UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

Human Subject Research Protection
Program Plan

June 24, 2021

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Scope

Throughout this document "organization" refers to the University of Arkansas for Medical Sciences.

Purpose

This organization is committed to protecting the rights and welfare of subjects in Human Subject Research. This document describes this organization's plan to comply with ethical and legal requirements for the conduct and oversight of Human Subject Research.

This organization's Human Subject Research Protection Program is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Subject Research. The Human Subject Research Protection Program 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

An individual who is an employee is considered an agent of this organization for purposes of engagement in Human Subject Research when that individual is on duty in any capacity as an employee of this organization.

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

Legal counsel has the final authority to determine whether someone is acting as an agent of this organization.

Clinical Investigation

Any experiment that involves a test article; one or more human subjects; and that is subject to the Food and Drug Administration (FDA) regulations by one of the following (21 CFR 50.3):

1) Meets the requirements for prior submission to the FDA under section 505(i) of the Federal Drug, Food and Cosmetic Act, meaning any use of a drug other than the use of an approved drug in the course of medical practice; or
2) Meets the requirements for prior submission to the FDA under 520(g) of the Federal Drug, Food and Cosmetic Act, meaning any activity that evaluates the safety or effectiveness of a device; or
3) Any activity, the results of which are intended to be submitted or inspected by the FDA to support applications for research or marketing permits for products.

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes [45 CFR 46.102(b)].

Engaged in Human Subject Research

This organization is engaged in Human Subject Research when its employees or agents are interacting or intervening with Human Subject(s) or accessing or using identifiable private information for the purpose of conducting Research. The OHRP guidance on "Engagement of Institutions in Research" will be applied in making engagement determinations for all projects, regardless of funding source.

Human Subject Research

Any activity that meets the definition of:

1) Research AND involves Human Subjects; or
2) Clinical Investigation or Clinical Trial

Human Subject

1) An individual who is or becomes a participant in research either as a recipient of a test article, as a control [21 CFR 50.3(g)], or an individual on whose specimen an investigational device is used;
2) A living individual about whom an investigator (whether professional or student) conducting research:
    a. Obtains information or biospecimens, of any kind, through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
    b. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens [45 CFR 46.102(e)]; or
3) In FDA-regulated research only, unidentified tissue specimens when used in medical device research involving *in vitro* diagnostics are human subject materials

For the purposes of this definition:

- *Intervention* means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or of the subject's environment performed for research purposes.
- *Interaction* means communication or interpersonal contact between investigator and subject or participant.
- *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 that the individual can reasonably expect will not be made public (for example, a medical record).
- *Identifiable Private Information* is private information for which the subject's identity is or may be readily ascertained by the investigator or associated with the information.
- *Identifiable Biospecimen* is a biospecimen for which the subject's identity is or may be readily ascertained by the investigator or associated with the biospecimen.

Principal Investigator
The person responsible for the conduct of the Human Subject Research at one or more sites. If the Human Subject Research is conducted by a team of individuals at a trial site, the principal investigator is the responsible leader of the team.

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

Systematic: Activities must be systematic to be considered research. Activities that involve predetermined methods for answering a specific question, testing hypotheses or theories are systematic and might include interviews, program evaluations, and observational studies. Activities that are not normally systematic are training activities where an individual is trained to perform a certain technique or task or to teach proficiency in using a certain method.

Generalizable Knowledge: Activities must contribute to generalizable knowledge or have an intent to extend beyond an internal use or department. Many theses, dissertations or preceptorships are intended to extend beyond the graduate's department and therefore are considered research. Activities that are typically not generalizable are course evaluations that cannot be generalized to others and quality assurance type activities that are only intended to assess and/or improve the performance of a unit, division, or department.

Mission
The mission of this organization's Human Subject Research Protection Program Plan is to protect the rights and welfare of subjects involved in Human Subject Research overseen by or conducted at this organization.

Ethical Requirements
In the oversight of all Human Subject Research, this organization (including its investigators, research staff, students involved with the conduct of Human Subject Research, IRB members and chairs, IRB staff, the organizational official, employees, and students) 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 the Common Rule to all research conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the Common Rule applicable to such research. The Common Rule will also be applied to any research contractually obligated to follow the Common Rule. IRB Policy requirements will apply to greater than minimal risk research that is not federally funded, supported, or regulated. Equivalent protections will be applied to minimal risk studies not subject to the Common Rule.

