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**Purpose**

Albert Einstein Healthcare Network (AEHN) is committed to protecting the rights and welfare of subjects in Human Research and promoting excellence in all aspects of human research. The purpose of this plan is to describe AEHN’s plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.

AEHN’s Human Research Protection Program (HRPP) is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. It is comprised of the AEHN leadership, Office of Research and Technology Development (ORTD), Institutional Review Board (IRB), investigators and their study staff and relevant departments and units. The HRPP is based on all above-mentioned parties fulfilling their roles and responsibilities described in this plan. The HRPP not only promotes compliance with relevant laws, regulations and professional and ethical standards at all levels, it addresses the needs and concerns of researchers and enhances support of their endeavors.

**Definitions**

**Agent**

An authorized individual is considered to be an agent of AEHN if the individual is performing institutionally designated activities or exercising institutionally delegated authority or responsibility pursuant to written policy and procedure. This would include all authorized AEHN employees, members of the AEHN medical staff, residents, fellows, and authorized volunteers when interacting with human subjects or using authorized information from AEHN medical records for activities that qualify as human research, and any individual conducting research with human subjects at AEHN-controlled facilities or for whom AEHN has responsibility.

An individual who is not an employee is considered an agent of AEHN for purposes of engagement in Human Research only when that individual has been specifically authorized to conduct Human Research on behalf of AEHN.

Legal counsel has the ultimate authority to determine whether someone is acting as an agent of AEHN.

**Clinical Trial**

Human Research intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of a drug or biologic, or the physiological or mechanical effects of a device, to identify any adverse reactions to a drug, device or biologic, to evaluate the safety or effectiveness of a drug, device or biologic, or to study absorption, distribution, metabolism, and excretion of a drug with the object of ascertaining its safety or efficacy.
Engaged in Human Research

AEHN is engaged in Human Research when its employees or agents: 1) interact or intervene with living individuals for the purpose of conducting Research; or 2) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)].

Human Research:

Any activity that either:

- Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or
- Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human Research”).

Human Subject as Defined by DHHS

A living individual about whom an investigator conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:

- **Intervention** means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
- **Identifiable Information** means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Human Subject as Defined by FDA

An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.

Investigator

The person responsible for the conduct of the Human Research at one or more sites. If the Human Research” is conducted by a team of individuals at a study site, the
investigator is the responsible leader of the team and may be called the principal investigator.

**Research as Defined by DHHS**

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Research as Defined by FDA**

Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
- Any activity 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.

**Mission and Goal**

The mission of AEHN’s HRPP is to protect the rights and welfare of the human subjects involved in research activities conducted under the authority of the AEHN IRB and Albert Einstein Healthcare Network.

The HRPP aims to ensure a safe and ethical research environment by promoting a culture of compliance with the highest legal and ethical standards for the conduct of human research in ways that are supportive and not unnecessarily burdensome to members of the research community.

**Ethical Requirements**

In the conduct of all Human Research, this organization (including its investigators, research staff, students involved with the conduct of Human Research, IRB members and chairs, IRB staff, the organizational official, employees, residents and fellows) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” also known as “The Belmont Report.”

- Respect for Persons
Human Research Protection Program Plan

- Beneficence
- Justice

Legal Requirements

Albert Einstein Healthcare Network commits to apply its ethical standards to all Human Research regardless of funding.

All Human Research must undergo review by an organizationally designated IRB. Activities that do not meet the definition of Human Research (e.g., quality improvement activities, program evaluation, careful patient monitoring with the sole intent of providing diagnosis, preventive treatment, or therapy to the particular individual, and surveillance activities that do not meet the definition of Human Research) do not require IRB review and approval and do not need to be submitted to the IRB unless there is a question regarding whether the activity is Human Research.

When the organization is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulation by a federal department or agency who is a signatory of the Common Rule, AEHN commits to apply the regulations of that agency relevant to the protection of Human Subjects.

When the organization is engaged in FDA Human Research that is conducted or funded by a federal department or agency, AEHN commits to apply the FDA-regulations relevant to the protection of Human Subjects.

Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the IRB Office for a determination.

Other Requirements

When reviewing research that involves community based research, the IRB considers the Community-Based Research Principles at http://depts.washington.edu/ccph/commbas.html. Community based research is research that takes place in community settings and involves community members in the design and implementation of research projects.

For clinical Human Research, the organization commits to apply the “International Council on Harmonisation – Good Clinical Practice E6”. This Good Clinical Practices document describes the responsibilities and expectations of all participants in the conduct of clinical trials, including investigators, monitors, sponsors and IRBs. [http://www.ich.org/cache/compo/276-254-1.html].

AEHN prohibits payments in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment or retention that are tied to the rate or timing of enrollment or retention (“bonus payments”).

