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Institutional Research

I. Policy Statement and Purpose

Athens State University is primarily a teaching institution. However, research is one of the three primary elements of the University's mission. The University advances the best interests of its students and the State of Alabama through teaching, service, research and other creative activities to empower students to make valuable contributions to their professional, civic, educational and economic endeavors.

In accordance with the University's mission, this policy establishes the standards associated with Athens State University's commitment to the protection and safety of human subjects involved in research. The University will adhere to the principles set forth in the Belmont Report located at *U.S. Department of Health and Human Services - Belmont Report*. In addition, the University establishes this policy for the purpose of creating supplemental guidelines that Athens State personnel (employees and students) will follow to ensure compliance with the federal regulations, policies, and procedures that govern human subject research. The standards are based on comparable practices at other institutions of higher education. Further, this policy provides a process for impartial fact finding and fair adjudication of allegations of research misconduct.

All employees and students of the University are committed to creating an environment that promotes ethical conduct and integrity in research and scholarly activities.

This policy applies to all employees, students, vendors/contractors, and all other individuals participating in any research and/or scholarly activity within the scope of the authority of the University's administration, faculty, or staff.

This policy will apply to research activities that contribute to general and specific knowledge that forms the complete body of knowledge in various fields of study. Research includes, but is not limited to, research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. This policy does not apply to classroom activities conducted by University employees or students as part of normal classroom procedures (i.e., opinion surveys). The *Student Code of Conduct and Discipline* policy governs matters related to classroom academic integrity violations and is distinct from this policy. Activities conducted by faculty and students outside of the classroom, or with the intent to publish, including but not limited to the administration of surveys are subject to this policy.

This policy does not apply to some activities that involve interactions with humans and data gathering that may not meet the definition of research because the information is designed to accomplish something else, such as program improvement. The project may be systematic, but is not considered research because the intent is to improve a process or service, rather than contribute to a body of knowledge (i.e., library survey of an academic unit to see if the library is meeting the unit's needs). These types of projects/surveys must be administered through the Office of Institutional Research and Assessment.

II. Definitions

Adverse Event: Any undesirable and unintended event that involves human subjects which could be reasonably related to participation in the study, regardless of whether it was listed on the informed consent document as an expected risk.

Generalizable Knowledge: The knowledge that is expressed in theories, principles, and statements of relationships that can be widely applied to our experiences. Generally, the term is used to refer to the intent to disseminate the research results and conclusions beyond an individual or internal group.

Greater than Minimal Risk: A probability and magnitude of harm or discomfort to a human subject exceeding that defined as minimal risk (as determined by the element or elements of greater risk).

Human Subject: Federal regulations define a human subject as a living individual about whom an investigator (faculty, staff or student) conducting research obtains (a) data through intervention or interaction with the individual or (b) identifiable private information. *Intervention* includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Other *interactions* include communication or interpersonal contact between the investigator and the subject. *Private Information* includes data about behavior that occurs in a context in which the individual will have provided the information for specific purposes and reasonably expects that the information associated with his/her identity will not be made public [45 CFR 46.102].

Informed Consent: Informed consent is understood to mean that the investigator has obtained documented permission from the participant(s) to conduct the research, and that the participant(s) have full foreknowledge about the nature of the research, any benefits, the risks and procedures involved, and the potential side effects or repercussions involving his/her well-being, physical and personal integrity and social standing.

Institutional Review Board (IRB): A committee, reporting to the Provost/Vice President for Academic Affairs, established to ensure that the University follows federal and state guidelines on the protection of human subjects involved in research. Members of the IRB are responsible for reviewing research applications. Only the full IRB is responsible for conducting review of full research applications.

IRB Administrator: The individual responsible for assisting investigators with mandatory online training and the IRB application process. This individual will be responsible for conducting review of exempt research applications.

IRB Committee Chair: The individual responsible for convening and chairing IRB meetings, preparing and executing the agenda and ensuring that the attendance at the prospective meetings will provide adequate review of all proposals.

IRB Sub-Committee: A sub-set of the full IRB that will be responsible for conducting reviews of expedited research applications.

