require the investigator to provide subjects with a written statement regarding the research in the form of an information or fact sheet. This information will be reviewed by the IRB. The written statement should contain, at a minimum:
  - A statement that the project involves research;
  - A description of the level of involvement and amount of time expected from subjects;
  - A description of the study
  - A description of the risks and benefits to subjects;
  - A statement describing the subject's rights;
  - A description of the compensation to be provided to subjects;
  - Contact information for both the investigator and the IRB.

Examples of circumstances in which a waiver of written consent may be considered include:

1. Situations where the researcher plans to use an abbreviated consent process, as in recruiting passersby for a brief, minimal risk survey.

2. To allow researchers to obtain oral consent for a telephone survey.
3. If researchers want subjects to imply their consent by returning a survey via the mail or the internet. This last approach is especially useful in preserving the anonymity of the subjects surveyed.

### **Oral and Written Translation of Informed Consent**

**Oral Translation:** a qualified individual who is not a family member of the prospective subject should perform Oral translation. The individual performing the interpretation should be available for ongoing communication between subjects and investigators; or an equally qualified interpreter should be available if the original interpreter is not available.

**Study teams may use the Language Line Services at 1.800.815.2002.**

**Written Translation:** Written translation of informed consent documents should be performed by a qualified individual. Though there is no standard definition of what constitutes a "qualified individual," the investigator should demonstrate due diligence in obtaining an adequate translation of the informed consent documents from an individual whose qualifications would appear adequate to a reasonable person. Back translations to English may be one method for validating the accuracy of the translation; however, back translations are not always sensitive to dialect and idiom. In this scenario the IRB would compare both English versions of the document.

Outside translations should be accompanied by an affidavit of accuracy or other certification of translation of specified documents.

## **Informed Consent Processes**

Informed consent consists of more than obtaining a signature on the consent document. It is a continuing dialogue between investigator/study team and subject involving a thorough discussion of the elements of the consent document in a manner that is understandable to the human subject. The process is to be conducted in a manner that allows potential subjects ample and appropriate time and consideration to make an informed decision. This interactive sharing of information may be accomplished via the following modes of communication not limited to: face-to-face (written), oral with research record documentation, video or web conferencing, telephone, mail, facsimile. The circumstances of the consent process should minimize the possibility of coercion or undue influence and are expected to be completed prior to the initiation of research related activities.

Informed consent will be obtained from the participant or his/her legally authorized representative. In Georgia, any adult may delegate to another adult the authority to give consent for him/herself by a lawful Advanced Directive for Health Care or durable power of attorney for healthcare. In the absence of such an individual then any married person, whether adult or minor, may give consent for him/herself and for his/her spouse. In the absence of an appointed individual, the following may provide consent in the following order of priority:



- Spouse;
- Any adult offspring for his/her parent;
- Any parent for his/her adult offspring;
- Any adult for his/her adult brother or sister;
- Any grandparent for his/her adult grandchild;
- Any adult grandchild for his/her grandparent;
- Any adult niece, nephew, aunt, or uncle related in the first degree; or

In the absence of any other person as indicated above, the PHCIRB may consider allowing an adult close friend of the prospective subject to provide consent. It is expected that the adult close friend has exhibited special care and concern for the subject, is generally familiar with the subject's views and desires, and is willing and able to act in the subject's best interests.

**NOTE:** any unsuccessful attempt to contact the person at a higher level of priority must be documented before attempting to contact a person at a lower level of priority.

Legally authorized representatives (LARs) are acting on behalf of participants, therefore, LARs must be told that their obligation is to try to determine what the participants would do if able to make an informed decision. This expectation covers the continuum of time LARs are needed, inclusive of re-consent processes.

1. In general, along with the informed consent discussion the following are expected:
  - a. Participant signature and date on the informed consent document and HIPAA Authorization form.
  - b. Individual conducting informed consent process signature and PI (if required) and date on the informed consent document.
  - c. Provide participant or their LAR a copy of the signed and dated informed consent document, a copy of the HIPAA Authorization form and Revocation Letter. Study team documentation of details of the consent process in the research record.
  - d. Study team document maintenance:
    - i. Fully executed original or copy of signed documents to be filed in participant research chart
    - ii. Signed document copies to be maintained in hospital charts (in-patient)
    - iii. Signed document copies to be maintained in physician office (out-patient)
2. For participants found to be unable to sign the informed consent document (due to physical impairment) obtaining consent from the participant with assistance from a witness is sufficient. The PHCIRB does not require a LAR to provide consent for these participants who are cognitively capable of consent but physically unable.

3. For participants found to be cognitively competent but unable to read (as in blind or illiterate) the following are expected:
  - a. Conduct the process in the presence of a witness.
  - b. Have the informed consent read to the participant.
  - c. Provide the participant ample time and opportunity to consider the information and ask questions.
  - d. Have participant 'make their mark', if able.
  - e. Have witness sign and date informed consent document.
  - f. Have the individual conducting the informed consent process sufficiently document that the process took place and that the participant voluntarily provided consent to participate in the research study.
4. For participants found to have fluctuating decision-making capacity the following are expected:
  - a. Conduct periodic competency assessments to monitor the decision-making capacity of participant to determine if changes in the information process is necessary to protect the rights and welfare of the participant.
  - b. Update the research record and obtain consent to indicate the participants continued willingness to participate, as appropriate.
5. When obtaining consent utilizing the facsimile process the following is expected after an adequate informed consent discussion:
  - a. Verify with the participant that the facsimile number(s) is/are correct and acceptable to send or receive the consent form document.
  - b. The participant will fax a copy of the signed consent and HIPAA Authorization to the study team member conducting the consent process.
  - c. The individual that conducted the informed consent process and enrolling investigator (if required) will sign the faxed consent to acknowledge receipt and document receipt in the medical record.
  - d. Ensure original documents are on file whenever possible. At a minimum, the original study team signed version should be on file.
6. When obtaining consent via email the following is expected:
  - a. Verify with the participant the email address(es) is/are correct and acceptable to send or receive the consent form document.
  - b. Utilizing an email account approved by the participant, the participant will email a signed copy of the signed informed consent document and HIPAA Authorization form to the individual conducting the informed consent process.
  - c. Upon receipt, the study team will print the documents and document date of receipt on the consent
  - d. The individual conducting the informed consent process and PI (if required) will sign the emailed consent to acknowledge receipt and document the receipt in the medial record.

- e. Ensure original study team signed version of the documents are on file.
7. When obtaining consent utilizing Adobe Pro with cellular telephone technology:
    - a. Verify with the participant the cellular telephone number(s) is/are correct and acceptable to send or receive the electronic consent document.
    - b. Upon receipt of the electronically signed and dated consenting documents from the participant, the designated study team member will also electronically sign and date the documents.
    - c. The study team will ensure a copy of the electronically signed documentation is on file.
  8. When obtaining consent via mail, the following is expected:
    - a. Two copies of the informed consent document and HIPAA Authorization will be mailed to the participant.
    - b. The participant will keep one copy of the documents for their records and mail and original signed set to the study team/site.
    - c. Upon receipt of the documents, the study team will document receipt date on the informed consent document.
    - d. The individual conducting the informed consent process and PI (if required) will sign the mailed consent to acknowledge receipt and document the receipt in the medial record.
    - e. Ensure original signed documents are on file.
  9. When re-consenting the following is expected:
    - a. Process to take place as soon as possible. Note instructions in the IRB correspondence letter for details.
    - b. The process may also be conducted via one of the remote processes described above.
  10. When a participant is unable to read the full consent document (as in being illiterate or does not speak the language in which the consent is written OR there is no opportunity to prepare a long form) the following 'short form' process is expected:
    - a. Prior IRB approval of a written summary of what is to be said the subject or LAR. The full consent form may serve as the written summary.
    - b. Presence of an impartial witness to the oral presentation.
    - c. Signature and date on the short form only by the participant or LAR.
    - d. Signature and date on the short form AND copy of the summary of the impartial witness.
    - e. Signature and date of person obtaining consent and PI (if required) on the summary.

f. A copy of the signed and dated summary will be provided to the subject or LAR, in addition to the copy of the signed and dated short form.

Amended consent form documents must be sent to the IRB for review and approval before they can be used.

**Providing Consent Forms to Subjects:**

Subjects or their Legally Authorized Representative (LAR) must sign and date the consent form prior to participating in the study, unless this documentation is waived by the IRB. A copy of the signed consent form (photocopy or duplicate signed original) shall be given to the person signing the form.

## References:

**Regulatory References:**

45 CFR 46.116, .117; 46.102(c)

21 CFR 50.20, .23, 25,.27

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# Study Closures Policy, 6420

## **POLICY:**

The Piedmont Healthcare IRB (PHCIRB) maintains written policies and procedures describing the conditions required for closing a research project as required by 21 CFR 56.108 (a)(3).

## **PURPOSE:**

To define the procedures and conditions required for closing a research project.

## **Procedures:**

The completion or closure of a research project reflects a change in activity that must be reported to the IRB. The Continuing Renewal & Closure Request Form must be submitted to the IRB when a study is completed and is ready for closure.

A research project is considered complete and may be closed when the following are true:

1. The study is permanently closed to enrollment, and
2. All participants have completed all protocol-related interventions, and
3. The collection of private identifiable data is completed, and
4. The analysis of private identifiable data is completed.

## **Researcher Responsibility:**

The Continuing Renewal & Closure Request Form should be submitted for IRB review within 30 days after study completion. Closure requests should be accompanied by documentation (DSMB reports, sponsor letters, etc.) that support the closed status of the research project.

## **PHCIRB Responsibility:**

The IRB Manager or IRB Coordinator will review all reports of study completion/closure and, if needed, request further information from the investigator to clarify any questions that may arise.

The Committee is notified of all study closures at the next convened meeting via the IRB agenda and IRB minutes through the electronic protocol tracking database (IRBNet).

The IRB will acknowledge the completion/closure of a research project and send written documentation to the Principal Investigator.

## Reference:

**Regulatory Reference:** 21 CFR 56.108 (a)(3)

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## Reporting of Unanticipated Problems Policy, 6421

### POLICY:

Federal regulations and guidance provided in 45 CFR 46.103(b)(5), 21 CFR 56.108(b)(1), 21 CFR 312.53(c)(1)(vii), and 21 CFR 312.66 require that organizations have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and relevant federal officials of any unanticipated problems involving risk to human subjects or others.