When Human Research is conducted or funded by the Department of Defense (DOD), the organization commits to apply DOD Directive 3216.02 to non-exempt classified research.
Sponsored Human Research

For both sponsored and non-sponsored Human Research the organization abides by its ethical principles, regulatory requirements and its policies and procedures. Sponsored research is research funded by an outside organization (e.g. government agency, foundation, pharmaceutical or device company, etc.) either through a grant, contract or letter agreement.

Scope of Human Research Protection Program

The categories of Human Research currently conducted at AEHN include, but are not limited to, research protocols involving medical interventions or procedures, or other health care related tests, tools or procedures (e.g. questionnaires, surveys or medical record reviews). Special categories of research include:

- FDA-regulated research
- Research involving drugs that require an IND. An Investigational New Drug Application (IND) is a request for authorization from the FDA to administer an investigational drug or biological product to humans.
- Research involving devices that require an IDE issued by FDA. An Investigational Device Exemption (IDE) is required for any device found to pose a significant risk of harm by any reviewing IRB or by the FDA.
- Research involving devices that require an abbreviated IDE. This type of IDE is allowed for devices that are not considered a significant risk device.
- Research involving pregnant women as subjects.
- Research involving children as subjects (up to age 18 years in Pennsylvania)
- Activities involving humanitarian use devices (HUD). A HUD is a device intended to benefit patients by treating or diagnosing a disease that affects fewer than 4,000 individuals in the United States per year.
- Emergency use of a test article in a life-threatening situation

The categories of Human Research involving special considerations and not currently being conducted at AEHN include:

- Research involving a waiver of consent for planned emergency research.
- Research involving fetuses. (Note: Pennsylvania (PA) law prohibits non-therapeutic research involving an “unborn child”. PA law defines an unborn child as “an individual organism of the species homo sapiens from fertilization until live birth.”)
- Research involving in vitro fertilization.
- Research involving non-viable neonates.
- Research involving neonates of uncertain viability.
- Research that plans to or is likely to involve prisoners as subjects.
- Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approval of an agency secretary or director (e.g. Secretary of the Department of Health and Human Services). Applies to research that the IRB does not believe meets the requirements of the
Human Research Protection Program Policies and Procedures


Human Research Protection Program Components

Organizational Official

The Director of the Office of Research and Technology Development (ORTD) is designated as the Organizational Official.

The Organizational Official has the authority to:

- Create the Human Research Protection Program budget.
- Allocate resources with the Human Research Protection Program budget.
- Appoint and remove IRB members and IRB chairs.
- Hire and fire IRB support staff.
- Determine what IRBs the organization will rely upon.
- Approve and rescind IRB authorization agreements.
- Place limitations or conditions on an investigator’s or research staff’s privilege to conduct Human Research.
- Create policies and procedures related to the Human Research Protection Program that are binding on the organization.
- Suspend or terminate IRB approval of research.
- Disapprove research approved by the IRB.

The Organizational Official is responsible to:

- Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirement.
- Institute regular, effective, educational and training programs for all individuals involved with the Human Research Protection Program.
- Ensure that the research review process is independent and free of coercion or undue influence, and ensure that officials of the organization cannot approve research that has not been approved by an IRB designated by the organization.
Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.

Investigate and remediate identified systemic problem areas, and where necessary remove individuals from involvement in the Human Research protection program.

Ensure, with collaboration of senior administration as needed, that the Human Research Protection Program has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.

Review sponsor contracts and funding agreements for compliance with the Human Research Protection Program policies and procedures.

Review and sign federal assurances and addenda.

Fulfill educational requirements mandated by OHRP.

Ensure that the above assignments are conducted objectively based upon clearly defined criteria and without prejudice or favoritism.

The Organizational Official reports to the AEHN’s Chief Operating Officer. Monthly meetings are held with the ORTD staff, which includes the IRB staff, Grants and Contracts staff, Research Compliance Officer as well as others involved in supporting research activities throughout the organization. The Organizational Official also communicates regularly with the IRB chair and vice chairs as well as legal counsel and attends department meetings to provide updates on research activities throughout the year.

The Organizational Official is an ex-officio member of several network committees including:

- Research Conflict of Interest Committee, which includes one physician member from each clinical department in AEHN and is responsible for reviewing all financial interests related to human subjects research and determining management plans as appropriate.
- Research Subcommittee of the Medical Staff Board, which includes members from each of the clinical departments in AEHN and is responsible for planning the annual Research Recognition Day event as well as allocating funds for the biannual Albert Einstein Society research award competition.
- Intellectual Property Committee, which includes five members of various clinical departments and is responsible for reviewing all invention disclosures and making recommendations on all intellectual property-related issues.

