Department: UAMS Institutional Review Board
Policy Number: 1.4
Section: Principles and Authority
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SUBJECT: Studies Requiring Review

Purpose: The purpose of this policy and procedure is to explain the types of studies for which the IRB has review oversight responsibilities.

Definitions:

Clinical Investigation: Any experiment that involves a test article and one or more human subjects and that is subject to the Food and Drug Administration (FDA) regulations. This includes all research using a test article in a human subject as well as experiments that support applications for research or marketing permits for products.

Human subject (subject and participant used interchangeably):

1) An individual who is or becomes a participant in research either as a recipient of a test article, as a control, or an individual on whose specimen an investigational device is used; OR

2) A living individual about whom an investigator (whether professional or student) conducting research obtains:

a. Data, of any kind, through intervention or interaction with the individual; OR
b. Identifiable private information even in the absence of intervention or interaction.

Provided an investigational device is not being used, research on cadavers or decedents, or data or specimens that are collected solely from decedents, is not Human Subject Research. It may, however, still be subject to HIPAA requirements and require submission to the IRB which also serves as the Privacy Board. If the Investigator only receives specimens/data that are stripped of all HIPAA identifiers as per Policy 13.3, and submits a signed assurance from the provider of the specimens/data reflecting this, then it is not Human Subject Research.

If the investigator is receiving coded private information, the proposal only qualifies as non-Human Subject Research, if the code is not derived from any one of the HIPAA identifiers; the specimens/data were not collected specifically for the proposed project; and there is no way for the investigator to readily ascertain the identity of the individuals from which the specimens/data was obtained (Examples: Code Key destroyed prior to research or there is a written agreement or SOP from code key holder that they will not share key with researcher).

Human Subject Research: Any activity that meets the definition of:

1) Research AND involves human subjects; OR
2) Clinical Investigation.

Interaction: Includes communication or interpersonal contact between Investigator and subject or participant.

Intervention: Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject's environment that are performed for research purposes.

Non-Human Subject Research: An activity determined by the IRB to not meet the definitions of Human Subject Research as per this policy.

Private Information: Information about behavior that occurs in a context in which an individual can reasonable 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, Medical records). Private Information must be individually identifiable (identity of subject is or may readily be ascertained or associated with the information) in order to constitute research involving human subjects.

Test Article: Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product or any other article subject to FDA regulations.

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 thesis, dissertation or preceptorship projects 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 improve the performance of a unit, division, or department.

Policy:
All activities, regardless of whether the activity requires full board review, or might qualify for one of the expedited or exempt categories, that are clearly Human Subject Research should submit a complete proposal, including protocol, to the IRB through either a New Biomedical Protocol Submission or a New Behavioral Submission in ARIA. No Human Subject Research study should be initiated prior to IRB approval.

The IRB has sole authority to determine whether an activity meets the definition of Human Subject Research. Any activity that might represent Human Subject Research should be submitted to the IRB for determination.

All research activities, including those deemed Non-Human Subject Research, must be carried out in an ethical and respectful fashion in compliance with the principles of the Belmont Report, all state and local laws and institutional policies.

Research conducted by, or under the direction of, any employee, faculty, staff or student of UAMS or any entity in which the UAMS IRB is designated as the IRB of record, is governed by these policies. This includes research conducted off site or research involving the use of non-public information to identify or contact human research participants or prospective participants.

Reference: Policy 1.3 Federalwide Assurances; Policy 2.3 To Other Institutions; Policy 2.7 Engagement

Procedure for Human Subject Research Determination:

1. Investigator will:

1.1 Email irb@uams.edu a proposal with the following information:

- 1.1.1 Investigator's Name and contact information
- 1.1.2 Any other personnel that will be involved
- 1.1.3 All project locations
- 1.1.4 Detailed synopsis of the project that includes the objectives, background and rationale of the project
- 1.1.5 Identification of any test articles (whether approved or not) to be used
- 1.1.6 Type of data or specimens to be studied and type of population from which they were, or will be, obtained

1.1.7 Whether the data/specimens were obtained systematically
1.1.8 Whether the data/specimens were collected for the purpose of contributing to generalizable knowledge (collected with a plan for dissemination outside of UAMS)
1.1.9 Whether the Investigator will receive or have access to identifiable private information (as defined above)
1.1.10 If Investigator is only receiving coded information, is there a link that would allow re-identification?
1.1.11 Whether there will be any interaction or intervention with a human subject (as defined above)?

1.2 If determined to be Non-Human Subject Research, notify the IRB if the project changes to assure changes do not affect original IRB determination.

1.3 If determined to be Human Subject Research, work with IRB Director or Designee to complete application in ARIA.

2. The IRB Director or Designee will:

2.1 For the purposes of determining whether a submitted activity is Human Subject Research, use the definitions and guidelines above to review the proposal and request additional information as needed.

2.1.1 If the proposed activity is a Clinical Investigation, draft a letter of determination for Chair signature indicating that the full submission process must take place. Assist Investigator with ARIA submission to minimize duplication of effort.

2.1.2 If the proposed activity is Research and involves Human Subjects, draft a letter of determination indicating that the full submission process must take place. Assist Investigator with ARIA submission to minimize duplication of effort.

2.1.3 If the proposed activity is determined to be Non-Human Subject Research, draft a letter of determination for Chair signature indicating the reasons why the proposed activities do not meet the definition of Human Subject Research.

2.2 All correspondence, including Non-Human Subject Research, will be documented in ARIA.