IRB Approval: The determination of the IRB that the research has been reviewed and may be conducted at the University within the constraints set forth by the IRB and by other institutional and federal requirements. [45 CFR 46.102(h)).

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Principal Investigator: individual desiring to conduct research and publish findings. Primary responsibility for assuring that the rights and welfare of the individuals involved are protected continues to rest with principal investigators conducting the research. This responsibility is shared by others engaged in the conduct of the research. Faculty who assign or supervise research conducted by students have an obligation to consider carefully whether those students are qualified to safeguard adequately the rights and welfare of subjects.

Research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102]

Research Misconduct: Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

a. **Fabrication** is making up data or results and recording or reporting them.
b. **Falsification** is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
c. **Plagiarism** is the appropriating of another person's ideas, processes, results, or words without giving appropriate credit.
d. Research misconduct does not include honest error or differences of opinion.

Unanticipated Problem: Any incident, experience, or outcome involving risks to subjects or others that is unexpected (in terms of nature, severity, or frequency), not foreseen, or not previously described in the research protocol or informed consent form.

III. Levels of IRB Review

LEVEL 1: EXEMPT

Research activities in which the only involvement of human subjects will be in one or more of the following categories and that do not involve vulnerable populations are exempt. Exempt applications will be reviewed by the IRB Administrator.

Exempt 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.

Exempt 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:

Exempt 2(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;

Exempt 2(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

Exempt 2(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).

Exempt 3**(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:

Exempt 3 (i)(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;

Exempt 3(i)(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

Exempt 3(i)(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).

Exempt 3(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.

Exempt 3(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.

Exempt (4) 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:

Exempt 4(i) The identifiable private information or identifiable biospecimens are publicly available;

Exempt 4(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;

Exempt 4(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

Exempt 4(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.*

Exempt 5 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.

Exempt 5(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.

Exempt 6 Taste and food quality evaluation and consumer acceptance studies:

Exempt 6(i) If wholesome foods without additives are consumed, or

Exempt 6(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.

Exempt 7 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).

Exempt 8 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:

Exempt 8(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);

Exempt 8(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

Exempt 8(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.

LEVEL 2: EXPEDITED

Research activities involving minimal risk and in which the only involvement of human subjects will be, in any of the following categories, considered under the expedited review procedure. Expedited applications will be reviewed by the IRB Sub-Committee.

1. Collection of data from voice, video, digital, or image recordings made for the research purposes.
2. Moderate exercise by health volunteers.
3. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
4. 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 subjects' behavior and the research will not involve stress to subjects.
5. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

LEVEL 3: FULL

Research activities involving more than minimal risk, sensitive or identifiable information, and/or vulnerable subjects must undergo a full IRB review. Vulnerable subjects include children under 18 years old, prisoners, pregnant women, mentally/cognitively impaired persons, economically/educationally disadvantaged persons, and any subjects likely to be vulnerable to coercion or undue influence.

IV. IRB Committee Composition and Meetings

The IRB will be appointed to serve a two-year term by the Provost/Vice President for Academic Affairs and will consist of a minimum of five members with varying backgrounds. The Provost/Vice President for Academic Affairs will appoint the IRB Administrator and the Chair of the IRB. Committee membership shall include, but is not limited to, 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 member who is not otherwise affiliated with the University.

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

The IRB will meet as needed to review proposals, review progress reports, generate committee reports or conduct business. Proposed research will be reviewed at convened meetings at which a majority of the members of the IRB are present. In order for research to be approved, it shall receive the approval of a majority of those members present at the meeting [45 CFR 46.108]. The IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals will be non-voting.

Minutes of IRB meetings will show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussions of controverted issues and their resolution.

V. Application/Review Process

All research conducted at or sponsored by the University that involves human subjects must be approved prior to research initiation. The IRB will be responsible for reviewing the three levels of research: **Exempt, Expedited, and Full.** Expedited applications will be reviewed by the IRB Sub-Committee. Exempt applications will be reviewed by the IRB Administrator. Full applications will be reviewed by the full IRB.

A main goal of the review is to determine if the research activities adhere to the ethical treatment of participants as required by federal guidelines and University requirements. The IRB has the authority to approve, disapprove, or require project modification. Approval must be obtained from the Provost/Vice President for Academic Affairs and the IRB prior to conducting any research. No research activities may be started without IRB review and approval.