Unanticipated problems consist of both adverse events that are unanticipated problems and unanticipated problems that are not adverse events.

## PURPOSE:

To provide the procedure for prompt reporting of Unanticipated Adverse Device Effects (UADE), and Unanticipated Problems (UPs) related to research involving human subjects to the Piedmont Healthcare IRB.

## DEFINITIONS:

**Adverse Event:** Any untoward physical or psychological occurrence in a human subject participating in research. It can be any unfavorable and unintended event, including an abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article. It does not necessarily have to have a causal relationship with the research.

**Anticipated (expected) Adverse Event:** An adverse event that is not an unanticipated adverse event. It is expected and should be stated in the consent form document, protocol, and investigator's brochure, as applicable.

**Related or possibly related to the research:** An event is related to the research if, in the opinion of the Principal Investigator, it could not have been produced by the subject's clinical condition or environment, follows a known pattern of response to intervention, disappears or decreases with reduction in dose or cessation of intervention and/or recurs with re-exposure and/or it was more likely than not to be the result of the collection/disclosure of identifiable private information in the research and/or the interventions used in the research.

**Serious Adverse Event:** An event is considered serious if it results in death, is life-threatening, requires hospitalization or prolongation of hospitalization, causes persistent or significant disability or incapacity, is a birth defect or congenital malformation, represents, in the Principal Investigator's judgment, other significant hazards or potentially serious harm to research subjects or others, or any other event as described in the research protocol.

**Unanticipated Adverse Device Effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

### Unanticipated Problem (UP):

**Per OHRP** - The phrase "unanticipated problems" involving risks to subjects or others is found but not defined in the HHS regulations at 45 CFR part 46. OHRP considers **unanticipated problems**, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Generally, events meeting the 3 criteria above will warrant prompt IRB reporting and consideration of substantive changes in the research (protocol and/or consent) or other corrective action to protect the safety, welfare, or rights of participants. Examples include:

1. A single occurrence of a serious, unexpected event that is uncommon and strongly associated with drug exposure.
2. A single occurrence, or more often a small number of occurrences, of a serious, unexpected event that is not commonly associated with drug exposure, but uncommon in the study population.
3. Multiple occurrences of an AE that, based on an aggregate analysis, is determined to be an unanticipated problem.
4. An AE that is described or addressed in the investigator's brochure, protocol or informed consent documents, but occurs at a specificity or severity that is inconsistent with prior observations.
5. A serious AE that is described or addressed in the investigator's brochure, protocol or informed consent documents, but for which the rate of occurrence in the study represents a **clinically significant** increase in the expected rate of occurrence.
6. Any other AE or safety finding that would cause the sponsor to modify the investigator's brochure, study protocol, or informed consent documents, or would prompt other action by the IRB to ensure the protection of human subjects.

It is important to understand that there are other types of incidents, experiences, and outcomes that occur that represent unanticipated problems but are NOT considered adverse events but require prompt reporting to the IRB. Consider the scenario below as an example:

An investigator conducting behavioral research collects individually identifiable sensitive information about illicit drug use and other illegal behaviors by surveying college students. The data are stored on a laptop computer without encryption, and the laptop computer is stolen from the investigator's car on the way home from work. This is an unanticipated problem that must be reported because the incident was (a) unexpected (i.e., the investigators did not anticipate the theft); (b) related to participation in the research; and (c) placed the subjects at a greater risk of psychological and social harm from the breach in confidentiality of the study data than was previously known or recognized.

The Venn Diagram below summarized the relationship between adverse events and unanticipated problems to help in determining what requires reporting:



# REPORTING REQUIREMENT:

Below is an algorithm for determining whether an adverse event represents an unanticipated problem to be reported per 45 CFR 46.103:

- a.
- b. Any events/problems that were initially determined not to be associated with the study procedures and that are subsequently determined to be **Possibly** or **Definitely** associated, must be reported according to the criteria listed above.
- c. Submit DSMB / DMC reports promptly, (10 working days of receipt of the report) via the Request for Modification form in IRBNet. The narrative section of the form must indicate that the PI reviewed the report and indicate if the report requires a revision to the protocol and/or consent(s).
- d. Submit serious adverse events not meeting the definition of unanticipated problem at the time of the continuing renewal request in tabular form on a spreadsheet.

## IRB Review:

1. The IRB will review all unanticipated problems submissions.
2. The IRB expects prompt submission of toxicity, IND safety, and DSMB/DMC reports.
3. The IRB will not acknowledge grouped submissions on current active studies, or other events that do not meet the criteria for reporting to the IRB. These submissions will be returned or withdrawn. Please notify study sponsors of this policy.
4. The IRB **will accept** other reports when the investigator is unsure whether the event should be reported, and the IRB will review such reports to determine whether the event meets the threshold for an unanticipated event presenting risk to the participant or others.

## IRB Actions:

When reviewing events outlined in this policy the IRB may take the following actions, that include but are not limited to:

- a. Acknowledge report with no additional requirements.
- b. Approve investigator's proposed changes/corrective actions.
- c. Administratively hold the study pending IRB receipt of further information from the PI.
- d. Require modification of the protocol.
- e. Require modification of the information disclosed during the consent process.

- f. Require provision of additional information to current participant (the information may relate to the participant's willingness to continue participation).
- g. Making arrangements for clinical care outside the research or additional follow-up for participants.
- h. Require provision of additional information to participants who have completed all study related activities, including follow-up.
- i. Require current participants to re-consent to continue participation.
- j. Alter the frequency of continuing review.
- k. Require observation of the research or the consent process.
- l. Require additional training of the investigator and/or key research personnel.
- m. Require notification of investigators at other sites.
- n. Obtain additional information.
- o. Terminate or suspend the research. If this action is taken, the IRB will notify the Institutional Official and any applicable federal agency.
- p. If the IRB does not consider the event to represent an unanticipated problem involving risks to participants or others, the IRB will inform the PI in writing of the determination.

## **IRB Reporting of Unanticipated Problems (UPs):**

The IRB will report all UPs to the IO and all relevant federal agencies per federal regulations and guidelines.

## **Reference:**

### **Regulatory Reference:**

45CFR46.103(b)(5), 21CFR 56.108 (b)(1)  
312.53(c)(1)(vii), and 21 CFR 312.66

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## Protocol Deviations and Violations Policy, 6422

### **POLICY:**

It is the policy of the Piedmont Healthcare IRB to review protocol deviations and violations. Protocol deviations and violations require either prompt reporting or reporting at continuing review, based upon criteria outlined in the protocol deviations and violations policy and procedures.

### **PURPOSE:**

To define the process for the accurate and timely submission and review of protocol deviations and violations for research operating under the approval of the Piedmont Healthcare Institutional Review Board (PHCIRB).

### **Definitions:**

Protocol deviations and violations are defined as when any unapproved change or departure from the study design or procedures of a research project that are under the investigator's control and that have not been reviewed and approved by the PHCIRB prior to its initiation or implementation takes place.

**Protocol Deviation:** A protocol deviation is non-compliance with the study protocol and/or procedures that do not usually impact study participant rights, safety, and/or welfare, compromise the integrity of the study data and/or study participant willingness to participate in the study.

Though a protocol deviation is usually a minor non-compliance issue that does not meet prompt reporting criteria, it may still meet prompt reporting criteria based on the PI, study coordinator, or sponsor's view of the event or an abnormally high frequency of the event.

Examples of Protocol Deviations may include, but are not limited to:

- Implementation of unapproved recruitment procedures
- Missing original signed and dated consent form (only a photocopy available)
- Missing pages of executed consent form
- Failure to follow the approved study procedure that, in the opinion of the PI or Sponsor, does not affect study participant rights, safety, and/or welfare, or data integrity
- Study procedure conducted out of sequence
- Failure to perform a required laboratory test
- Missing lab results
- Over-enrollment
- Enrollment of study participants after PHCIRB approval of the study expires
- Failure to submit continuing review application to the PHCIRB before study expiration.

**Protocol Violation:** A protocol violation is defined as non-compliance with the study protocol and/or procedures that may impact study participant rights, safety, and/or welfare, the integrity of study data and/or study participant willingness to participate in the study.

Examples of Protocol Violations include, but are not limited to:

- Failure to obtain informed consent
- Informed Consent performed by someone other than individuals authorized and trained to obtain consent
- Enrollment of a participant who did not fulfill all inclusion/exclusion criteria
- Performing study procedures not approved by the PHCIRB
- Failure to report a serious adverse event to the PHCIRB
- Failure to perform a required lab test that, in the opinion of the PI and/or Sponsor, may affect participant rights, safety and/or welfare, or data integrity
- Investigational product dispensing or dosing error.

## Responsibilities:

**IRB:** The federal regulations specifically require that IRBs review proposed changes in a research activity, and to ensure that such changes in approved research are not initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject [45CFR46.103(b)(4)(iii) and 21CFR56.108(a)(4)]. Research activity includes all aspects of the conduct of the research study, e.g., recruitment methods, consent process, procedures used to protect privacy and confidentiality, etc. - all of the information outlined in the protocol submission and reviewed and

approved by the IRB. Noncompliance with these regulations and requirements during the conduct of a research study results in a protocol deviation or violation, and as such must be reported to the IRB.

**Investigator:** Conduct human-subjects research in accordance with the approved protocol.

## **Procedures:**

### **Investigator**

Using the Protocol Deviation / Violation Report form, the PI must promptly report deviations or violations that meet one or more of the following criteria:

1. Affect the rights, safety, or welfare of the subjects
2. Affect the integrity of the study data
3. Were instituted to protect the subject from immediate hazard
4. Affect the subject's or subjects' willingness to continue participation

A protocol deviation or violation requiring prompt submission must be reported to the IRB within 10 working days of the knowledge of the deviation.

Any protocol deviation or violation that does not meet one or more of the four (4) criteria listed above must be reported at the time of continuing review in a summary format.

Any permanent change in the protocol resulting from a protocol deviation or violation needs to be submitted as an amendment and approved before the investigator can implement the change.

The Principal Investigator will review and sign each protocol deviation/violation report submitted to the IRB.

### **IRB**

Upon receipt of a deviation/violation report requiring prompt submission the IRB will make a determination whether the deviation/violation is eligible for expedited or full board review will be made. Determinations beyond the scope of the IRB Manager will be made after discussion with a committee member with sufficient expertise.

Incomplete reports will be returned to the study team for completion or additional information.

