

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

I. Purpose

The purpose of this policy and procedure is to explain the types of projects for which the IRB has review oversight responsibilities and how to obtain a determination as to whether a project is Human Research.

II. Definitions

A. ARIA: Abbreviation for Automated Research Information Administrator. Electronic IRB submission system.

B. 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 by one of the following:

- 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.

C. 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.

For the purposes of this definition:

- **Intervention** means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject's environment that are 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 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, a medical record).
- **Identifiable Information** means information that is individually identifiable (identity of subject is or may readily be ascertained or associated with the information).

D. Human Research: Any activity that meets the definition of:

- 1) Research AND involves Human Subjects; OR
- 2) Clinical Investigation.

E. Non-Human Research: An activity that does not meet the definitions of Human Research as per this policy.

- F. 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.

- G. 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.

III. Policy

- A. Human Research:** All activities where UAMS employees, students and agents are clearly engaged in Human Research must submit a new protocol application to the IRB through ARIA. UAMS follows OHRP Guidance on "Engagement of Institutions in Research". This applies to all Human Research, regardless of whether the activity is exempt, expedited or requires full board review. No Human Research study may be initiated prior to IRB approval.
- B. Determinations:** Activities, in which it is unclear as to whether it is Human Research, must be submitted to the IRB for determination according to the procedures described below. In questionable cases, the IRB retains the authority to make the final determination whether an activity meets the definition of Human Research.
- C. Decedents/Cadavers:** A research project involving cadavers or data/specimens collected solely from decedents is not Human Research, provided the research does not involve the use of a Test Article. The research may, however, still be subject to HIPAA requirements. If conducting this type of research, contact the IRB, which also serves as the Privacy Board, for more information on decedent research.
- D. Case Reports:** For the purpose of this policy, a case report is defined as the collection and/or presentation of existing clinical information from three or fewer patients to illustrate an interesting or unique situation. Activities meeting this definition are not considered Human Research by the UAMS IRB and do not require IRB Review or Approval. The use and disclosure of patient information in this manner is still subject to HIPAA requirements.
- E. Non-Human Research:** Projects which are clearly Non-Human Research are not required to submit a Determination Form to the IRB. Investigators may choose to submit a determination if they wish. Some third parties such as journals, commercial tissue suppliers and funding agencies ask for documentation of institutional acknowledgment of even Non-Human Research projects.

The IRB has the expertise and experience in the application of the regulatory definitions. Investigators are encouraged to proceed with caution when making their own determinations of when something is clearly Non-Human Research. If the IRB reviews a project previously determined by an Investigator to be Non-Human Research and disagrees with the Investigator's determination, the IRB decision will be the authoritative decision and IRB Policy 12.6 will be followed.

IV. Procedure for Human Research Determination

- A.** Submit completed Determination Request Form to irb@uams.edu. The IRB Director or Designee will determine whether the activity is Human Research and provide a Determination Letter.
- 1. Human Research:** If the activity is determined to be Human Research, a new protocol application will need to be submitted in ARIA.
 - 2. Non-Human Research:** If the activity is not Human Research, no further IRB review is needed unless the scope of the activity changes. If the intent or scope of the activity changes, contact the IRB for an additional determination.