**Human Research Protection Program Plan**

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## Scope

This plan applies to all Pearl Institutional Review Board (IRB) staff. Throughout this document “Organization” refers to Pearl IRB, a commercial independent IRB.

## Purpose

This Organization is committed to protect the rights and welfare of subjects in Human Research. The purpose of this plan is to describe this Organization’s plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.

This Organization’s Human Research Protection Program (HRPP) is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The HRPP is based on all individuals in this Organization along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

## Definitions

### **Agent**

A person acting on behalf of Pearl IRB has the ultimate authority to determine whether someone is acting as an agent of this Organization.

### **Clinical Trial**

A biomedical or behavioral research study of human subjects designed to answer specific questions about therapeutic interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new therapeutic interventions are safe and effective.

### **Engaged in Human Research**

An Organization is engaged in Human Research when its employees or agents are interacting or intervening with Human Subjects for the purpose of conducting Research. This Organization follows OHRP guidance on “Engagement of Institutions in Research” to apply this definition.

### **Human Research**

Any activity that is either:

* “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or
* “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 (whether professional or student) 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 (identified or unidentified) 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 trial site, the investigator is the responsible leader of the team and may be called the principal investigator (PI).

### **Research as Defined by DHHS**

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.[[1]](#footnote-1) A “Systematic investigation” relevant to the Organization’s research portfolio is defined as step by step methodical research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. “Generalizable knowledge” relevant to the Organization’s research portfolio is defined as knowledge that could be applied to populations outside of the population served by the covered entity.

### **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

The mission of this Organization’s HRPP plan is to protect the rights and welfare of subjects involved in Human Research that is overseen by this Organization.

### **Ethical Requirements**

In the oversight of all Human Research this IRB 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
* Beneficence
* Justice

### **Legal Requirements**

* This Organization commits to apply its ethical standards to all Human Research regardless of client funding source.
* Human Research must undergo review by the IRB. Activities that do not meet the definition of Human Research (e.g., most classroom activities, quality improvement activities, program evaluation, and surveillance activities) do not require review and approval by the IRB and does not need to be submitted to the IRB unless there is a question regarding whether the activity is Human Research.
* The Organization commits to apply the regulations of the DHHS relevant to the protection of Human Subjects.
* This Organization 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 Pearl IRB who will provide a determination.

### **Other Requirements**

* When reviewing research that involves community based research, the IRB considers Community-Based Research Principles (i.e., http://www.washington.edu/research/main.php?page=communityPrinciples).
* The Organization prohibits review of Human Research conducted or funded by the Department of Justice (DOJ).
* When Human Research is conducted or funded by the Department of Defense (DOD), this Organization commits to apply the DOD Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B and D[[2]](#footnote-2). When Human Research is conducted or funded by the Department of the Navy, the Organization commits to apply SECNAVINST 39000.39D.
* When Human Research is conducted or funded by the Department of Education (ED), this Organization commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.
* When Human Research is conducted or funded by the Department of Energy (DOE), this Organization commits to applying the DOE O 443.1A and to use “Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with the DOE Requirements.”
* When Human Research is conducted or funded by, or when the results of research are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA), this Organization commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.

### **Sponsored Human Research**

For both sponsored and non-sponsored Human Research; this Organization abides by its ethical principles, regulatory requirements and its policies and procedures.

### **Scope of Human Research Protection Program**

The categories of Human Research overseen include:

* Forms of human research that do not include prisoners, non-living individuals, pregnant women, and neonates.

The categories of Human Research not overseen include:

* Research conducted outside the United States or its territories.

### **Human Research Protection** **Program Policies and Procedures**

Policies and procedures for the HRPP are available on the following Web site: <http://www.pearlirb.com/resources/forms>.

## Human Research Protection Program Components

### **Organizational Official**

The Chief Operating Officer (COO) is also designated the Organizational Official (OO).