A protocol deviation/violation involving emergency use or one that may affect the safety of the subject will be reported to the full board. A copy of the report and any supporting documentation will be provided to all IRB Committee Members at the next convened meeting.

During initial review of the deviation/violation report, if it is decided that the report is serious, or significantly changes the risk factor of the investigation, the IRB manager will immediately submit the report to the IRB Chair or designee.

If the committee is satisfied with the site's explanation and corrective action plan, and requires no further information or changes to the protocol, the deviation/violation can be acknowledged. The IRB will determine if any additional action or follow-up is required following review. Additional actions may include (but are not limited to):

1. Modification of the protocol and/or consent form
2. Audit of investigator's site by the IRB
3. Increase frequency of continuing review period for the study
4. Suspension or termination of the study.

## Reference:

### Regulatory Reference:

45 CFR 46.103 (b)(4)(iii)

21 CFR 56.108 (a)(4)

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## Human Subjects Training - Investigator and Key Research Personnel Policy, 6423

### **POLICY:**

It is the policy of the Piedmont Healthcare IRB (PHCIRB) that all investigators and key research personnel participating in human subjects research have adequate training and are qualified to engage in proposed research at Piedmont Healthcare and its affiliates.

### **PURPOSE:**

To define the human subjects training requirements for investigators and key research personnel and describe the responsibilities of the investigators and the PHCIRB in ensuring compliance with this policy.

### **Definition:**

**Key Research Personnel:** This includes principal investigators, co-investigators, sub-investigators, research coordinators, and any other research team members who have contact with research participants and/or participants' research data and identifiers. Individuals whose primary contact with the participants is in the context of clinical care, but offer no additional role in research, are not considered key research personnel.

## Training and Education Requirements:

The PHCIRB partners with the WIRB-Copernicus Group (WCG) Academy for the administration of the chosen research learning modules required. The WCG Academy is a cloud computing, FDA-adopted, CFR Part 11 compliant training program individuals involved in the conduct of research. Modules are assigned to individuals based on their level of involvement in research and are stratified by the following three categories: chart review research, drug research, medical device research. **In select instances Collaborative Institutional Training Initiative (CITI) training may be allowed if the researcher in question has an affiliation with an organization that requires CITI training. This will be reviewed and approved on a case by case basis by the PHCIRB.** Completed training is certified for a three year period.

1. Key research personnel should contact the Office of Research Services (ORS) office to establish the appropriate learning modules required to be taken. The ORS staff will then work with the Academy administrators to give you access to the program for module completion.
2. Prior to the expiration of the program certification, research personnel are required to take refresher courses. It is the responsibility of the trainee to maintain current certifications.
  - a. As a courtesy, the WCG Academy will issue a 30-day expiration reminder via e-mail to trainees. **NOTE:** WCG Academy accounts will be activated to give the trainee access to the program 60 days prior to expiration of certification. It is the responsibility of the trainee to maintain a current e-mail address on file .
  - b. If a Principal investigator's training certificate expires, enrollment must cease until either:
    - i. the refresher courses are completed, or
    - ii. a sub-investigator with certification is delegated the principal investigator role.

The original principal investigator may resume that leader role after s/he is again compliant with the education requirement. Note: If an investigator has a subject enrolled in a study prior to the investigator's certification expiring, and that subject requires medically necessary care from the investigator, that subject can receive necessary medical care from the investigator to ensure that the rights, safety and welfare of the subject is maintained. However, the investigator must complete the recertification before any new subjects can be enrolled under the investigator's care.

3. Each investigator and key research personnel engaged in the conduct of human subjects research is also required to review and be familiar with the principles of The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as well as applicable federal and state laws and institutional policies regarding human subjects research. .
4. New studies will not be reviewed and/or IRB approval will not be granted until the PI completes the training programs.
5. Continuing review approval letters will not be issued to a PI with expired certifications.



## Investigator Responsibilities:

Before submitting a research project for PHCIRB review, the principal investigator will ensure the following:

- a. Completion of the required research learning modules on human research protections;
- b. All other investigators and key research personnel complete the required research learning modules and are adequately trained in the proposed research project;
- c. Conduct research in accordance with the ethical principles of The Belmont Report, federal and state regulations, institutional policies and procedures, PHCIRB policies and procedures.

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<b>Applicability:</b>	<i>Piedmont Healthcare System</i>

# Medical Devices – Significant Risk / Non-Significant Risk Determinations Policy, 6425

## POLICY:

The Piedmont Healthcare IRB (PHCIRB) shall follow federal guidelines in determining Significant Risk and Non-Significant Risk in medical devices used in clinical research.

## PURPOSE:

To define the procedures and conditions for how the PHCIRB will determine which device studies pose significant risk (SR) or non-significant risk (NSR).

## Definitions:

**Significant Risk (SR) Device:** Per 21 CFR 812.3 (m), an SR device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

**Non-Significant Risk (NSR) Device:** A device that does not pose a significant risk to human subjects and one that does not meet the definition for an SR device as outlined above.

## Primary Differences Between SR and NSR Medical Device Studies:

The primary differences between SR and NSR studies are in the IDE approval process and in the sponsor's record keeping and reporting requirements, as outlined below.

### 1. Significant Risk (SR) Device Studies

- SR device studies must follow all the IDE regulations at 21 CFR 812.

- SR device studies must have an IDE application approved by FDA before they may proceed.

## 2. Non-significant Risk (NSR) Device Studies

- NSR device studies must follow the abbreviated requirements at 21 CFR 812.2(b).
- These abbreviated requirements address labeling, IRB approval, informed consent, monitoring, records, reports, and prohibition against promotion.

However, there is no need to make progress reports or final reports to FDA.

- NSR device studies do not have to have an IDE application approved by FDA.
- Sponsors and IRBs do not have to report the IRB approval of an NSR device study to FDA. Thus the IRB's NSR determination is important because the IRB serves as the FDA's surrogate for review, approval, and continuing review of the NSR device studies. An NSR device study may start at Piedmont as soon as the PHIRB reviews and approves the study and without prior approval by FDA.

# PROCEDURES:

The Piedmont Healthcare IRB shall comply with the requirements of 21 CFR Part 812. These regulations permit IRBs to approve a research study involving investigational devices after differentiating between significant risk (SR) and non-significant (NSR) devices. A SR device must have an investigational device exemption (IDE) number from the FDA, while a NSR device does not. If a clinical research study is submitted to the IRB for a device that has an IDE, the device is considered a SR device.

FDA determinations of significant or non-significant risk are final.

Should the IRB need to make an independent determination as to whether or not a medical device used in a research activity is SR or NSR per 21 CFR 812, it will do so by a review of the following items:

- a. FDA letter approving or providing conditional approval of the IDE or a 510K clearance or any other supplementing FDA correspondence address the device such as:
  - a. Pre-market approval letter
  - b. Supplemental letter
  - c. Amendment letter
  - d. Information sheets

- b. The sponsor's description (when applicable) of device risk level determination
- c. Whether a proposed NSR device meets the definition of 'significant risk'
- d. The nature of the harm that could potentially result from use of the device in the intended population
- e. Investigator's Brochure
- f. Package insert
- g. Description of subject selection criteria
- h. Description of monitoring procedures
- i. Other applicable evaluations

The IRB's risk determination will be documented in the IRB meeting minutes.

If an investigator submits a NSR research protocol that is determined by the IRB to be a SR study, the investigator and FDA will be notified in writing. No further action will be taken by the IRB on the research until the sponsor or investigator has met the requirements for a SR study described in 21 CFR 812.

## **Sponsor/Investigator Responsibilities:**

Sponsors are responsible for making the initial risk determination and Investigators will present documentation to support it to the IRB as part of the IRB submission. If the sponsor identifies a device as NSR, the sponsor must provide the PHCIRB an explanation of its determination and any other information that may help the IRB in evaluating the risk of the device. For Significant Risk device studies, the sponsor must submit an IDE application to FDA and obtain the agency's approval of the study. Sponsors/Investigators must provide the IDE number and/or a copy of the IDE approval letter to the IRB as a part of the IRB submission.

## **IRB Responsibilities:**

Unless FDA has already made a risk determination for the device study, the IRB must review the sponsor's SR or NSR determination for every investigational medical device study it reviews and modify the determination if the IRB disagrees with the sponsor.

If the device already has an approved IDE, the IRB will require documentation from the sponsor that the IDE number applies to the device to be used for the study under consideration. This may be reflected in the sponsor's protocol, or correspondence from the sponsor or FDA. FDA will provide a written determination of SR/NSR status at the request of the IRB.

The PHCIRB will make the SR or NSR determination about a device study by reviewing relevant information at a convened meeting. If the IRB determines the device is NSR, the IRB may approve the study using the criteria at 21 CFR 56.111. In that case the study may then begin without submission of an IDE application to FDA.

If the IRB disagrees with the sponsor's NSR assessment and decides the device study is a SR study, the IRB will tell the Investigator, and when appropriate, the sponsor. The IRB may conditionally approve the study as an SR device study, but the study may not begin until FDA approves the sponsor's IDE application, or provides a determination that the device as proposed for use in the investigation is Non-significant Risk.

## SR/NSR Determinations Versus Minimal Risk Determinations

Making a SR/NSR determination for a device study is different than determining "minimal risk." The term "Minimal Risk" is used in the regulations in part to identify certain studies that the IRB may approve through an expedited review procedure.

SR/NSR determinations are separate and distinct from Greater than Minimal Risk/Not Greater than Minimal Risk determinations. For a device study to be eligible for expedited review, it must be an NSR device AND the research must present no greater than minimal risk to the subject (21 CFR 56.110). Upon making its initial determination that a proposed device study is NSR, and that the study is "minimal risk," the IRB may expedite the study under Category 9 at the time of continuing review the following year, assuming no change in risk level during the last approval period occurs.

## Reference:

**Regulatory Reference:** 45 CFR 46; 21 CFR 56

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## Reporting and Handling of Complaints Policy, 6426

### POLICY:

The Piedmont Healthcare Institutional Review Board (PHCIRB) will actively investigate and address, as appropriate, any reported complaints or concerns under its purview.

### PURPOSE:

To establish the procedures to be followed upon receipt of a report of complaint or concern as it pertains to the IRB or its functions as well as research conducted at Piedmont Healthcare. This policy is applicable, but not limited to, to the research community, research participants, IRB members and staff, and others.