All Human Subject Research must undergo review by an organizationally designated IRB. Activities that do not meet the definition of Human Subject Research (e.g., some classroom or training activities or certain quality improvement activities that do not meet the definition of Human Subject 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 Subject Research.

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

When this organization is engaged in Human Subject Research regulated by the FDA, 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 Subject Research should be referred to the IRB Office for a determination.

Other Requirements

All policies and procedures applied to Human Subject Research conducted domestically are applied to Human Subject Research conducted in other countries.

This organization prohibits payments to professionals in exchange for referrals of potential subjects ("finder's fees") and payments designed to accelerate recruitment tied to the rate or timing of enrollment ("bonus payments.")

Sponsored Human Subject Research

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

Scope of Human Subject Research Protection Program

The categories of Human Subject Research overseen include all forms of human research except:

- Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approval of an agency secretary or director.
- Research involving a waiver of consent for planned emergency research.

Human Subject Research Protection Program Policies and Procedures

Policies and procedures for the IRB component of the Human Research Protection Program are available on the IRB website: http://irb.uams.edu/ Policy changes will be posted on the website and announced in the research blog.

Human Subject Research Protection Program Components

Organizational Official

The Vice Chancellor for Research and Innovation is designated as the Organizational Official.

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

- Create the Human Subject Research Protection Program budget.
- Allocate resources within the Human Subject Research Protection Program budget.
- Appoint and remove IRB members and IRB chairs.
- Hire and fire research review 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 staffer's privilege to conduct Human Subject Research.
- Create policies and procedures related to the Human Subject 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 has the responsibility to:

- Oversee the review and conduct of Human Subject Research under the jurisdiction of the Human Subject 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 Subject 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 an IRB designated by the organization.
- Implement a process to receive and act on complaints and allegations. regarding the Human Subject Research Protection Program.
- Investigate and remediate identified systemic problem areas, and where necessary, remove individuals from involvement in the Human Subject Research protection program.
- Ensure that the Human Subject Research Protection Program has sufficient resources, including IRBs appropriate for the volume and types of Human Subject Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Review and sign federal assurances (FWA) and addenda.
- Fulfill educational requirements mandated by OHRP.

Office of Research Compliance (ORC)

The Office of Research Compliance reports directly to the Vice Chancellor for Compliance and Managing Associate General Counsel. ORC operates independently of the IRB and has the responsibility to:

- Institute regular, effective, educational and training programs for all individuals involved with the Human Subject Research Protection Program.
- Implement an auditing program to monitor compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance, and to improve compliance in identified problem areas. This program reviews individual research projects and IRB operations, among other areas.
- Attend meetings of the IRB.

All Members of the Organization

All individuals within the organization have the responsibility to:

- Be aware of the definition of Human Subject Research.
- Consult the IRB when there is uncertainty about whether an activity is Human Subject Research.

- Not conduct Human Subject Research or allow Human Subject 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 Subject Research Protection Program or concerns about the Human Subject Research Protection Program to the Organizational Official.
- Report allegations or findings of non-compliance with the requirements of the Human Subject Research Protection Program to the IRB.

IRBs

The IRBs designated by the Organizational Official to be the IRBs relied upon by the Human Subject Research Protection Program are described in the IRB rosters available on the IRB's website.

This organization may rely upon the IRB of another organization or an independent IRB if one of the following is true:

- The IRB is the IRB of an AAHRPP-accredited organization or operates under equivalent standards.
- This organization's investigator is a collaborator on Human Subject Research primarily conducted at another organization and the investigator's role does not include interaction or intervention with subjects.
- The organization is engaged in the Human Subject Research solely because it is receiving federal funds. (Employees and agents of the institution do 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 this organization have the authority to:
  - Approve, require modifications to secure approval, and disapprove all Human Subject Research overseen and conducted by the organization. All Human Subject Research must be approved by an IRB designated by the Organizational Official. Officials of this organization may not approve Human Subject Research that has not been approved by the IRB.
  - Suspend or terminate approval of Human Subject 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 Subject Research.
  - Determine whether an activity is Human Subject Research.

Conflict of Interest Office

The Conflict of Interest office is responsible for assessing reports of competing interests and requiring management plans when conflicts are identified. Management plans are intended to minimize the competing interests' effects on the conduct of the study, thereby protecting human subjects.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Subject Research Protection Program requirements described in the policies and procedures maintained on the IRB website.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the Organizational Official.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide advice upon request to the Organizational Official, IRB, and other individuals involved with the Human Subject Research Protection Program.
- Determine whether someone is acting as an agent of the organization.
- Determine who meets the definition of "legally authorized representative" and "children" when Human Subject Research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.
- Review sponsor contracts and funding agreements for compliance with Human Subject Research Protection Program Policies and Procedures.