Individuals responsible for conducting research are required to complete **mandatory** online training modules. Final approval to conduct research will not be granted until all required training modules have been completed.

The following process must be followed when seeking approval to conduct research:

1. The investigator must determine the level of research to be conducted and complete either the *Application for Institutional Research (Full or Expedited)* **OR** the *Application for Institutional Research Exemption.*
2. The investigator must complete the initial **mandatory** training to include 1) Belmont Report and CITI Course Introduction, 2) History and Ethical Principles, 3) Defining Research with Human Subjects and 4) The Federal Regulations. Additional training may be required by the IRB after review of the application. Information regarding access to the training modules may be obtained from the IRB Administrator.
3. The investigator must submit the completed application packet and mandatory training verification to the Provost/Vice President for Academic Affairs. The application packet includes, but is not limited to, 1) application, 2) proposed informed consent, 3) relevant grant applications, and 4) any recruitment materials.
4. Within five (5) business days of receipt, the Provost/Vice President for Academic Affairs will forward the application packet to the IRB Administrator.
5. **Exempt Review**: Within two (2) business days, the IRB Administrator will review the exempt application.
   Expedited Review: Within three (3) business days, the IRB Administrator will contact the IRB Chair to convene a sub-committee meeting to review the expedited application.
   Full Review: Within five (5) business days, the IRB Administrator will forward the full application electronically to the IRB Committee chair. The IRB Committee chair will distribute to the full IRB and will convene a meeting within five (5) business days to conduct the initial review of the application.

   - **Full application review** may take up to 20-30 business days
   - **Expedited application review** may take up to 5-10 business days
   - **Exempt application review** may take 3-5 business days**.**
6. The IRB Administrator will communicate, in writing, the final decision to the investigator and the Provost/Vice President for Academic Affairs. The IRB's response will be:
   - approve the application with no revision needed, OR
   - approve the application provided that documented areas of concern are addressed, OR
   - reject the application and provide a rationale as to why the application was rejected.

7. Questions and/or approved application will be sent to the email address that is provided on the application.
8. The IRB Administrator will forward application and supporting documentation to the Office of the Provost/Vice President for Academic Affairs to be stored in a secure location. All records shall be retained for at least three (3) years and records relating to the research which is conducted shall be retained for at least three years after the completion of the research. [45 CFR 46.115].

Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects shall be retained for at least three (3) years in the Office of the Provost/Vice President for Academic Affairs. Further, records of continuing review activities and copies of all correspondence between the IRB and the investigators will be retained in the Office of the Provost/Vice President for Academic Affairs for at least three (3) years.

VI. Criteria for IRB Approval of Research

In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable. The IRB will be particularly cognizant of the special problems of research involving vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent is sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent is appropriately documented.
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects (when appropriate)
7. Adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

VII. Rights of Appeal

If research is disapproved, suspended or terminated, the investigator may appeal the decision, in writing, to the Provost/Vice President for Academic Affairs within five (5) calendar days. Within five (5) calendar days of receipt of appeal, the Provost/Vice President for Academic Affairs will meet with the IRB Administrator, the IRB Committee Chair and the principal investigator. Final decision of appeal rests with the Provost/Vice President for Academic Affairs. The Provost/Vice President for Academic Affairs will notify the IRB

Administrator, the IRB Committee Chair, and the principal investigator, in writing, the final decision within five (5) calendar days of the aforementioned meeting.

VIII. Continuing Review

Investigators are responsible for reporting project changes, project termination or completion to the IRB Administrator within ten (10) calendar days utilizing the *appropriate* form(s).

Project Review
The continuing review date will be determined and noted on the initial approved application for research. Prior to the review date, the IRB Administrator will solicit, from the principal investigator, a progress report that will be reviewed by the full IRB.

All projects deemed to be exempt from review will not require continuing review provided that there are no changes in research design or methodology.