### PROCEDURES:

In general, complaints or concerns are reported directly to the PHCIRB by contacting the PHCIRB Chair or PHCIRB Manager at 404.605.3638.

- i. **Complaints about the PHCIRB or its functions:** Complaints/concerns involving the leadership of the PHCIRB (PHCIRB Chair) or the functions of the office may be reported to the Institutional Official (IO) who has administrative authority over the parties. Persons so desiring may make such reports by contacting the Chief Medical Officer at 404.425.1306. Complaints/concerns found to have merit will be addressed by the IO in a manner befitting the nature of the issue. Complaints/concerns found to be of no substance will require no action.

- ii. **Research related complaints:** The PHCIRB will promptly probe into any complaint/concern to evaluate the nature and accuracy of the issue for consideration of what, if any, course of action is needed. All assessments will be careful to investigate whether the complaint/concern constitutes an unanticipated problem involving risks to participants or others as well as any other reportable matters.
  - a. The PHCIRB will log all complaints/concerns in the Complaints spreadsheet for tracking of receipts, investigations, resolutions, and reporting.
  - b. Complaints/concerns found to be of no substance will require no action other than report to the full committee via note on the agenda.
  - c. Lesser issues may result in notification to the researcher to advise of the receipt of the complaint/concern and any PHCIRB determined required actions. These actions will be reported to the full committee via note on the agenda and subsequent minutes.
  - d. Investigations that reveal an unanticipated problem involving risks to participants or others will result in:
    - i. Notification to the researcher to advise of the complaint/concern;
    - ii. Request for researcher response to the issue in writing inclusive of a corrective action plan;
    - iii. All compiled materials will be brought before the full committee at a convened meeting for final IRB determination and/or referral to other oversight committees;
    - iv. Notification to the appropriate institutional officials and/or department or agency head per 45 CFR 46.103 (b)(5) and 21 CFR 56.108 (b);
  - e. The PHCIRB will review responses and assess for satisfactory resolution of any issues. If needed, the PHCIRB will work with investigators to ensure a comprehensive action plan is put into place and properly executed;
  - f. Other reportable matters are inclusive of complaints/concerns received by researchers (from participants or others) which he/she believes the PHCIRB should be aware of; and
  - g. The researcher must also provide a summary of complaints to the PHCIRB on the Protocol Deviation/Violation Report form at the time of the renewal request.

## Reference:

**Regulatory Reference:** 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)

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## Administrative Suspension and/or Termination of Research Policy, 6427

### **POLICY:**

The Piedmont Healthcare Institutional Review Board (PHCIRB) will act on its authority to either suspend or terminate prior approved research upon determination that the research is not being performed in accordance with IRB requirements; is serious or continuing non-compliance; or is likely to cause serious harm to research participants or others.

### **PURPOSE:**

To establish the procedures to be followed to comply with federal, regulatory and institutional policies concerning PHCIRB suspension or termination actions.

### **Definitions:**

**Suspension:** An action taken by the PHCIRB, PHCIRB Chair, or Institutional Official (IO) or designee to temporarily withdraw approval for some or all research activities in the interest of protecting research participants. Suspended protocols are considered open but may not continue enrollment or research activities that are not essential to the protection of research participants. The PHCIRB will advise researchers of the timing of the continuing renewal request requirement.



**Termination:** An action taken by the PHCIRB to permanently withdraw approval for all research activities (excepting those activities required to protect research participants). Terminated protocols are considered closed and do not require a continuing renewal.

**Serious non-compliance:** Failure to act or willful violation of policies or regulations which create increased risk to research participants, adversely affects the rights, welfare and safety of research participants or adversely affects the scientific integrity of the study.

**Continuing non-compliance:** A pattern of repeated non-compliance that indicates a lack of ability or willingness to adhere to policies or regulations; or repeated noncompliance that if allowed to continue is likely to increase risk, adversely affect the rights, welfare and safety of research participants, or adversely affect the scientific integrity of the study.

## Procedures:

In general, suspensions or terminations will be the decision of the full committee subsequent to investigation and determination that research is not being conducted as expected per federal, regulatory, or institutional policies. Instances requiring immediate suspension of research in order to protect the rights and welfare of human subjects may be carried out under the authority of the PHCIRB Chair or designee. This action will be taken pending the results of an investigation and is required to be reported to the full committee at a convened meeting. Any follow up items can be discussed by the committee that can make additional sanctions regarding the case. Actions not requiring immediate suspension will be taken to the full committee and the inquiry phase for determination of follow up actions and confirmation of study status.

## Notification and investigation

- i. The PHCIRB will provide written notification to the researcher, Institutional Official (IO), Office of Research Services (ORS), the Food and Drug Administration (if applicable), Office for Human Research Protections (OHRP), Office of Compliance (if applicable), Contracts (if applicable), and the department chair informing of the suspension or termination along with the rationale to support the decision.
- ii. Suspension determination letters to the researcher will request a response and cooperation with the investigation/inquiry phase of the process. Results of the inquiry are compiled and prepared for deliberation and determinations by the full committee.

## Deliberation and determination

- i. At a convened meeting the PHCIRB is presented with the investigation results for discussion and determinations that may include the following:
  - a. Continued suspension pursuant to further investigation, if indicated, for determinations of serious harms to research participants or others.
  - b. Determinations of serious or continuing non-compliance will be handled per PHCIRB policy #6416.
  - c. Termination of research in order to protect the rights and welfare of research participants.

- d. Re-approval of the research which places the research project in proper active status as determined by the full committee.
- e. Either of the above scenarios may include additional required actions by the PHCIRB not limited to the following:
  - i. Ensure research activities have halted, with the exception of re-approval determinations.
  - ii. Suspend the research privileges of the researcher and transfer of leadership responsibility to another researcher;
  - iii. Require additional educational requirements for the researcher and/or the study team;
  - iv. Require the continuation of some research activities in the interest of the rights and welfare of research participants;
  - v. Require monitoring of the researcher and/or the research project;
  - vi. Require random auditing of the researcher and/or the research project;
  - vii. Require notification of suspension or termination of current and former research participants;

## Reference:

**Regulatory Reference:** 45 CFR 46.103(b)(5) and 46.113; 21 CFR 56.108(b)(3) and 56.113

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## Requirements for Piedmont Healthcare Institutional Review Board Approval of Research Policy, 6429

### **POLICY:**

The Piedmont Healthcare Institutional Review Board (PHCIRB) will approve only those research proposals meeting specific approval criteria per OHRP and FDA regulations and institutional policies. All research involving human subjects, all other activities which even in part, involve such research, regardless of sponsorship, must be reviewed and approved by the PHCIRB.

### **PURPOSE:**

To clarify how the PHCIRB will comply with 45 CFR 46.110 and 46.111 as they relate to research that qualify for either Expedited or Full Board procedures. This policy applies to all research proposals submitted for PHCIRB review and approval.

### **CATEGORIES FOR PHCIRB CONSIDERATION:**

In order for the PHCIRB to evaluate and approve human subjects research proposals it must determine the following in its consideration of both Expedited and Full Board review projects:

- Risks to subjects are minimized;

- Risks to subjects are reasonable in relation to anticipated benefits;
- The selection of subjects is equitable;
- Appropriate procedures are followed for obtaining and documenting informed consent or waiving or altering informed consent documentation or procedures;
- The study design has adequate provision for monitoring the data collected in order to ensure subject safety;
- There are adequate provisions to protect subject privacy and data confidentiality; and
- Additional safeguards are included to protect the rights and welfare of any vulnerable populations included in the proposal.

### **Risks to subjects are minimized:**

The PHCIRB shall evaluate whether risks to subjects are minimized by the use in the protocol of procedures that:

- are consistent with sound research design;
- do not unnecessarily expose subjects to risk; and
- when appropriate, are procedures that are already being performed on the subjects for diagnostic or treatment purposes.

### **Risks to subjects are reasonable in relation to anticipated benefits:**

The PHCIRB shall evaluate whether risks to the subjects posed by participation in the research are justified by the anticipated benefits to the subjects, if any, and the importance of any knowledge that may reasonable be expected to result from the research. In undertaking this evaluation, the PHCIRB shall judge whether either the anticipated benefit to the subjects from participating in the research, or the new knowledge to be gained from the research, justifies asking a person to undertake the risks of participation in the research. In evaluating risks and benefits, the PHCIRB will consider only those risks and benefits that may result from the research as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research. In addition, the PHCIRB will not consider possible long-range effects of applying knowledge gained in the research. The PHCIRB will disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits.

### **Selection of subjects is equitable:**

In making this assessment the PHCIRB will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research vulnerable populations.

### **Informed consent:**

The PHCIRB will review the informed consent procedures and documentation to ensure that informed consent will be appropriately obtained and documented, or alternatively that all criteria are met for the waiver or alteration of informed consent or documentation thereof as required per 45 CFR 46.116 and 46.117.

## **Data and safety monitoring and study design:**

The PHCIRB will ensure that when appropriate, the research plan makes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. The PHCIRB must evaluate whether the protocol employs sound research design that can reasonably be expected to result in an answer to the proposed research question and that the procedures used in the research are consistent with such sound design.

## **Privacy and Confidentiality:**

The PHCIRB will review the protocol to determine whether adequate procedures are in place to protect the privacy of subjects and to maintain the confidentiality of the data. The PHCIRB shall determine whether the activities in the research constitute an invasion of privacy by obtaining and evaluating the manner in which investigators gain access to subjects or subjects' information, as well as assessing the subjects' expectations of privacy in the research situation.

## **Vulnerable populations:**

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, the PHCIRB must ensure that additional safeguards are included in the study design to protect the rights and welfare of these subjects.

## **Other specific Expedited Review considerations**

Per 45 CFR 46.110, certain kinds of research involving no more than minimal risk (and for minor changes to previously approved research) may be evaluated under the expedited review procedure by the PHCIRB chair or an experienced designee. In reviewing the research, the expedited reviewer may exercise all the authorities of the full IRB except that the reviewer may not disapprove research. A research activity may be disapproved only after review in accordance with the non-expedited review procedure.

## **Case-by-case determinations**

The PHCIRB may, at its discretion, consider research proposals that have conditions for full approval as placed by governing regulatory entities. In such cases, the PHCIRB will follow the procedures above to ensure the proposal meets all criteria for PHCIRB approval of the research. For each case, as with all other research proposals, the PHCIRB maintains the authority not limited to placing additional restrictions, approving, and requiring modifications.

