Department:	**UAMS Institutional Review Board**
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Section:	**Principles and Authority**
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SUBJECT: Studies Requiring Review and Human Subject Research Determinations

POLICY

The UAMS IRB has review and oversight responsibilities for human subject research done at UAMS and Arkansas Children's. The UAMS IRB may cede that responsibility to other IRBs or may act as the reviewing IRB for outside institutions, as permitted by regulation and other requirements. The IRB also has a procedure to follow for obtaining a determination of whether a project is Human Subject Research requiring review.

DEFINITIONS

A. **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
B. **Clinical Investigation:** Any experiment that involves a test article and one or more human subject 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 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; or
    2. Meets the requirements for prior submission to the FDA under 520(g) of the Federal Food, Drug, 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:
        a. Obtains information or biospecimens 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
        c. For the purposes 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 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 which the individual can reasonably expect will not be made public (for example, a medical record).
            - **Identifiable information** is private information for which the identity of subject is or may readily be ascertained by the investigator or associated with the information.

- **An identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Or

- **In FDA-regulated research only**, unidentified tissue specimens when used in medical device research involving in vitro diagnostics are human subject specimens.

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

1. Research AND involves Human Subjects; OR
2. Clinical Investigation OR
3. Clinical Trial

E. **Non-Human Research:** An activity that does not meet the definitions of Human Subject Research as per this policy
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F. **Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

1. 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.

2. Generalizable Knowledge: Extending beyond an internal use within an institution. Thesis and dissertation projects intended to extend beyond the graduate's department are considered research. Activities that are typically not generalizable are course evaluations that cannot be generalized to others and quality assurance type activities intended to evaluate or improve the performance of a unit, division, department, or organization.

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.

PROCEDURE

A. **Human Subject Research**: All activities where UAMS employees, students and agents are clearly engaged in Human Subject Research require a new protocol application to the IRB through the IRB e-system. UAMS follows the OHRP Guidance on "Engagement of Institutions in Research". This applies to all Human Subject Research, regardless of funding source and of whether the activity is exempt, expedited or requires full board review. No Human Subject Research may be initiated prior to IRB approval.

B. **Determinations**: If the project team is uncertain whether an activity meets the definition of human subject research, or would like documentation that the activity is not human subject research, they may submit the Human Subject Research determination form in the IRB e-system for review. Only the determination sent in response to these e-system submissions will be considered valid. The IRB retains the authority to make the final determination whether an activity meets the definition of Human Subject Research.

Investigators are not required to submit a determination request if they already know whether their project meets the definition of human subject research but may do so if they wish. Some third parties such as journals, commercial tissue suppliers and funding agencies ask for documentation of institutional acknowledgment even of projects that do not meet the definition of human subject research. Any activity found to be Human Subject Research will require a complete new submission in the IRB e-system.

The IRB has the expertise and experience in applying the regulatory definitions to make these determinations. Investigators should proceed with caution if they make their own determinations that something does not meet the definition of Human Subject Research. If the IRB reviews a project previously determined by an Investigator to be Non-Human Subject Research and disagrees with the Investigator's determination, the IRB decision will be the authoritative decision and IRB Policy 12.6 will be followed.

If the scope of a project initially found to not be human subject research changes, the project team should contact the IRB to see if another determination form or a new submission is needed.

C. **Decedents/Cadavers**: A research project involving only cadavers or data/specimens collected solely from or about decedents is not Human Subject Research, provided the research does not involve the use of an in vitro diagnostic device. 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/Case Series**: For the purpose of this policy, a case report is defined as the collection and/or presentation of existing clinical information from a limited number of patients to illustrate an interesting or unique situation. Case series/reports are descriptions of situations that have already occurred and do not involve any systematic data collection activities (e.g. predetermined data points to collect) or data analysis. Activities meeting this definition are not considered Human Subject Research by the UAMS IRB and do not require IRB Review or Approval.

The use and disclosure of patient information in this manner remains subject to HIPAA requirements.

E. **Not research:** The following activities are deemed not to be research:
   1. Scholarly and journalistic activities, such as oral history, that focus directly on the individuals about whom the information is collected.
   2. Public health surveillance activities, including the collection and testing of information or biospecimens conducted, supported, requested, ordered, required, or authorized by a public health authority.
   3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigation purposes.
   4. Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.

REFERENCES

45 CFR 46.102(b)
21 CFR 50.3(c)
45 CFR 164.501
AAHRPP Elements I.1.A, II.2.A, III.1.A
AAHRPP Tip Sheet 2
OHRP Guidance titled, "Engagement of Institutions in Human Subjects Research"
FDA Guidance titled, "In Vitro Diagnostic (IVD) Device Studies-Frequently Asked Questions"