

Institutional Review Board (IRB) for research involving human subjects

“ REMINDER: We now use Cayuse as our protocol management software. For information about Cayuse, please [click here](#) .

HUMAN SUBJECTS RESEARCH

Federal law requires institutional review of protocols that involve the use of human subjects for “systematic investigations, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” The Code of Federal Regulations Subpart A of 45 CFR 46 established the “Common Rule,” where fourteen agencies of the federal government came together to require that: 1) agencies establish institutional review boards; 2) delineate levels and criteria for protocol review; and 3) ensure in most cases that investigators secure the informed consent of participants before embarking on their projects. The Office of Research Integrity in the Department of Health and Human Services (DHHS) has responsibility for oversight of federally-funded human subjects’ research.

[Visit the Office of Human Research Protections here>>](#)

A-STATE INSTITUTIONAL REVIEW BOARD

Approved revision March 2, 2022

VII. Federal Regulatory Committees

VII.A. Institutional Review Board for the Protection of Human Subjects in Research

Function: In accordance with federal law and university policy the IRB is charged with overseeing compliance with federal regulations related to human subjects research.

Membership: Membership of the IRB is governed by U.S. Department of Health and Human Services regulation 45 CFR 46.107. The IRB is a standing committee of A-State. The IRB is not a shared governance committee.

Description: The A-State IRB endeavors to have representation from each of the academic colleges and the Northeast Arkansas community. Members are appointed by the Provost and Executive Vice Chancellor for Academic Affairs and Research (in consultation with the Vice Provost for Research & Technology Transfer and deans of the colleges) according to federal guidelines and the needs of the university. A good-faith effort should be made in the selection of membership to reflect the diversity in the A-State community, including but not limited to race, gender, cultural background, and research experience. The IRB Chair will be appointed by the Provost and Executive Vice Chancellor for Academic Affairs (in consultation with IRB members and the Director of Research Compliance).

Consistent with the law, A-State maintains an Institutional Review Board (IRB) that has oversight responsibility for campus-wide human subjects’ research, with the primary purpose of ensuring that the rights and welfare of participants are protected.

Human subjects research is categorized in one of three classifications including full board review, expedited review, exempt status, and student protocols.

IRB COMMITTEE MEMBERS

Non-Scientific Members Eric Cave, PhD, Chair Professor of Philosophy	Edward Salo, PhD Associate Director of Heritage Studies, Professor of History
Scientific Members Christina Akbari, PhD Associate Professor of Communication Disorders	Eric Scudamore, PhD Associate Professor of Exercise Science
James Church, PhD Professor of Exercise Science	Margaret Hance, PhD Associate Professor of Psychology
James Farris, PhD Associate Professor of Physical Therapyp	Amanda Carpenter, PhD Assistant Dean for Research, College of Nursing & Health Professions
Community Members Carolina Elmore Non-Scientific Member El Centro Hispano	
Non-Voting Members Jenny Estes Director of Research Compliance (Non-Scientific Member and IRB Administrator)	

For Information, please contact the
Director of Research Compliance
(870) 972-2694 | IRB@astate.edu

FULL BOARD REVIEW

Full Board review is required for all research involving greater than minimal risk to subjects and for research involving any protected subject populations including pregnant women and their fetuses, prisoners, and certain other vulnerable populations. Only the full board can reject an application to conduct research activities involving human subjects.

EXPEDITED REVIEW

Expedited review is appropriate for research that involves no more than minimal risk or for review of minor changes to previously-approved research projects. An expedited review may include the IRB chairperson alone, or one or more experienced reviewers. Protocols eligible for expedited review include:

- Collection of hair and nail clippings in a non-disfiguring manner;
- Collection of excreta and external secretions;
- Collection of data from subjects 18 years of age or older using non-invasive procedures that are routinely employed in clinical practice;
- Collection of blood samples from subjects who are 18 years of age or older, in good health, and are not pregnant, such collection not to exceed twice weekly venipuncture and a maximum of 450 milliliters in an eight-week period;
- Anonymous voice recordings made for research purposes, such as investigations of speech defects;
- Moderate exercise by healthy volunteers;
- Study of existing data, documents, records, pathological specimens or diagnostic specimens;
- Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate the subject's behavior and the research will not involve stress to subjects;
- Research involving manipulation of the subject's behavior which does not involve stress or risk;

Expedited review may also be appropriate for minor changes or requests for extensions in previously-approved research during the period (one year or less) for which approval is authorized.