## Reference:

**Regulatory Reference:** 45 CFR 46.110; 46.111; 46.116; 46.117; 46.203; 46.204; 46.207; 46.303-46.306

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## Humanitarian Use Devices Policy, 6430

### POLICY:

The Piedmont Healthcare Institutional Review Board (PHCIRB) shall review and approve the use of Humanitarian Use Devices (HUDs) pursuant to FDA regulations and PHCIRB policies and procedures. An HUD is the only situation where federal regulations require the IRB to approve and monitor an activity that is not research.

### PURPOSE:

This policy will describe HUD uses and the responsibilities of the HUD user, the PHCIRB, and the HDE holder.

# DEFINITIONS:

**Humanitarian Use Device (HUD):** a medical device intended to benefit patients in the treatment and diagnosis of a disease or condition that affects or is manifested in fewer than 8,000 individuals in the United States per year.

**Humanitarian Use Device Exemption (HDE):** a marketing application for an HUD (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). An HDE is exempt from the **effectiveness** requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions.

**HDE holder:** the individual who obtains the Humanitarian Device Exemption (HDE) from the FDA.

**Investigational Device Exemption (IDE):** allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification submission to the FDA.

**Research:** In this context, research refers to the physicians' intent to collect safety and effectiveness data about a device for a **new** use.

# HUD USES:

**Note: for all scenarios below, the PHCIRB may impose more stringent restrictions for the use of the HUD as a means of ensuring additional protections, as the committee deems appropriate.**

**Non-research HUD.** The use must be within the indication approved by the FDA as described in the HDE. The regulations do not require the use of an informed consent document outside the setting of a research protocol. Therefore, such a document is not required in this instance because the FDA does not consider the use to be research and has already approved the HUD for marketing. For such cases, the PHCIRB does not require an informed consent document but will require the physician to give patients an information sheet describing/explaining:

1. FDA HDE program
2. Device and labeling information
3. That although the device is authorized by the FDA, the effectiveness of the device for the specific indication has not been proven or demonstrated.
4. Procedures
5. Risk/benefit ratio
6. Physician contact information.

**Criteria:**

In general, for HUD patients that qualify according to disease or condition  
For groups of HUD patients that meet certain criteria  
Under an HUD treatment protocol  
On a case by case HUD basis

**Research HUD.** This use is applicable when the researcher intends to collect data on the safety and effectiveness of the HUD for the FDA approved indication to support a PMA for the HUD. A research protocol and research informed consent document reviewed and approved by the PHCIRB are required. An IDE is not required when the data collection occurs as described above.

**Emergency use of an HUD.** This use is applicable in emergency situations where the physician determines that IRB approval cannot be obtained in time to prevent serious harm or death to a patient, the need to use the device in a manner inconsistent with the approved investigational plan, or use by a physician who is not part of the clinical study team. Emergency use of an approved device may occur before an IDE is approved.

**Criteria:**

No alternative treatment  
Life-threatening or serious disease or condition  
No time to obtain FDA approval

**Compassionate/Off-label use of an HUD.** This use is applicable for cases where a patient does not meet the requirements for inclusion in a clinical investigation but for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. This option is applicable for individual patients or small groups. Note: an IDE is required if the physician collects safety and effectiveness data on the device as the use will occur outside the approved HDE.

**Criteria:**

No alternative treatment  
Serious disease or condition  
FDA approval prior to use

## **RESPONSIBILITIES:**

**HUD User:** Research and non-research HUD use:

1. Ensure that the HDE exists for the use of the HUD.
2. Obtain permission from HDE holder for use of HUD.
3. Ensure HUD use meets HDE requirements.



4. Verify that the HUD will be used for treatment, diagnosis, or research in accordance with the labeling of the device, intended purpose, and the designated population for which the FDA approved its use.
5. Submit a plan/protocol for use of the HDE to the PHCIRB.
6. Obtain PHCIRB approval for use prior to use.
7. Submit documentation to PHCIRB for continuing review of HDE. This will entail a summary of the clinical indications for use of the HUD in each patient, adverse events or unanticipated problems involving risk to participants or others that are possibly or probably related, the clinical outcomes of each participant, if known, and any Medical Device Reports per 21 CFR 803.

Emergency HUD use:

1. Ensure and provide documentation to PHCIRB attesting that the criteria for emergency use are met.
2. Obtain concurrence of IRB chair for HUD use, if possible.
3. Obtain an independent assessment of HUD use from a physician uninvolved in the study, if possible prior to use. Assessment must be forwarded to the PHCIRB within the (5) business day post emergency use reporting window.
4. Obtain HDE holder permission and patient informed consent, if possible prior to use. HDE holder permission must be forwarded to the PHCIRB within the (5) business day post emergency use reporting window.
5. After emergency use, within 5 business days, send report to IRB and HDE holder regarding use.

Compassionate/ Off-label HUD use:

1. Ensure criteria for compassionate use are met.
2. Submit documentation to HDE holder supporting use.
3. Obtain FDA correspondence regarding amendment to HDE from the HDE holder. This information will be submitted to the IRB.
4. Obtain PHCIRB approval.
5. Obtain IDE for **research** on uses of HUD not covered by HDE.
6. Submit documentation to PHCIRB for continuing review of HDE. This will entail a summary of the clinical indications for use of the HUD in each patient, adverse events or unanticipated problems involving risk to participants or others that are possibly or probably related, the clinical outcomes of each participant, if known, and any Medical Device Reports per 21 CFR 803.

**PHCIRB:** Research, non-research, compassionate/ off-label HUD use:

1. Perform full board review at initial submission per 21 CFR 56.111. NOTE: PHCIRB review and approval of individual HUD uses is not required, rather the PHCIRB may approve the use of the device as it deems necessary.
2. Specify limitations on the use of the device based upon:
  - a. One or more measures of disease progression
  - b. Prior use and failure of any alternative treatment modalities
  - c. Reporting requirements to the PHCIRB
  - d. Appropriate follow up precautions and evaluations
  - e. Any other criteria deemed appropriate
3. Verify that the device does not pose an unreasonable risk of illness or injury to recipients and that the risk: benefit ratio is favorable.
4. Verify that the proposed use of the device is consistent with the current labeling of the device and does not exceed the scope of the FDA approved indication.
5. Perform full board or expedited review at continuing renewal per 21 CFR 56.109 and .110.
6. Withdraw HDE approval:
  - a. should the physician fail to follow IRB or FDA requirements
  - b. in the event of unexpected serious harm to patients.

Emergency HUD use:

1. Concurrence of IRB Chair for use, when possible.

**HDE Holder:** Research and non-research HUD use:

1. Complete HDE application to FDA satisfaction. This includes establishment that no comparable device is available for proposed use.
2. Provide permission letters to HUD users for submission to the local IRB.
3. Hold both HUD and HDE prior to shipment of a device to a facility with an established Institutional Review Board that operates in compliance with FDA regulations.
4. Ensure initial and continuing IRB review and approval.

5. Report clinical experience to FDA via annual reporting.
6. Maintain IRB correspondence.

Compassionate HUD use:

1. Submit HDE amendment to FDA for approval, obtain approval and forward to HUD User for submission to IRB.

## Reference:

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## IRB Determinations on Research Policy, 6431

## POLICY:

It is the policy of the Piedmont Healthcare Institutional Review Board (PHCIRB), to review proposed nonexempt human subjects research activities. At a convened meeting the IRB can approve, require modification, disapprove, suspend or terminate research. If the proposed research qualifies for expedited review, the designated reviewer may exercise all of the authorities of the IRB except disapproving the research.

## **PURPOSE:**

This policy outlines PHCIRB's determinations on proposed research as applicable to initial, continuing review and amendments.

## **DEFINITIONS AND ACTIONS:**

**Approve:** Determination given when all criteria for approval are met to satisfaction in accordance with 45 CFR 46.111 as well as institutional, federal, state and local requirements.

**Require modifications:** This determination specifies conditions under which research can be approved, pending the completion of minor clarifications or modifications to the protocol, informed consent document(s) and/or accompanying document(s). The IRB may designate the IRB chairperson (and/or other individual(s) with appropriate expertise or qualifications) to review responsive materials from the investigator and determine that the conditions have been satisfied, and further review by the IRB at a subsequent convened meeting would not be necessary. The proposed research may not begin until a letter of approval is received from the IRB.

**Disapprove:** Determination given if the proposed research fails to meet one or more criteria outlined in the regulations at 45 CFR 46.111 and, if applicable, subparts B, C, or D. The IRB will send a detailed letter to the research outlining all reasons of disapproval. The investigator will have an opportunity to respond in person or in writing.

**Suspended:** Determination given when research is not being conducted as expected per federal, regulatory, or institutional policies. (Reference Policy #6427).

**Termination:** This is the action taken to permanently withdraw approval for all research activities on a project. The applicable exception are those activities required to protect research participants.

**Table or defer:** Situation where the IRB cannot make the determination required for approval. The IRB may require the investigator to make substantive changes to the protocol or informed consent documents, or submit clarifications or additional documents. The research may not proceed until the IRB reviews the revised research project and approves it at a subsequent convened meeting.

**Risks:** The risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research. The IRB should not consider possible long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility. The minutes will reflect both full committee and expedited review determinations on risk assessment.

**Frequency of Review:** At the time of initial approval the duration of the approval period and the interval by which continuing review must occur (e.g., 4 months, 6 months, or 1 year) in order for the research to continue will be specified. However, a review must not be greater than once per year.

## IRB Actions:

When conducting an initial, continuing review, or a review of proposed changes to a previously approved research study, PHCIRB can take any of the following actions:

## REFERENCE:

**Regulatory Reference:** 45 CFR 46.102(h), 109(a); 21 CFR 56.115

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## Observation and Monitoring of the Consent Process Policy, 6432

## POLICY:

Pursuant to federal regulations 45 CFR 46.109(e) and 21 CFR 56.109(f), the IRB shall have authority to observe or have a third party observe the consent process and the research. The Piedmont Healthcare IRB (PHCIRB) may evaluate the appropriateness of the informed consent process to consider where and whether the process takes place in a setting that is designed to minimize the possibility of undue influence or coercion.

## **PURPOSE:**

To define how the PHCIRB may monitor the consent process and verify that the process and accompanying documentation are likely to assist potential participants to make an informed decision to participate in research.