**Research Compliance Officer**

The Research Compliance Officer serves in a support role to the IRB. Responsibilities include:

- Provide guidance on federal regulations
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
• Conduct investigations of research as a result of problematic issues or allegations that research is being conducted without IRB review or approval
• Provide education and training to research community on institutional policies and procedures as well as federal requirements for Human Research

The Research Compliance Officer attends the monthly IRB meetings to provide input on compliance related questions as needed and to provide educational sessions to the IRB. The Research Compliance Officer reports to the Organizational Official. Communication occurs regularly among these administrators because of their reporting structure. Ad hoc meetings are also held between IRB staff, Research Compliance Officer and IRB Chair when potential research compliance issues are identified.

All members of the organization
All individuals within the organization are responsible to:
• Be aware of the definition of Human Research.
• Consult the IRB when there is uncertainty about whether an activity is Human Research.
• Not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB designated by the Organizational Official.
• Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the Organizational Official.
• Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB.

IRBs
All human research is reviewed by AEHN’s IRB, National Cancer Institute’s Central IRB (CIRB: oncology trials sponsored by collaborative oncology groups only) or Western IRB (for Phase III and IV industry sponsored and initiated, multi-site trials only), unless AEHN has entered into either an agreement with another central IRB identified and approved by the Organizational Official or authorization agreement with a separate institution that has a current, unexpired, Federalwide Assurance (FWA) on file with the Office of Human Research Protections (OHRP), and whose IRB is judged by AEHN’s IRB chairperson to be qualified to review the research.

With regard to authorization agreements, AEHN may rely upon the IRB of another organization provided one of the criteria is met:

• The IRB is the IRB of record for the Jefferson Oncology Group clinical trials.
• The IRB is the IRB of a local, AAHRPP accredited organization.
AEHN’s investigator is a collaborator on Human Research primarily conducted at another organization and the investigator’s role does not include interaction or intervention with subjects.

AEHN is engaged in the Human Research solely because it is receiving federal funds. (The local investigator does not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)

The IRBs relied upon by AEHN have the authority to:

- Approve, require modifications to secure approval, and disapprove Human Research overseen and conducted by AEHN. All Human Research must be approved by an IRB designated by the Organizational Official. Officials of the organization may not approve Human Research that has not been approved by the IRB.
- Suspend or terminate approval of Human Research not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the Human Research.
- Determine whether an activity is Human Research.
- Have the final authority to decide whether the financial interest management plan, if any, is sufficient to allow the Human Research to be approved.

AEHN IRB members and IRB staff are responsible to follow Human Research Protection Program policies and procedures.

**IRB Chair**

The IRB Chair is responsible to:

- Preside over meetings of the fully convened IRB and ensure that the IRB carries out its duly authorized responsibilities as required by federal regulations, ethical principles, state laws and institutional policy.
- Review and approve protocol submissions that qualify for expedited review pursuant to federal regulations, ethical principles, state laws and institutional policies, or delegate such authority to a qualified and experienced IRB member to conduct such review and approval.
- Ensure that reports related to safety, noncompliance, and unanticipated problems in research are reviewed, attended to, and reported pursuant to federal regulations, state laws, and institutional policy.
- Work with Organizational Official to ensure that membership of the IRB is recruited, appointed and oriented such that the IRB is duly qualified to fulfill its obligations to review, require modifications to, approve (or disapprove) research protocols that represent the breadth of research submitted to the IRB by AEHN investigators.
• Serve as a liaison between the HRPP and the AEHN research community to promote communication and understanding of the concerns of the IRB, the research community and other HRPP partners.
• Respond to local and federal investigations relating to protocols and actions, as required.

**IRB Vice Chair**

The IRB Vice Chair serves as the Chair of the IRB in the absence of the IRB Chair and has the same authority and duties as the Chair.

**Investigators and Research Staff**

Investigators and research staff are responsible to:

• Personally conduct or supervise the research activities in accordance with the IRB-approved protocol and only make changes in a protocol after receiving approval from the IRB, except when necessary to protect the safety, rights, or welfare of research subjects.
• Provide adequate supervision of those to whom the study-related tasks are delegated and be accountable for regulatory violations resulting from failure to adequately supervise the conduct of the research.
• Follow the Human Research Protection Program requirements described in the Investigator Manual.
• Follow the Human Research Protection Program policies and procedures that apply to staff.
• Comply with all determinations and additional requirements of the IRB, the IRB chair, the Research Compliance Officer, and the Organizational Official.

**Legal Counsel**

Legal Counsel is responsible to:

• Provide advice upon request to the Organizational Official, IRB, and other individuals involved with the Human Research Protection Program.
• Determine whether someone is acting as an agent of the organization.
• Determine who meets the DHHS and FDA definitions of “legally authorized representative” and “children” when Human Research is conducted in jurisdictions not covered by policies and procedures.
• Provide advice about how to resolve conflicts among applicable laws.