EXEMPT and exempt-limited STATUS

Exempt and exempt-limited protocols must be submitted to the IRB for determination of eligibility. Exempt eligible protocols may be administratively reviewed; however, protocols requiring exempt-limited review must be reviewed by a member of the IRB. Categories include:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special

education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

1. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

1. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

1. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

1. Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

1. Storage or maintenance for secondary research for which broad consent is required:

Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

2. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

STUDENT PROTOCOLS

Research and clinical practica (usually in the form of research methods classes, evaluation projects and/or directed studies) are designed to allow students to the conduct of research and are typically limited in scope and do not lead to general knowledge. Rather than bypass the IRB process, however, faculty who teach research methods classes are requested to submit blanket protocols to the IRB for its review. Note, however, that if the intent of research conducted by graduate and undergraduate students is to develop or contribute to general knowledge, their protocols must be classified and reviewed by the IRB including, but not limited to, all independent research projects, master's theses, and doctoral dissertations.

PROCESS

A-State investigators must seek IRB review for human subjects' research (including oral histories) before conducting their projects. Steps in the process include:

CITI Training: All research team members with access to the raw data, including faculty advisors, must complete CITI training prior to submitting a protocol to the IRB. To do so, please self-register at www.citiprogram.org. When registering, you must (1) affiliate with Arkansas State University and (2) provide your A-State email address as your primary email address in CITI. Complete either the Biomedical or the Social and Behavioral Responsible Conduct of Research and Human Subject Research courses.

CAYUSE: Cayuse is our protocol management software. New users must request a Cayuse account. To submit a protocol

- Log in to Cayuse Human Ethics (formerly Cayuse IRB)
- Click New Study in the upper right corner of the dashboard
- Enter the title of the study, click the checkmark
- Click New Submission in the upper right corner and select Initial Submission
- Click Complete Submission, answering all questions and attaching documents as prompted. Common attachments include informed consent documents, site permission letters, questionnaires, etc. When the application is ready for review, click Complete Submission at the left and confirm that you wish to submit. Then, on the Submission Details page, click Certify and confirm. Your advisor and any Co-PIs also must also log in; read through the protocol; and, if approved as written, certify the protocol.
- To submit an amendment, continuing review, closure, unanticipated problem, adverse event, or deviation, select the protocol from your dashboard. On the Study Details page, click New Submission in the upper right corner to select the type of submission. Click Complete Submission, answer the questions and attach documents as needed. When the application is ready for review, click Complete Submission at the left and confirm that you wish to submit. Then, on the Submission Details page, click Certify and confirm. Your advisor and any Co-PIs also must also log in; read through the submission; and, if approved as written, certify the protocol.

Depending on the committee's review, you may receive an email that the protocol has been returned to the PI for corrections or that it has been approved, etc.

CRITERIA

Key questions to ask as you prepare your applications include the following:

- Does the value of the project outweigh risk to participants?
- Have you adequately protected participant confidentiality either by masking identifying information and physically separating the key from the data or by not collecting identifying information during data collection?
- Have you established adequate safeguards for vulnerable populations (i.e., children, prisoners, mentally disabled individuals, and pregnant women and their fetuses)?
- Have you clearly identified your inclusion and exclusion criteria for subject participation?
- Do you have an adequate data protection and disposal plan?
- Does your consent form meet federal guidelines, providing potential participants with information about the study, their ability to opt in or out at any time, how the study may be helpful to them or to society, how confidentiality will be maintained, who to contact with questions about the study, who to contact with questions about the IRB?
- Do you clearly articulate how the consent process will be administered?