## **Process monitoring:**

The PHCIRB may monitor the consent process in order to ensure that process is carried out in accordance with all protocol, IRB and regulatory requirements. The monitoring process will also evaluate and ensure that potential participants have adequate time to consider participation in the research and that someone is available to answer all of the participant's questions prior to being enrolled into the research protocol. In reviewing the adequacy of informed consent procedures for proposed research, the PHCIRB may, at its discretion, determine that special monitoring of the consent process by an impartial observer (consent monitor) is required. Such monitoring may be particularly warranted when the research presents significant risks to subjects, or if subjects are likely to have difficulty understanding the information to be provided. Monitoring also may be appropriate as a corrective action when the PHCIRB has identified problems associated with a particular researcher or a research protocol. (Also see PHCIRB policy # 6416).

## **PROCEDURE:**

When the PHCIRB requires consent monitoring to be performed the following procedure will be followed:

- a. The PHCIRB will assign an appropriate IRB member, IRB staff member, or an outside consultant to perform the monitoring.
- b. The assignee shall be thoroughly familiar with:
  - a. The informed consent process for research and applicable regulations
  - b. The specific consent(s) for the study being monitored
  - c. The proposed consent process as outlined in the protocol and/or supplemental study review materials.
- c. PHCIRB staff will:
  - a. Work with study team to verify a participant's willingness to have the consent process observed.
  - b. Assist with the coordination and timing of process monitoring.

- d. The assignee will observe the consent process and provide written constructive feedback (via the PHCIRB Consent Observation and Monitoring Form) to the researcher and study team within 10 business days of the observation.
- e. The assignee will provide a report of observation to the PHCIRB Chair along with any recommended corrective actions.
- f. The PHCIRB Chair will review the report and decide if committee review is required. If there are no concerns, the PHCIRB Manager will document the file and process/close out the item. If the report is to be reviewed at the convened meeting the committee will vote on whether to accept the report and any recommended corrective actions.
- g. Following review of the report by the PHCIRB Chair or committee, the PHCIRB shall notify the researcher of the results of the monitoring and any required corrective actions, if applicable.

When the PHCIRB observes the informed consent process for monitoring and education purposes the following procedure will be followed:

- The observee will be sent an email request for potential observation dates, specific study, location, times, and site details, if appropriate.
- The observee will ensure that the potential participant is aware of and receptive to a third party observer of their consenting process.
- The observer will become familiar with the information to be presented to the potential participant.
- The observer will observe the consent process and provide written constructive feedback (via the PHCIRB Consent Observation and Monitoring Form) to the observee, his/her supervisor, and the principal investigator within 10 business days of the observation.
- Any observations of concern as to completion or appropriateness may be discussed with supervision, the principal investigator, and/or the IRB Chair to determine if corrective actions are necessary.

## Reference:

**Regulatory Reference:** 45 CFR 46.109(e), 21 CFR 56.109(f)

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## Health Insurance Portability and Accountability Act (HIPAA) Policy, 6433

### **POLICY:**

The Piedmont Healthcare Institutional Review Board (PHCIRB) will also act as the entity Privacy Board for all research under its jurisdiction to determine if HIPAA regulations apply, and, if applicable, to ensure compliance with the HIPAA regulations as outlined in 45 CFR parts 160 & 164.

### **PURPOSE:**

This policy describes the authority of the PHCIRB in reviewing research matters involving the use or disclosure of Protected Health Information (PHI). The PHCIRB will make determinations as to whether the use or disclosure requires (a) authorization from the research participant or (b) grant of a partial or complete alteration or waiver of HIPAA authorization.

Per the Privacy Rule established by HIPAA, the PHCIRB will enforce the minimum necessary rule standards for use and disclosure of PHI. To use or disclose PHI, a researcher must first obtain signed documentation from the research participant granting such permission, or obtain a partial or complete waiver of HIPAA authorization as granted by the PHCIRB. The documentation of the alteration or waiver of authorization will be recorded in the minutes.

### **Definitions:**

**Business Associates:** Persons or entities that create, use, or disclose PHI to perform or assist in the functions of a covered entity.



**Covered entity:** per the HIPAA Privacy Rule, covered entities are healthcare providers, health plans and healthcare clearinghouses.

**Health Information:** any information, whether oral or recorded in any form, that relates to the past, present, or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present or future payment of healthcare to an individual.

**Minimum Necessary Rule:** In determining the type and scope of the PHI for which the PHCIRB determines use or access under a waiver or alteration of the HIPAA Authorization requirement is necessary, the IRB must limit access to only that PHI which is reasonably necessary to accomplish the purpose for which the request is made.

**PHI (protected health information):** individually identifiable health information that is created or received by a HIPAA-covered or hybrid entity.

## **HIPAA Identifiers:**

Federal HIPAA regulations define the following as identifiers of an individual or of relatives, employers, or household members of the individual:

1. Names
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;

13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data).

All 18 elements above must be removed (scrubbed) from health information in order for it to qualify as 'anonymous' data.

**Other applicable privacy laws:** In some cases privacy laws other than HIPAA may apply to data used for human subjects research such as Georgia State laws regarding genetic information, NIH policies concerning Certificates of Confidentiality, and the policies of funding agencies, etc...

## **HIPAA Waivers:**

**Partial and complete HIPAA waivers.** The PHCIRB will grant an alteration (partial waiver) or HIPAA Waiver based on assessment of the requests as entered in the New Protocol Application form and the determination that the request satisfactorily meets the following criteria:

1. The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;
2. The privacy risks to persons whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits, if any to these persons, and the importance of the knowledge that may reasonably be expected to result from the research.
3. That the research could not practicably be conducted without the waiver or alteration;
4. That the research could not practicably be conducted without access to the use of protected health information; and
5. The use or disclosure involves no more than minimal risk to privacy of individuals based on the following:
  - a. There is an adequate plan to protect the identifiers from improper use and disclosure.
  - b. There is an adequate plan to destroy the identifiers at the earliest opportunity as consistent with the conduct of the research.
  - c. There are written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for authorized oversight of the research study, or for other research for which the use of disclosure of PHI would be permitted.

It is important to note that partial HIPAA waivers are limited to the identification of potential subjects and determining eligibility. After that specific purpose has been accomplished, the study team may no longer access PHI for research purposes without obtaining full HIPAA Authorization from the research subject.

## **HIPAA Authorization:**

Participant HIPAA authorization for the use and disclosure of PHI will be obtained using the Piedmont Healthcare Research Subject HIPAA Authorization Form for Use or Disclosure of Protected Health Information (PHI) document. This form is fully compliant with the regulations governing participant authorization for research purposes.

**Right to Revoke HIPAA Authorization:** A participant may withdraw consent to participate in a research study in writing, verbally or by failure to further participate. However, under HIPAA, unless the informed consent/Authorization form states otherwise, HIPAA requires a subject to revoke his/her Authorization in writing in order to revoke the subsequent use or disclosure of his/her PHI. The Authorization is required to state that the participant has the right to make a revocation of the Authorization in writing, along with stating any lesser means for revocation that may be permitted (e.g., verbal revocation). [NOTE: Even though an Authorization form may specify that the revocation of Authorization is to be in writing, if a verbal revocation is received, or if the participant verbally withdraws from the study, then the Researcher should not access any further PHI of the participant from that point on.]

## **Reference:**

**Regulatory Reference:** 45 CFR parts 160 & 164

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## Investigator Responsibilities Policy, 6434

### **POLICY:**

It is the policy of Piedmont Healthcare IRB (PHCIRB) that all investigators engaging in the conduct of research involving human subjects do so in accordance with The Belmont Report, federal and state regulations, institutional policies and procedures, and PHCIRB policies and procedures.

### **PURPOSE:**

To describe the minimum requirements for investigators to fulfill PHCIRB expectations for the proper conduct of research involving human subjects. The intent of this document is to help investigators better understand and to meet their responsibilities with respect to leading and/or supervision of activities to protect human subjects and ensuring the integrity of the data collected from research investigations.

### **Responsibilities:**

- A. **The investigator should have sufficient time to properly conduct and supervise the clinical trial.**

Investigators are expected to afford research projects the level of supervision appropriate to the assigned staff, nature of the research and target patient population. Investigators should develop a plan for the supervision and oversight of the research inclusive of routine staff meetings to address study related issues in a timely manner. Adherence to a rigorous plan to oversee the research will assist the investigator in protecting the rights, safety, and welfare of research subjects. In addition, proper supervision of the research will require the investigator to ensure:

- a. That any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task;
- b. That study team members are compliant with PHCIRB policy # 6423 as it describes the research education training module completion criteria;
- c. That the study team have an adequate understanding of the research and are properly trained on study specifics;
- d. That the research is conducted in accordance the PHCIRB approved protocol, the Investigator Assurances statement (available in IRBNet Library Manager), and all applicable regulations governing research; and
- e. That any conflicts of interest on part of the principal investigator or key study personnel are disclosed.

NOTE: The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the research study.

**B. Design and/or implement research consistent with the Belmont Report.**

The PHCIRB is duty bound to review and make decisions on all research protocols involving human subjects. In that role the PHCIRB must protect human subjects from undue risk and from deprivation of personal rights and dignity. To best accomplish this level of protection the PHCIRB requires investigators to adhere to the ethical principles of research as established in the Belmont Report:

1. Respect for persons
  - a. Treat individuals as autonomous agents.
  - b. Respect persons with diminished autonomy.

This principle is assured when voluntary participation from a research subject is obtained via the informed consent process.

2. Beneficence
  - a. 'The Golden Rule': Do unto others as you would have them do unto you.

This principle is assured when an appropriate balance exists between potential benefits that can be gained and the expected risk assumption by a research subject.

3. Justice

- a. Distribute the risks and potential benefits of research equally among those who may benefit from the research.

This principle is assured when there is an equitable selection of research subjects as it relates to the sharing of both research risks and research benefits.

**C. Compliance with all applicable federal regulations impacting the protection of human subjects.**

The research program at Piedmont Healthcare is established pursuant to and in accordance with the laws, regulations and principles per the governing bodies listed below.

All research that involves drugs or devices is regulated by the Food and Drug Administration (FDA) under Title 21 of the Code of Federal Regulations (CFR).

The Office of Human Research Protections (OHRP) regulates research under Title 45 CFR part 46.

All other applicable state and local laws and regulations. Note: the PHCIRB defers to legal counsel for interpretation of state law (when applicable).