When conducting continuing review and evaluating whether research continues to satisfy the criteria for IRB approval of research or if the project should be reviewed more than annually, the IRB will review the following aspects of the research:

- Risk assessment and monitoring;
- Adequacy of the process for obtaining informed consent;
- Investigator and institutional issues; and
- Research progress

Following the review, the IRB Administrator will complete the *Certification for Annual Project Review* form and forward a copy to the investigator, the IRB Committee Chair, and the Provost/Vice President for Academic Affairs.

If the IRB determines that the research should be suspended or terminated, the IRB Administrator will complete the *Certification for Project Suspension/Termination* form providing the rationale for the suspension or termination. Copies of this form will be sent to the principal investigator, the IRB Committee Chair, and the Provost/Vice President for Academic Affairs.

Project Changes

The full IRB will review any changes in projects involving human subjects. Investigators are responsible for submitting the *Certification for Project Changes* form to report changes and requesting review of the changes for continuing IRB approval. The IRB has the authority to approve, deny or request modifications to the requested project changes. Copies of this form,

indicating approval of project changes, will be sent to the principal investigator, the IRB Committee Chair and the Provost/Vice President for Academic Affairs.

No project changes may be implemented without approval of the full IRB. If changes are implemented without IRB approval, the IRB has the authority to suspend or terminate the research.

Project Suspension/Termination

Following any review, should the IRB determine that the research be suspended or terminated, the IRB Administrator will complete the *Certification for Project Suspension/Termination* form providing rationale for the suspension or termination. Copies of this form will be sent to the principal investigator, the IRB Committee Chair, and the Provost/Vice President for Academic Affairs. Within thirty (30) calendar days of notification, the Provost/Vice President for Academic Affairs, will report the suspension/termination to the Office for Human Research Protections (OHRP). (*See Section VII Rights of Appeal)*

Project Completion

Within ten (10) calendar days of completion of the research, the principal investigator must submit the *Certification for Project Completion* form to the IRB Administrator. The IRB Administrator will confirm the completion of the project, close the IRB file and forward all research documents to the Office of the Provost/Vice President for Academic Affairs. The IRB Administrator will forward copies of the completion form to the principal investigator, the IRB Committee Chair and the Provost/Vice President for Academic Affairs.

IX. Reporting Unanticipated Problems and Adverse Events

An unanticipated problem includes any untoward sign, result, event, misadventure, injury, dysfunction, adverse drug reaction, or any other undesirable happening or unanticipated problem that involves risks to subjects or others not previously reported, and that could reasonably be related to the activities of the study.

All unanticipated problems and serious adverse events shall be reported in writing to the IRB Administrator within seven (7) calendar days. The IRB Administrator will notify the IRB Committee Chair and the Provost/Vice President for Academic Affairs within seven (7) calendar days of receiving the written report. Within seven (7) calendar days, the IRB Committee Chair will convene the full IRB to review the report and notify the Provost/Vice President for Academic Affairs of the decision. Within seven (7) calendar days of notification, the Provost/Vice

President for Academic Affairs will submit an official report to the Office of Human Research Protections (OHRP).

Based on the findings in the report, the IRB has the authority to suspend, terminate or require modification to the research project.

X. Informed Consent

Informed consent is an ongoing process. The Informed Consent form must be completed by each participant involved in research. The Informed Consent document must be approved by the IRB and signed by the participant or the participant's legally authorized representative. A copy of the signed document will be given to the participant and the original retained with the research documentation.

An investigator must retain the signed consent document for at least three (3) years past the completion of the research activity in accordance with and to the extent required by 45 CFR 46.117.

XI. Research Misconduct

Please refer to the *Institutional Research Misconduct* policy.

XII. Responsibility for this Operating Policy

Policy Owner

As part of the initial approval of this policy by the President and subsequent to the original dissemination of the policy, the Provost/Vice President of Academic Affairs is the policy owner for the ongoing evaluation, review, and approval of this policy. Subsequent reviews and revisions to this policy must be in accordance with approved operating policy procedures and processes.

This policy will be reviewed every two years or more frequently as needed by the Policy Owner. Revisions will be reviewed/affirmed by the Faculty Senate and the Cabinet and approved by the University President. This policy will be updated/published in the University's Policy Library.

Responsibility for Policy Implementation

The President has assigned the responsibility of implementing this policy to the Institutional Review Board, under the direction of the Provost/Vice President of Academic Affairs.