**Biosafety Committee**

Research involving the use of biological materials, including; recombinant DNA/RNA, agents infectious to humans, animals or plants, CDC/USDA Select Agents (including listed biotoxins), and other genetically altered organisms and agents must be
reviewed by an Institutional Biosafety Committee (IBC). Since AEHN does not have its own IBC, the Office of Research and Technology Development will make arrangements for the IBC from another local institution to perform the reviews as needed.

**Radiation Safety Officer**

AEHN’s Radiation Safety Officer supports the IRB’s efforts to protect participants by providing information to the IRB regarding tests or procedures involving the use of radiation that are not considered part of standard of care.

**Department/Division Chairs**

Department/Division Chairs are responsible to:

- Review Human Research Initial Applications and certify the following:
  - The Principal Investigator is qualified by education, training and experience to personally conduct and/or supervise the research described in the protocol.
  - The Principal Investigator has completed all applicable institutional credentialing processes to conduct this research.
  - The Principal Investigator has sufficient resources to carry out this research as proposed.
- Oversee the review and conduct of Human Research in their department or division.
- Forward complaints and allegations regarding the Human Research Protection Program to the Organizational Official.

**Monitoring and Auditing**

In order to ensure compliance and improve performance, the Research Compliance Officer will conduct routine review and/or monitoring of active studies, as well as directed (for-cause) audits. Audits will focus on areas of concern that have been identified by any entity (i.e. federal, state, or institutional). Random audits may also be conducted.

**Education and Training**

Training of IRB members, investigators and staff involved in human research activities is tracked by the IRB. The web based Collaborative Institutional Training Initiative (CITI) training program is used for this purpose.

All IRB members, IRB staff, and others involved in the review of Human Research must complete the online Collaborative Institutional Training Initiative (CITI) human subjects online training program for IRB members (www.citiprogram.org). This training is valid for a two-year period, after which time a refresher CITI course or additional training must be completed.

All investigators and all research staff must complete the online Collaborative Institutional Training Initiative (CITI) human subjects online training program for
sponsored research ([www.citiprogram.org](http://www.citiprogram.org)) prior to submission of their research for IRB review. This training is valid for a two-year period, after which time a refresher CITI course or additional training must be completed. Research personnel who do not complete this continuing education requirement will be placed on the IRB restricted research personnel list. New IRB approvals will not be granted, active protocols may be suspended, and further engagement in research activities may no longer be permitted for individuals placed on the IRB restricted research personnel list. You can be removed from the IRB restricted research personnel list by completing the continuing education requirement.

Additionally, the Research Compliance Officer and/or IRB Chair may present training sessions for researchers throughout the year. The Organizational Official may identify and implement additional educational and training requirements. Annually, IRB members and IRB staff will be strongly encouraged to attend the Public Responsibility in Medicine and Research (PRIM&R) or the National Association of IRB Managers (NAIM) conferences to increase knowledge of the federal regulations. The Office of Research and Technology Development will provide funding through the IRB fund for conference registration and travel expenses when available.

**Are there additional requirements for Department of Defense (DOD) research?**

Yes, when appropriate research protocols must be reviewed and approved by the IRB prior to DOD approval. Consult with the DOD funding component to see whether this is a requirement. DOD employees (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and check with their supervisor prior accepting such payments. DOD components might have stricter requirements for research-related injury than the DHHS regulations. There also may be specific DOD educational requirements and certifications required.

**Questions and Additional Information for the IRB**

The IRB Office is open from 8 AM to 4 PM for your questions, information, and feedback. Contact and location information for the IRB Office is as follows:

- **Name:** Beth Lynch
- **Phone:** (215) 456-7217
- **FAX:** (215) 456-8122
- **Address:**
  Office of Research and Technology Development
  5501 Old York Road
  Korman 100
  Philadelphia, PA  19141
- **Email:** lynchbet@einstein.edu
Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, IRB Office, Organizational Official, Legal Counsel, Research Compliance Officer, Department Chairs or using Comply Line (1-800-COMPLY).

The IRB is responsible to investigate allegations and findings of non-compliance and take corrective actions as needed. The Organizational Official is responsible to investigate all other reports and take corrective actions as needed.

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

Contact information for the Organizational Official is as following:

- Name: Mary Klein, PhD
- Phone: (215) 456-7216
- FAX: (215) 456-8122
- Address:
  Office of Research and Technology Development
  5501 Old York Road
  Korman 100
  Philadelphia, PA 19141
- Email: mklein@einstein.edu

Disciplinary Actions

The Organizational Official may place limitations or conditions on an investigator’s or research staff’s privilege to conduct Human Research whenever in the opinion of the Organizational Official such actions are required to maintain the Human Research Protection Program.

Approval and Revisions to the Plan

This Human Research Protection Program Plan is to be approved by the Chief Executive Officer. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Organizational Official is responsible to review this plan to assess whether it is providing the desired results. The Organizational Official has the authority to amend this plan as deemed necessary.