

# University of Arkansas for Medical Sciences

## Sponsor and xIRB (local context) Information

### Institutional Information

- Full Legal Name: University of Arkansas System d/b/a the Board of Trustees for The University of Arkansas acting for and on behalf of the University of Arkansas for Medical
- Institution Category: Academic Medical Center; Public Institution
- Mailing Address: 4301 W. Markham St., Little Rock, AR 72205
- IRB Website: <https://irb.uams.edu/>
- [Human Research Protection Program Plan](#)

### Federalwide Assurance (FWA):

- FWA #: FWA00001119
- FWA Expiration: June 10, 2029
- The FWA has NOT been extended to non-federally funded research. (We have “unchecked the box.”)
- More Information: [https://irb.uams.edu/about\\_us/compliance-statement/](https://irb.uams.edu/about_us/compliance-statement/)

### IRB Committee Registration Numbers: The IRB committee registration numbers are:

IRB00000742 (IRB Committee 1; meets the first Tuesday of every month)

IRB00004852 (IRB Committee 2; meets the second Tuesday of every month)

IRB00000593 (IRB Committee 3; meets the third Tuesday of every month)

IRB00000745 (IRB Committee 4; meets the fourth Tuesday of every month)

IRB00012538 (Ad hoc committee; can be convened if needed for time sensitive reviews, e.g. emergency uses).

Current and archived IRB rosters are available on the [IRB’s webpage](#)

IORG Number: IORG0000345, expiring May 1, 2026

### Accreditation: Association for the Accreditation of Human Research Protection Programs (AAHRPP)

- UAMS has been fully accredited by the AAHRPP since 2005. Most recent accreditation was in September 2021.

## **HIPAA**

- UAMS is a hybrid entity for HIPAA purposes.
- UAMS allows the combining of HIPAA authorization forms with consent forms, and also allows the forms to be separate.

**All UAMS IRB Policies:**      [Please click the link here.](#)

**Institutional Affiliations:** The University of Arkansas for Medical Sciences acts as the IRB of record for the Arkansas Children’s Research Institute.

- Arkansas Children’s Research Institute: <https://www.archildrens.org/research>

## **SMART IRB**

UAMS participates in the SMART IRB reliance system.

## **Research Team Training**

All research staffers must complete the Basic Human Subject Protection training course for either Biomedical or Social Behavioral Research (whichever is applicable) at CITIprogram.org. This requirement applies to anyone who will interact with human subjects or access human subject material (i.e. identifiable data or specimens). UAMS will consider comparable training from another institution on a case-by-case basis.

## **Compliance Statement**

The University of Arkansas for Medical Sciences (UAMS) IRB is duly constituted, fulfilling all requirements for diversity and has written procedures for initial and continuing review of human subject’s research; prepares written minutes of convened meetings; and retains records pertaining to the review and approval process.

The UAMS IRB is organized and operates in compliance with DHHS regulations as described in 45 CFR part 46 (i.e., The Common Rule) and, after January 20, 2019, the Revised Common Rule and with FDA regulations as described in 21 CFR Parts 50 and 56. The UAMS IRB applies equivalent protections to unregulated research.

[View statement here](#)

## **Conflict of Interest**

The goal of the Conflict of Interest Office is to promote the UAMS mission and assure academic and professional integrity. UAMS is committed to following and enforcing its conflict of interest policies. We help all faculty and staff members avoid potential or perceived conflicts of interest.

In order to identify and review conflicts of interest and the appearance thereof, all UAMS staff members (excluding PRN, Temporary and Classified employees) are expected to disclose all outside activities and financial interests that might be, or have the appearance of being, conflicts of interest or commitment. All members are required to submit a Disclosure Form within two

weeks of initial employment and annually thereafter. Updated forms must also be submitted within thirty days of a change in circumstances that may give rise to a potential conflict of interest. The CoI office site is at <https://coi.uams.edu/>.

The IRB recognizes and will carry out its obligation to ensure human research subjects' rights and welfare are not compromised by competing interests. No Reviewer may participate in the review of any study in which the Reviewer or Immediate Family has a Conflicting Interest, except to provide information regarding the study as requested. This applies to all IRB review functions, including new, expedited, review of unanticipated problems and noncompliance. No individual may serve as a Reviewer or participate in the day-to-day IRB operations if that person's primary employment is as a professional fund-raiser to raise funds or solicit grants for research at UAMS, AC/ACRI or other affiliated institutions.