FREQUENTLY ASKED QUESTIONS

What is the A-State policy regarding the use of human participants in research?

All research involving human participants conducted by faculty, staff, or students of Arkansas State University (A-State) must be reviewed and approved by the A-State Institutional Review Board (IRB). The IRB operates according to the guidelines in the Code of Federal Regulations (45 CFR 46) and other state and institutional guidelines.

What does the IRB do?

It is the responsibility of the IRB to review research protocols involving human participants to ensure that the rights of the participants are protected, that they are not subject to unreasonable harm (physical and emotional), and that information about them is kept confidential.

What is research?

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Please note: The following activities are deemed not to be research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- 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. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- 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 investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions..

What is a human subject?

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject. This includes online surveys.

How do I know if I should submit a research protocol to the IRB?

If your research project (including observation, interviews and surveys) involves human participants, you must submit an IRB protocol, even if you believe the research is exempt..

When should I submit my review request to the IRB?

You may submit your request at any time, but you must receive IRB approval before you begin recruiting participants or collecting data. For a full board review, please submit your request 2 weeks prior to the next scheduled IRB meeting date. The IRB convenes on the first Wednesday of the month during the academic year.

What do I submit?

You should submit an IRB request that includes the appropriate request form, an informed consent form or survey cover letter, training certifications for all researchers involved, and any tests, surveys, or interview questions you will be using in your study.

There are several types of IRB review and specific request forms for each type of review. Details regarding the types of review and the required request forms can be found [here](#).

What is informed consent?

Both written consent and verbal consent for participation in research must involve an informed consent process. Informed consent involves an education and information exchange that takes place between the researcher and the potential subject.

Sometimes the information to be imparted to potential subjects is complex or possibly distressful and may require some time for it to be absorbed and appreciated. In these circumstances, the researcher should present the information and discuss the issues with potential subjects on more than one occasion, or allow a period of time to elapse between imparting the information and requesting a signature on the consent form. During this waiting period, potential subjects should be encouraged to discuss their possible participation with family members, close friends, or trusted advisors. With IRB approval, other approaches to communicating complex information can be used, including the use of audio-visual materials and brochures.

Informed consent is not merely a document to be signed or handed to the research subject. It is an ongoing process meant to keep your subject informed of the risks and expectations of your research.

To whom do I submit my request?

IRB review requests must be submitted via [Cayuse Human Ethics \(formerly Cayuse IRB\)](#).

What happens after I submit my IRB protocol?

After you, all Co-PIs and faculty advisors certify your study in Cayuse, it routes to an IRB analyst for pre-review. It is then either assigned for review or returned if revisions are necessary prior to review. You will receive an email with either suggestions for further revision, or a determination (exempt, approved, not approved, etc.) Once a determination is reached, a letter will be emailed to you. A copy will be filed with your study in Cayuse.

The type of IRB review dictates the length of time necessary for a decision. Exempt, Exempt-Limited, and Expedited Review studies may be reviewed within two weeks of receipt of a complete and accurate protocol, depending on the number of issues with the protocol and the IRB's availability. Full Board Review protocols are reviewed at the monthly IRB meetings. The IRB convenes on the first Wednesday of the month during the academic year. Protocols requiring full board review should be submitted at least two weeks prior to the IRB meeting.

How will I be notified of the status of my request?

You will receive an email requesting revisions or explaining the determination (exempt, approved, not approved, etc.). Once a determination is reached, a letter will be emailed to you and a copy will be filed within your study in Cayuse.. Please retain the determination letter for your records.

What is the best way to prepare my IRB Review request?

You should work closely with your faculty advisor (if you are a student) well in advance of beginning the actual research. It will be important for all researchers to apply what you learned in the CITI online training course when you complete your IRB proposal.

Revision #16

Created 2025-11-21 19:51:49 UTC by Luna Acosta

Updated 2026-05-07 18:59:59 UTC by Gregory Umhoefer