**D. Ensure IRB approval of proposed research prior to initiation of the project.**

Research conducted without prior IRB approval is considered serious non-compliance and a violation of federal, institutional and PHCIRB policies. OHRP regulations prohibit the commencement of research activities without prior IRB approval even in emergency situations.

**E. Ensure any changes to previously approved research is reviewed and approved by the PHCIRB.**

The federal regulations specifically require IRBs to review proposed changes in a research protocol and to ensure that such changes in the approved research are not initiated without IRB review and approval. The only exception is when a change may be necessary to eliminate apparent immediate hazards to a study participant per 45 CFR 46.103(b)(4)(iii) and 21 CFR 56.108(a)(4).

**F. Obtain informed consent in accordance with federal regulations and as approved by the PHCIRB.**

Prior to the conduct of any research activities involving human subjects, the permission of the study participant (or a legally authorized representative) must be obtained via the informed consent process. This is true for all research activities unless the conditions for a waiver or alteration of informed consent are met as determined by the PHCIRB during its review and approval of the research.

NOTE: It is the responsibility of the investigator to monitor the decision making capacity of study participants especially when there is the possibility of either decreased mental functioning or fluctuating decision-making capacity.

**G. Submit progress reports of approved research at regular intervals as determined by the PHCIRB.**

In general, renewal requests accompanied by progress reports (DSMB/C/P notes, monitoring reports, serious adverse event reporting, etc...) may be required on an annual basis for consideration of continued approval on a research study. Assessments of re-review requirements are made by the PHCIRB in consideration of appropriate intervals based on the degree of risk proposed by the research. Investigators must allow sufficient time for development and review of renewal submissions. Courtesy service notifications are provided at the 60 and 30 day marks prior to expiration time periods to advise the study team of the upcoming study renewal.

**H. Event reporting.**

All internal deaths (regardless of attribution) MUST be reported to the PHCIRB within 10 working days of the study team's knowledge of the death. Investigators are required to comply with guidance described in PHCIRB policy # 6421 as it relates to required reports for:

- . Serious adverse events (SAE)
- a. Unanticipated problems (UP), and
- b. Unanticipated adverse device effects (UADE).

Investigators are also required to comply with guidance described in PHCIRB policy# 6422 as it relates to required reports for:

- c. Protocol violations, and
- d. Protocol deviations.

In general, SAE, UP, UADE, deviation, and violation reporting is not expected on the following project types:

5. observational,
6. non-interventional,
7. questionnaires, etc.

Such reporting is not required as an event is not anticipated to have a causal relationship to participation in the study. HOWEVER, the researcher is encouraged to use professional discretion and report any and all concerning unexpected reactions that occur.

#### I. **Patient safety and compliance with hospital work place policy**

It is expected that all personnel will comply with the Piedmont Healthcare Drug and Alcohol Free Work Place Policy. Investigators found to be in violation of the policy will have research privileges suspended in the interest of patient safety. In addition, the researcher will be replaced in each of their roles as principal investigator or sub-investigator, required to get professional assistance, and required to go through a formal re-instatement of research privileges process.

Note: It is the responsibility of the principal investigator and other study team members to report the observance of any individuals in violation of policy #1033 and therefore also liable for compromising patient safety.

## Guidance document:

Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects.

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf>

## Reference:

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## Quality Improvement/Quality Assurance Program for PHCIRB Operations Policy, 6435

### **POLICY:**

Functions of the Piedmont Healthcare Institutional Review Board (PHCIRB) include a quality improvement and quality assurance (QI/QA) program that is carried out under the direction of the PHCIRB Manager. The PHCIRB will follow the QI/QA program to ensure that its operations are adequate to achieve appropriate levels of quality and compliance. The QI/QA program will focus on pertinent areas including IRB operations, IRB member review activities, and investigator activities.

### **PURPOSE:**

The aims of the QI/QA program are to measure the level of compliance with regulations and internal control systems, and to plan improvements to the program. Quality improvement is a continuous process that can involve changes to policies, procedures, systems and training.

### **Program elements:**

The PHCIRB QI/QA program is composed of three elements:

1. The PHCIRB will monitor up to three protocols per quarter with the review findings to be presented at a convened meeting. Feedback may be provided to the study team.

2. Internal review of protocol tracking tool to be carried out by the PHCIRB staff. This assessment will occur bi-annually and reviewed within the IRB office. Any points for follow-up on any findings will also be reviewed within the IRB office and presented at a convened meeting if warranted.
3. Internal review of IRB board functions to be carried out by the PHCIRB staff as part of the quality assurance initiative. This assessment will occur bi-annually with findings to be presented at a convened meeting.

## **Monitoring and observations:**

In considering the adequacy of informed consent procedures, the IRB may require special monitoring of the consent process by an impartial observer (consent monitor) in selected studies to reduce the possibility of coercion and undue influence or whenever the IRB has concerns that the consent process may not be administered appropriately. Such monitoring may be particularly warranted where: a) the research presents moderate to high risks to participants or to vulnerable populations, b) if participants are likely to have difficulty understanding the information to be provided, d) when the procedures or interventions are particularly complicated. Monitoring/observation may also be appropriate as a corrective action where the IRB has identified consent-related problems associated with a particular investigator, a research project or where research staff are less experienced.

Monitoring/observation reports will become part of the protocol file and will be available as part of the review materials in that packet. (Also see PHCIRB policy #6432).

## **Internal reviews:**

The Protocol Tracking Tool Review Checklist is designed to assess the system for proper functioning as it relates to the completion of all relevant data fields. Any omissions, or incorrect information noted will be promptly addressed internally and/or with system developers for satisfactory resolution.

When a project is chosen for monitoring, all associated IRBNet protocol tracking files will be reviewed by IRB staff using the Study Review checklist. In addition, the IRB Manager and Chair will determine any additional document review activities that will be performed on the study. Information gathered from these reviews will be provided to the Chair in summary reports. Based on measured accuracy and completeness, the IRB may refine systems and create improvement plans to ensure that all required documentation is included in the files, and that they are used effectively to protect participants from risk and harm. Any deficiencies in the protocol files that are discovered will be corrected under the direction of the IRB Manager.

At least annually the IRB Manager will present the monitoring activities under the quality improvement program at a regularly scheduled IRB Meeting if there are any findings. Findings in the summary reports, issues raised through the monitoring process and resolution of corrective action plans shall be discussed. Appropriate modifications to IRB procedures, improvement initiatives and additional training to be introduced shall be discussed and approved by the IRB.

## **Quality Assurance guidelines:**

The IRB Manager shall ensure that the QA plan is implemented, reviewed periodically, and revised when appropriate. The following shall serve as guidelines for periodic review and revision of the QA plan:

- Verify that the IRB has kept abreast with changes in regulations as promulgated by the governing agencies.
- Verify that the IRB system is sufficiently responsive so that researchers can plan, obtain approval, and meet reporting requirements in a timely manner.
- Verify that the IRB provides adequate support and education for its members and staff to fulfill their responsibilities. Confirm that IRB members clearly understand their duties and can keep pace with work volume.
- Verify that the IRB committee meetings are functioning in a consistent manner across all review boards.
- Verify that the IRB functions facilitate the educational and research missions of the institution.
- Verify that the burden of IRB membership is equitably shared across the institution and relevant to the research presented for review and approval.
- Verify that IRB decisions are communicated efficiently and effectively.
- Verify that reports to federal agencies are submitted and monitored for follow-up.

## Reference

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## IRB Reporting Responsibilities Policy, 6436

### **POLICY:**

The Piedmont Healthcare Institutional Review Board (PHCIRB) shall fulfill all reporting obligations to institutional oversight as well as governmental regulatory agencies as codified in applicable federal regulations. The PHCIRB is not required to report to federal agencies already made aware of reportable events through other reporting mechanisms such as but not limited to, the investigator, the sponsor, or other organization.

### **PURPOSE:**

To describe what reports the PHCIRB is obligated to make available to internal departments as well as governing federal agencies.

### **Definitions:**

**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.

**Continuing non-compliance:** [term not defined in the regulations] a pattern of repeated non-compliance that indicates a lack of ability or willingness to adhere to policies or regulations; or repeated noncompliance that if allowed to continue is likely to increase risk, adversely affect the rights, welfare and safety of research participants, or adversely affect the scientific integrity of the study.

**Serious non-compliance:** [term not defined in the regulations] failure to act or willful violation of policies or regulations which create increased risks to research participants, adversely affects the rights, welfare and safety of research participants or adversely the scientific integrity of the study.

## **Institutional reporting:**

The PHCIRB shall make available any annual reports of IRB functions and IRB Quality Improvement and Quality Assurance results to the Institutional Official as requested.

## **OHRP Reporting:**

In accordance with the regulations promulgated under 45 CFR 46(OHRP), 21 CFR 56 (FDA), and in compliance with PHCIRB policy # 6416, the PHCIRB shall provide the following incident reports:

- i. Any unanticipated problems involving risks to subjects or others;
- ii. Any serious or continuing noncompliance
- iii. Any suspension or termination of IRB approval

Requirements for OHRP reporting are subject to guidance at: <https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html> and reportable to [IRPT.OS@hhs.gov](mailto:IRPT.OS@hhs.gov).

## **FDA Reporting:**

In accordance with the regulations promulgated under 45 CFR 46(OHRP), 21 CFR 56 (FDA), and in compliance with PHCIRB policy # 6416, the PHCIRB shall provide the following incident reports:

- i. Any unanticipated problems involving risks to subjects or others;
- ii. Any serious or continuing noncompliance
- iii. Any suspension or termination of IRB approval

Incident report structure to the FDA:

- a. IND or IDE number;
- b. Title of research project;
- c. Name of principal investigator ;

d. A detailed description of the reason for the suspension or termination

The information required above is applicable to drugs, biologics, and medical devices and is reportable to the following locations/contacts found at: <https://www.fda.gov/science-research/report-problems-fda/mandatory-irb-reporting-fda-contacts>.

## Guidance documents:

Guidance on Reporting Incidents to OHRP: <http://www.hhs.gov/ohrp/compliance/reports/incidreport062011.pdf>

FDA reporting requirements:

[http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/ucm136102.htm?utm\\_campaign=Google2&utm\\_source=fdaSearch&utm\\_medium=website&utm\\_term=termination%20report&utm\\_content=1](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/ucm136102.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=termination%20report&utm_content=1)

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45 CFR 46.103 (a) and (b)(5)

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## Expanded Access to Investigational New Drugs Policy, 6440

### **POLICY:**

In accordance with federal regulation defined in 21 CFR 50, 56, and 312 a pathway for patient access to an investigational medical product for treatment outside of clinical trials has been established. This scenario is applicable in immediate (emergent) life-threatening or serious disease conditions when no comparable alternative options are available.