Deans/Department Chairs

Deans and Department Chairs have the responsibility to:

- Oversee the review and conduct of Human Subject Research in their department or school.
- Forward complaints and allegations regarding the Human Subject Research Protection Program to the Organizational Official.
- Ensure that each Human Subject Research study conducted in their department or school has adequate resources.

Office of Research Regulatory Affairs

The Office of Research Regulatory Affairs has the responsibility to:

- Provide support and monitoring for all UAMS-held INDs and IDEs.

Translational Research Institute

The Translational Research Institute has the responsibility to:

- Provide institutional review for clinical research budgets and Medicare coverage analysis for non-cancer clinical trials.
- Consult on the following aspects of research, including community-engaged research:
    - Designing and planning research proposals

- Technical assistance with community-engaged research and community-based participatory research techniques
- Identifying collaboration sites, available resources, and community partners
- Establishing Community Review Boards (CRB)
- Identifying funding opportunities

Cancer Clinical Trials and Regulatory Affairs (CCTRA)

The CCTRA has the responsibility to:

- Provide institutional review for cancer clinical trials ensuring trials adhere to National Cancer Institute guidelines.
- Provide institutional review for clinical research budgets and Medicare coverage analysis for cancer related clinical trials.
- Provide assistance on all cancer-related clinical trials including but not limited to Regulatory, Budget and financial tracking, data management, nursing, and specimen processing.

Education and Training

IRB members, IRB staff, and others involved in the review of Human Subject Research must complete the online Collaborative Institutional Training Initiative (CITI) human subject online training program. See the IRB Web site for a link to this training.

This training is valid for three years, after which time a refresher CITI course must be completed. IRB staff also train IRB members on the SOPs, checklists, and worksheets applicable to IRB members including regulatory and guidance requirements.

Investigators and research staff must complete the online Collaborative Institutional Training Initiative (CITI) human subject online training program. See the IRB Web site for a link to this training. This training is valid for three years, after which time a refresher CITI course must be completed. If there are substantial regulatory changes, updated training may be required.

HRPP Evaluation and Quality Improvement

Individual HRPP components shall be responsible for their own internal assessments regarding the quality, efficiency, and effectiveness of their divisions. Areas to be assessed may include, but not be limited to, adequacy of staffing and salary support; education and training needs; adequacy of physical facilities; and adequacy of computer systems and hardware. These assessments may be done at specified times or be part of the component's routine activities. HRPP components shall address identified gaps within their departments.

At least twice in every five-year period, the HRPP will conduct a larger quality, efficiency, and effectiveness assessment involving at least two HRPP components. This assessment

may involve surveys, audits, or other methods to assess issues such as how well two or more components coordinate their activities; one component's perception of another's performance (e.g. investigators and research staff providing feedback about another HRPP component), or review of software/systems used by multiple HRPP components.

Questions and Additional Information for the IRB

The IRB Office seeks your questions, information, and feedback. Contact and location information for the IRB Office are as follows:

UAMS Institutional Review Board
Office Location: Biomed I, Room 170/172
4301 W. Markham, MS 636
Little Rock, AR 72205
Email: irb@uams.edu
(501) 686-5667

Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Subject Research Protection Program may be reported orally or in writing. Concerns may be reported to the IRB Chair, IRB Director, Organizational Official, ORC, Legal Counsel, Deans, or Department Chairs. Concerns may be reported anonymously by calling the Compliance Hotline at (888) 511-3969.

The IRB, or ORC as appropriate, has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The Organizational Official 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 Organizational Official or designee.

To make such reports, contact:

Shuk-Mei Ho, PhD
Vice Chancellor for Research and Innovation
Biomed II, Room 155
4301 W. Markham, MS #718
Little Rock, AR 72205
Email: ShukMeiHo@uams.edu
(501) 686-5391

Disciplinary Actions

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

Approval and Revisions to the Plan

This Human Subject Research Protection Program Plan is to be approved by the Chancellor. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Organizational Official has the responsibility to review this plan to assess whether it is providing the desired results. At the request of the Organizational Official, the Chancellor has the authority to amend this plan as deemed necessary.

Approved:

Cam Patterson, M.D., MBA
Chancellor

July 16, 2021
Date