The UAMS IRB retains the right to determine whether any conflicts of interest are appropriately managed to ensure human subjects' rights, safety, and welfare are protected.

### **Ancillary Reviews**

Ancillary reviews are conducted outside of the purview of the IRB office. Please refer to the UAMS study team for study-specific details.

### **Research with Non-English Speaking Individuals**

Information provided to a subject during an informed consent discussion must be in a language understandable to the subject or the subject's Legally Authorized Representative (LAR). If the subject's or LAR's English proficiency is limited to the extent that they cannot understand consent information and materials in English, the consent process and consent document must be in a language the subject or LAR can understand. A short form may be used to document consent only when non-English-speaking subjects are unexpectedly encountered or when approved by the IRB.

[See IRB Policy 15.4.](#)

### **Children in Research**

The age of majority in Arkansas is 18. Minors may provide their own consent for health care and research in limited circumstances under state law, typically relating to reproductive health.

**Children who are considered to be in the custody of the state.** Foster children are in the custody of the Arkansas Department of Human Services (DHS) and therefore are wards of the state. As such, only DHS may provide consent for their participation in research. Specifically, since foster care is under the Division of Children and Family Services (DCFS), the Director of that division will review all requests for research projects. Foster parents cannot provide permission for a foster child to participate in research.

Investigators considering a research project specifically targeting these children must contact the Director of the Arkansas Division of Children and Family Services before finalizing the protocol.

The study must address special considerations. DCFS staff are to assist with efforts to protect this special population.

[See IRB Policy 17.1.](#)

### **Research with Persons with Diminished Functional Capacity**

Adult subjects are routinely viewed as capable of consenting to enroll and participate in research. Subjecting unimpaired participants to risks associated with IRB-approved research is ethically permissible when the participants decide that doing so is in their interests or in line with their values and provide consent. However, functional abilities exist along a continuum, and can fluctuate due to various physical and psychological conditions. These conditions can include, but are not limited to, acute or chronic medical conditions, and psychiatric, neurologic, developmental, or behavioral disorders. Prospective adult participants with impaired functional abilities are presumed to be capable of giving consent to enroll and participate in a research study unless there is substantial evidence they are not capable.

[See IRB Policy 17.2.](#)

### **Research Involving Legally Authorized Representatives**

Some (potential) subjects are unable to provide their own consent for participation in the research, due to diminished functional abilities or not having reached the age of majority under Arkansas law. For these (potential) subjects, a legally authorized representative may be designated to provide consent/permission for research participation on the potential subject's behalf, and to continue to confirm consent throughout study participation, as long as the incapacity persists or until the (potential) subject reaches the age of majority.

[See IRB Policy 17.13.](#)

### **Confidentiality Protections**

In its reviews, the UAMS IRB shall consider whether research subjects' identifiable private information is appropriately protected with regard to its collection, storage, use, and sharing, as applicable. Considerations include whether a study is subject to HIPAA, sensitivity of the information, and systems use to record, store, and transmit information.

### **Informed Consent Requirements**

UAMS has specific formatting and content requirements for consent forms. For multisite studies, UAMS requires its local PI's and IRB's contact information to be included in the consent form, including when the main PI's and reviewing IRB's contact information is included. In addition, certain specific entities must be listed in consent forms' confidentiality section. For additional information about these requirements and others, see [IRB Policy 15.1.](#)

## Mandated Reporting

- A mandated reporter is anyone required to report suspected abuse. Mandated reporting requirements must be disclosed to subjects when applicable and relevant to the study. Suggested language is below; this may be altered as long as the same information is conveyed.
  - By law, the study team must release certain information to the appropriate authorities during the study if the study team suspects abuse or neglect involving children or endangered or impaired adults.
- In studies where subjects will be tested for HIV or other reportable diseases, a statement must be included that describes how the subject and Department of Health will be notified of a positive test result and that subject will be given information about counseling options if HIV positive or found to have any other reportable disease. Information about communicable disease reporting can be found at the [Arkansas Department of Health's website](#).

## Institutional Contacts

### Institutional Official

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### UAMS IRB Senior Director

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### UAMS IRB xIRB liaison

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### UAMS IRB office main contact information

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