The COO has the authority to take the following actions or delegate these authorities to a designee:

* Suggest Appointments or removal IRB members requiring approval by the IRB Co-chairs.
* Determine what IRBs the Organization might partner with.
* Approve and rescind partnership agreements with IRBs.
* Suggest the creation of policies and procedures related to the HRPP that are binding on the Organization. Institute regular, effective, educational, and training programs for all individuals involved with the HRPP.
* Ensure that the HRPP has sufficient resources, including staff appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
* Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
* The IRB Co–chairs have the authority to take the following actions or delegate these authorities to each other:
* Suspend research approved by the Organization.
* Oversee the review and conduct of Human Research under the jurisdiction of the HRPP.
* 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 requirements.
* 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 the Organization.
* Implement a process to receive and act on complaints and allegations regarding the HRPP.
* Investigate and remediate identified systemic problem areas and; where necessary, removal of individuals from involvement in the HRPP.
* Review and sign federal assurances (FWA) and addenda.
* Fulfill educational requirements mandated by OHRP.
* Report suspensions, terminations, and non-compliance to the federal government.

Individuals who are responsible for business development, or any staff who has a personal or professional conflict of interest, are prohibited from carrying out day-to-day operations of the review process.

### **IRB**

The IRB has the authority to:

* Approve, require modifications to secure approval, and disapprove Human Research. All Human Research must be approved by the IRB prior to initiation.
* Suspend or terminate approval of Human Research not being conducted in accordance with an IRBs’ 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.
* Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the Human Research to be approved.
* Conduct continuing reviews of approved research. Review proposed amendments, adverse events, protocol deviations, and matters of non-compliance.
* Require research progress reports.
* Audit and/or monitor the research and researchers for adherence to the federal regulations and policies and IRB policies and procedures.

The IRB reviews research activities to ensure that:

* Risks to subjects are minimized;
* Risks to subjects are reasonable in relation to anticipated benefits;
* Selection of subjects is equitable;
* Informed consent is obtained or appropriately waived from all prospective subjects and documented;
* The research protocol includes a plan for data and safety monitoring, if applicable;
* Subjects' privacy and confidentiality are protected; and
* Appropriate additional safeguards are incorporated for specified vulnerable subjects.

Designated IRB members and IRB staff have the responsibility to follow HRPP policies and procedures.

### **Legal Counsel**

Legal Counsel has the responsibility to:

* Provide advice upon request to the COO, IRB, and other individuals involved with the HRPP.
* Determine whether someone is acting as an agent of the Organization.
* Determine who meets the definition of “legally authorized representative” and “children” when Human Research is conducted in jurisdictions not covered by policies and procedures.
* Resolve conflicts among applicable laws.

## Education and Training

Individuals who serve on Pearl IRB are to review this plan as part of initial orientation. The IRB is to conduct refresher training as needed to maintain awareness of this policy.

IRB members, IRB staff, and others involved in the review of Human Research must complete a human subjects research training program. This training is valid for a two-year period, after which time a refresher course or additional training must be completed. IRB staff also train IRB members on the SOPs, checklists, and worksheets applicable to IRB members including regulatory and guidance requirements.

## Questions and Additional Information for the IRB

The IRB wants your questions, information, and feedback.

Contact and location information is:

Pearl IRB Coordinator

29 E. McCarty Street Suite 100

Indianapolis, IN 46225

Email: info@pearlirb.com

(317)899-9341, extension 2

## Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the HRPP may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the Coordinator, IRB Chairs, or COO.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The COO has the responsibility 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 COO or designee.

To make such reports, contact:

Pearl IRB Coordinator

29 E. McCarty Street Suite 100

Indianapolis, IN 46225

Email: info@pearlirb.com

(317)899-9341, extension 2

## Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and organizational requirements will conduct periodic 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.

## Disciplinary Actions

The IRB may place limitations or conditions on a study whenever in the opinion of the COO such actions are required to maintain the HRPP.

## Approval and Revisions to the Plan

This HRPP Plan is to be approved by the COO. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The COO has the responsibility to review this plan to assess whether it is providing the desired results. The COO has the authority to amend this plan as deemed necessary.

Approved:

*Gretchen M. Bowker*

Chief Operations Officer/Organizational Official

*18 April 2014*

1. 1 45 CFR 46 102.d [↑](#footnote-ref-1)
2. Quick applicability table for DHHS Subparts:

   |  |  |  |  |  |
   | --- | --- | --- | --- | --- |
   |  | DHHS | DOD | ED | EPA |
   | Subpart B | X | X |  | X |
   | Subpart C | X | X |  |  |
   | Subpart D | X | X | X | X |

   [↑](#footnote-ref-2)