Patients receiving such treatment in an emergency use may not be considered to be research participants.

The Piedmont Healthcare IRB (PHCIRB) will review all expanded access protocol requests to ensure the rights and safety of patients using investigational drugs are protected and that the patients are aware of any potential risks.

### **PURPOSE:**

This policy describes the requirements for and responsibilities for expanded access from the viewpoints of the FDA, investigator and IRB.

### **Definitions:**

**Expanded Access:** FDA authorized use of an investigational drug (or biologic product) to treat patients with serious or life-threatening diseases or conditions who have no satisfactory or comparable alternative therapy to diagnose, monitor, or treat the disease or condition.

**Immediately life-threatening disease or condition:** A stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

**Serious disease or condition:** A disease or condition associated with morbidity that has substantial impact on day-to-day functioning.

## Qualifications:

- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

## Types of Expanded Access Requests

- **Single/Individual Patient:** FDA permission for the use of an investigational drug to be used for the treatment of an individual patient. NOTE: this access also includes Emergency Use of an investigational drug.
  - a. Treatment duration is limited to a single course of therapy UNLESS the FDA authorized multiple courses or chronic therapy.
- **Intermediate-size patient population:** FDA permission for the use of an investigational drug to be used to treat a patient population that is smaller than the patient population typically treated under a treatment IND or treatment protocol.
- **Treatment IND or Treatment Protocol:** FDA permission for 'widespread' use of an investigational drug for treatment use under a Treatment IND or Treatment Protocol.
  - a. Under a Treatment IND the treating physician holds the IND for the drug and serves as both investigator and sponsor.
  - b. Under a Treatment Protocol the sponsor holds the IND for the drug.

## FDA Responsibilities:

- Authorize expanded access use in advance of use in individuals. This is inclusive of Emergency Use requests.
- Determine
  - Satisfaction of the life-threatening and serious disease or condition definitions are met.
  - That there is a satisfactory risk/benefit ratio of the treatment.



- That providing the drug treatment will not interfere with the investigation that could support marketing approval.
- Provide authorization in written format. Verbal authorization can be provided in emergency use situations. The FDA requires a written submission for single/individual requests within 15 working days after emergency use occurs.

## Investigator Responsibilities:

- Confirm that all the criteria for the specific expanded access request has been met with the sponsor (if applicable) and the FDA, complete and submit the following items via IRBNet. The submission may be a new IND or a protocol amendment to an existing IND:
  - Copy of access request submitted to the FDA.
  - Informed consent form.
  - FDA approval/authorization letter for the request.
  - A brief description of the target medical condition and treatment plan.
  - An assessment from an uninvolved physician that supports the use.
  - A follow up summary with results of the expanded use, including any safety related information.
  - Letter from sponsor agreeing to the expanded access use.
  - Provision of drug use report to IRB in event prior IRB approval could not be obtained in an emergency use situation. Such reports are to be submitted to the IRB within five working days of use.
- At the conclusion of treatment, the licensed physician or sponsor must provide FDA with a written summary of the results of the expanded access use, including adverse effects.

## IRB Responsibilities:

- Full board review.
- Communication to investigator regarding any determinations.

## Reference:

**Regulatory Reference:** 21 CFR 50, 56, and 312

All revision dates:

5/30/2019, 7/1/2015



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## Independent Piedmont Affiliated Physicians use of Piedmont Services for Research, 6441

### **POLICY:**

Piedmont Healthcare maintains documentation of all research activities utilizing Piedmont inpatient services and/or enrolling Piedmont inpatient subjects occurring within the Piedmont entity through the use of the IRBNet protocol tracking system, independent of researcher affiliation.

### **PURPOSE:**

To describe the Piedmont Healthcare Institutional Review Board (PHCIRB) process for maintaining documentation of research projects conducted by independent Piedmont affiliated physicians who are conducting research on subjects who are inpatient at a Piedmont facility.

### **Definitions:**

**AAHRPP:** Association for the Accreditation of Human Research Protections Programs, Inc., is an independent, non-profit accrediting body that ensures that human research protections programs (HRPPs) meet established standards for research quality and human subjects protections.

**Authorization Agreement:** Document that notes the ceding of PHCIRB oversight to a particular IRB and outlines the responsibilities of both parties related to initial and continuing review of a research study.

**Central IRB:** For multisite studies, this is the regulatory body designated to conduct reviews of the research on behalf of all participating sites agreeing to a centralized review process. Piedmont Healthcare will agree to rely on the reviews of central IRBs that have obtained full AAHRPP accreditation.

**IRBNet:** Secure web-based protocol tracking system adopted by the Piedmont entity.

**Piedmont Healthcare Institutional Review Board (PHCIRB):** The Piedmont entity local designated committee charged with responsibility to provide robust review, approval, and oversight monitoring of research to ensure the protection of the rights, safety, and well-being of human subjects participating in research.

**Piedmont Healthcare Office of Research Services (ORS):** The Piedmont entity designated office that oversees research activities occurring with Piedmont, facilitates research with affiliates, coordinates approvals, provides researcher training, and ensures that clinical research projects are conducted in a manner compliant with Piedmont policies and procedures.

**Independent Piedmont Affiliated Physicians:** physicians who are not employed by Piedmont Healthcare.

**Working Agreement:** Piedmont specific document that outlines which Piedmont services a researcher may utilize within the Piedmont entity for a research project.

## Independent researcher initial submission responsibilities:

1. Obtain proper credentials to utilize Piedmont services and/or facilities.
  - a. Contact Kenya.Jones@piedmont.org in Piedmont Healthcare's Central Verification Office to initiate the credentialing process.
  - b. Complete human subjects training through the WIRB Copernicus Group Academy (WCGA) or Collaborative Institutional Training Initiative (CITI) if your home institution requires CITI training. Contact the ORS at ors@piedmont.org to be enrolled in the training modules appropriate for the level of research being proposed.
2. Contact the ORS at [ors@piedmont.org](mailto:ors@piedmont.org) to initiate the budgeting and contracting requirements at Piedmont.
1. include Piedmont services requested, contract requirements, etc.
3. Register in IRBNet. Select 'New User Registration' from the Electronic Systems section located at: <https://www.piedmont.org/research/research-eforms-and-systems>.
- . Go to (<http://www.irbnetresources.org/tresources/member-training.html> - username: piedmont, password: training) for a 9 minute training guidance and navigation video.

- a. Reference Appendix E from the Electronic Systems section located at: <https://www.piedmont.org/research/research-eforms-and-systems>.
4. Researcher may use the New Application Form located in the Piedmont Healthcare IRB Researcher Forms section located at <https://www.piedmont.org/research/research-eforms-and-systems> OR upload the completed application form submitted to the AAHRPP accredited IRB of record document. Other submission requirements/IRBNet uploads include:
  - . Proof of Piedmont credentialing
  - a. Proof of completion of WCGA researcher learning requirements or CITI, if mandated by home institution
  - b. Executed Institutional Authorization Agreement (IAA)
  - c. Executed Working Agreement
  - d. Oversight IRB approval(s)
  - e. Protocol(s)
  - f. Consent(s)
  - g. FDA letters, if applicable
  - h. Brochures (investigator and/or patient)
  - i. Relevant supplemental materials (questionnaires, diaries, etc.)
5. Await PHCIRB correspondence via IRBNet indicating project acknowledgment prior to use of any Piedmont services or facilities.

## **Independent researcher renewal submission responsibilities:**

1. Complete the Affiliated Site Renewal and Closure Notification Form located in the Piedmont Healthcare IRB Researcher Forms section located at <https://www.piedmont.org/research/research-eforms-and-systems>.
2. In IRBNet, upload the completed application form and requested and relevant document that may include:
  - a. Central IRB approval letter(s):
    - i. renewal approval
    - ii. protocol amendment approvals processed during the last approval period
    - iii. Consent amendment approvals processed during the last approval period
    - iv. Other supplemental document amendment approvals processed during the last approval period

- b. Summary of adverse events or unanticipated problems involving risks to participants during diagnostic procedures completed within the Piedmont entity.
3. Maintain PHCIRB re-approval acknowledgment correspondence in your research file.

## **Independent researcher closure submission responsibilities:**

1. Complete the Affiliated Site Renewal and Closure Notification Form located in the Piedmont Healthcare IRB Researcher Forms section located at <https://www.piedmont.org/research/research-efoms-and-systems>.
2. In IRBNet, upload the completed application form and requested and relevant document that may include:
  - a. Central IRB closure notification letter.
  - b. Any findings or outcomes summaries, when applicable.
3. Maintain PHCIRB re-approval acknowledgment correspondence in your research file.

## **PHCIRB Independent researcher submission processing responsibilities:**

1. Access IRBNet system to verify submissions document completion per submission type. Whenever applicable, documents to include:
  - a. Executed Authorization Agreement
  - b. Executed Working Agreement
  - c. Oversight IRB approval(s)
  - d. Protocol(s)
  - e. Consent(s)
  - f. FDA letters, if applicable
  - g. Brochures (investigator and/or patient)
  - h. Relevant supplemental materials (questionnaires, diaries, etc.)
  - i. Renewal approval
  - j. Protocol amendment approvals processed during the last approval period

- k. Consent amendment approvals processed during the last approval period
  - l. Other supplemental document amendment approvals processed during the last approval period
  - m. Summary of adverse events or unanticipated problems involving risks to participants during diagnostic procedures completed within the Piedmont entity
  - n. Central IRB closure notification letter
  - o. Any findings or outcomes summaries, when applicable
2. Complete IRBNet administrative steps for processing:
    - a. Processing of review
    - b. Assigning to agenda
    - c. Completing PHCIRB determination process (acknowledgment).
  3. Advise researcher of PHCIRB acknowledgment of submission via IRBNet correspondence.
    - a. Central IRB closure notification letter
    - b. Any findings or outcomes summaries, when applicable
  4. Maintain electronic research file for life of project.

## Regulatory References

21 CFR 56.114, 21 CFR 56.115 (a)

21 CFR 56.108(a), 56.115(a)(6)

All revision dates:

3/11/2019, 12/19/2017