# Protection of Human Subjects in Research

1. **Purpose**

The following is the policy of the University of Arkansas, Fayetteville (hereafter referred to as the University) regarding the protection of human subjects in research. It applies to all University research activities and to all employees and other persons acting as representatives of the University, including at off-campus locations.

1. **Policy**
2. The University adopts all the principles described in both the [Nuremburg Code](https://history.nih.gov/research/downloads/nuremberg.pdf) and the [Belmont Report](https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf).
3. University activities that a) involve human subjects, as defined by the Department of Health and Human Services (HHS) or the Food and Drug Administration (FDA), and b) that meet the definition of research as defined by either HHS or FDA, qualify as human subjects research and are subject to this policy, irrespective of funding source or status.
	* 1. A human subject is defined by HHS as a “living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information or biospecimens.”

The FDA defines a human subject as “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be a healthy human or a patient.”

* + 1. HHS defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

The FDA defines clinical investigation to be synonymous with research and means any experiment that involves a test article and one or more human subjects.

1. University faculty, staff and students will comply with the authority and guidance of HHS policies and procedures set forth in [45 CFR Part 46](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML), Subparts A – D. Subpart A constitutes the Basic HHS Policy for Protection of Human Research Subjects, also known as the Common Rule, and represents the foundation for the protection of human subjects in research. As applicable, University faculty, staff and students shall comply with FDA policies at [21 CFR Part 50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50), Protection of Human Subjects and at [21 CFR Part 56](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56), Institutional Review Boards.
2. As applicable, University faculty, staff and students will comply with the [General Data Protection Regulation](https://www.uark.edu/privacy-policy/gdpr.php) pertaining to privacy and data protection for all individuals within the European Union and the European Economic Area.
3. **IRB Responsibilities**
4. The University shall constitute an Institutional Review Board (IRB) with members nominated by the Vice Chancellor for Research and Innovation or the Committee on Committees and appointed by the Provost and Executive Vice Chancellor for Academic Affairs (Provost). The IRB shall comprise, at a minimum, five members with varying backgrounds to promote review of human subjects research conducted by the University. Membership must include the following:
* At least one member whose primary concerns are in a scientific area;
* At least one member whose primary concerns are in a non-scientific area; and
* At least one community member otherwise unaffiliated with the University.

The IRB will also include the following members:

* One graduate student;
* Two or three faculty members each from the College of Education and Health Professions and Fulbright College of Arts and Sciences;
* One faculty member from each of the following colleges: Walton College of Business; Bumpers College; the College of Engineering; the School of Architecture; and the School of Law;
* *Ex officio* and voting, the Director of University Health Services; and
* *Ex officio* and non-voting, the Director of Research Compliance.

For review of protocols that involve one or more categories of vulnerable research subjects (e.g. children, prisoners, pregnant women, or handicapped or mentally disabled persons), the IRB will ensure that members are sufficiently knowledgeable and experienced in working with these populations. A non-voting expert consultant may be appointed on an ad hoc basis to provide the necessary expertise for review of these protocols. For protocols involving prisoners, at least one voting member must be either a prisoner or a prisoner representative with the appropriate background and knowledge to serve in that capacity.

1. The IRB is registered with [HHS Office of Human Research Protections](https://www.hhs.gov/ohrp/) (OHRP). The

registration is renewed on a triennial basis.

1. On behalf of the University, the IRB has the following functions:
	* 1. Review and vote on approval of all non-exempt protocols and amendments to protocols that involve activities meeting the definition of human subjects research as described in Section II;
		2. Conduct a limited review of protocols that are exempt under Categories 2, 3, 7 and 8 of the revised Common Rule;
		3. Document IRB activities in accordance with federal regulations and University policies;
		4. Keep abreast of changes to regulations and other sources of best practices to ensure continued institutional compliance;
		5. Serve as a resource for investigators conducting any research subject to review by the IRB;
		6. Make policy recommendations to the Office of Research Compliance;
		7. Coordinate with IRBs at other institutions as necessary to comply with federal

requirements pertaining to the use of a single IRB for the review of multi-institutional studies; and

* + 1. Report to the Provost and to HHS OHRP, through the Director of Research Compliance, any unanticipated problems that arise during the conduct of human subjects research.
1. **IRB Operations**
2. The IRB typically meets on a monthly basis, except in such months during which there are no protocols requiring review by the full committee and no other IRB business needing attention Meeting dates are listed on the University’s Research Compliance [website](https://research.uark.edu/units/rscp/). A quorum (50% + 1 of voting members) is required to conduct official IRB business.
3. No member of the IRB may be involved in the review or approval of a project in which

 s/he has or may expect to have a conflict of interest as defined in [Fayetteville Policy 404.0, Conflict of Interest and Conflict of Commitment](https://vcfa.uark.edu/fayetteville-policies-procedures/vprs/4040.php), except to provide information as needed to the committee. Examples of such conflicts would include:

* Being included as an investigator or study personnel on the protocol being reviewed, or being an immediate family member of anyone included on the protocol being reviewed;
* Serving as a research coordinator, consultant or advisor on the protocol;
* Having a close personal or professional relationship with the submitting investigator that would interfere with the reviewer’s objectivity; or
* Receiving any payments, royalties, equity, intellectual property rights, or other benefits from an entity whose financial interests would appear to benefit from approval of the protocol under review.

If any member must recuse himself or herself for review of a protocol, the committee will confirm that a quorum still exists before proceeding.

1. Protocols may be approved for up to one year. Protocols may be renewed following

review by the IRB. No work on any project subject to this policy may be conducted until approval is granted. Under no circumstances will a protocol be approved retroactively.

1. In accordance with federal regulations, the University maintains a Federalwide

 Assurance for the Protection of Human Subjects, on file with HHS OHRP.

1. **Implementation**

The Director of Research Compliance, under the direction of the Vice Chancellor for Research and Innovation, and in collaboration with the IRB and the IRB Coordinator, shall oversee the University’s compliance with applicable laws and regulations and shall have primary responsibility for ensuring that this Policy is properly implemented and followed.