JACKSONVILLE STATE UNIVERSITY

Manual of Policies and Procedures

POLICY NUMBER: II:08:01 **DATE: January 1, 1988**

REVISION/REVIEW DATES: May 1997, Dec 2002, Aug 2008, Oct 2011, Mar 2015, July 2021, August 2026

SUBJECT: Research Involving Human Subjects

APPROVED: Dr. Don C. Killingsworth, Jr., President

SCOPE AND PURPOSE OF INSTITUTIONAL REVIEW BOARD

The primary purpose of the Institutional Review Board (IRB) is to protect the rights and welfare of human subjects involved in research activities being conducted under the authority of Jacksonville State University (JSU). All research involving human subjects conducted at JSU or under the aegis of the University, irrespective of funding source, must be reviewed, approved, and monitored by the IRB. The IRB operates in accordance with JSU Policy on Research Involving Human Subjects (Policy II:08:01) and federal regulations (45 CFR 46 Protection of Human Subjects).

JSU's Human Research Protection Program (HRPP) operates under an active Federalwide Assurance (FWA) approved by OHRP, and the JSU IRB is registered with OHRP; current identifiers are posted on the JSU IRB website. Federal funds may not be obligated or expended for non-exempt human subjects research for any period not covered by both an FWA and IRB approval consistent with 45 CFR Part 46 (NIH Grants Policy Statement § 4.1.15). The HRPP adheres to the Common Rule (45 CFR Part 46, Subpart A) and its additional protections for pregnant women, human fetuses, and neonates (Subpart B); prisoners (Subpart C); and children (Subpart D). Research involving FDA-regulated products must additionally comply with FDA regulations (21 CFR Parts 50 and 56), and research involving protected health information (PHI) must comply with the HIPAA Privacy Rule.

This policy applies to all human subjects research conducted by JSU faculty, administrators, staff, students, trainees, agents, contracted consultants, and collaborators whenever JSU is engaged in the research (as described in OHRP engagement guidance), regardless of funding source or performance site. All research involving human subjects conducted at JSU or under the auspices of the University must be reviewed and approved by, or receive a documented exempt or not-human-subjects-research determination from, the JSU Institutional Review Board (IRB) before the research begins, and must be monitored by the IRB for the duration of the research.

Information on IRB procedures, criteria for review, application forms, and required research involving human subjects training is available at http://www.jsu.edu/academicaffairs/irb.html. Federal regulations pertaining to protections for human subjects can be accessed at https://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html. Questions regarding research involving human subjects at JSU may be directed to the Office of Institutional Research and Effectiveness or to the Institutional Review Board located in 203 Angle Hall.

INSTITUTIONAL RESPONSIBILITIES

Jacksonville State University, through the Institutional Review Board (IRB) and the Office of Institutional Research and Effectiveness, maintains centralized administrative oversight and legal responsibility for all research involving human subjects conducted under the authority of the University. The institution is responsible for maintaining complete official records of submitted protocols, amendments, and reportable events; ensuring IRB members and researchers receive appropriate training in ethical standards; conducting post-approval monitoring or compliance reviews; and exercising institutional authority to suspend, terminate, or require modifications to any research activity that fails to comply with federal regulations (45 CFR 46), institutional policy, or IRB determinations.

Institutional Official (IO). The Provost and Executive Vice President for Academic Affairs (or designee) serves as the Institutional Official, bearing institutional authority and responsibility for the HRPP, including signing the FWA, ensuring adequate resources for the program, and safeguarding the independence of the IRB.

Human Protections Administrator (HPA). The Assistant Vice Provost of the Office of Institutional Research and Effectiveness serves as the Human Protections Administrator, providing day-to-day operational oversight of the HRPP and serving as the primary institutional contact for human subjects protections.

IRB Office. The IRB Office is housed in Academic Affairs (IRB@jsu.edu; 203 Angle Hall) and publishes procedures, forms, guidance, and annual reports on the JSU IRB website.

IRB COMMITTEE RESPONSIBILITIES

The IRB Human Subjects Review Board is composed of at least 8 voting members, including the Chair, appointed by the President pursuant to the regulations (45 CFR 46.107) and the Faculty Handbook. Members will come from diverse academic disciplines, at least one scientific and one nonscientific, that collectively represent the university. The committee will include at least one external member. A quorum for a convened meeting consists of a majority of the IRB's members, including at least one member whose primary concerns are in nonscientific areas, and research may be approved only by a majority vote of members present (45 CFR 46.108(b)).

All IRB members must complete protections for human subjects training prior to participating in protocol review. JSU requires completion of the CITI Program training courses: Social & Behavioral Research and Social and Behavioral Responsible Conduct of Research. The IRB Chair will provide onboarding for new members as well as additional opportunities for training to ensure effective and informed review. JSU requires the IRB Chair to take additional CITI Program training courses including: The IRB Chair and Revised Common Rule.

PRINCIPAL INVESTIGATORS RESPONSIBILITIES

Principal Investigators (PIs) retain primary responsibility for the ethical conduct of research and ongoing regulatory compliance. Following initial approval, PIs must fulfill the following obligations:

- **CITI Training:** Prior to involvement in human subjects research, investigators and study team members must complete CITI training (Social & Behavioral Research and Social and Behavioral Responsible Conduct of Research) and maintain currency as specified by the IRB. More information about training can be found on JSU's IRB website.

- **Adherence to Approved Protocols:** Research must be conducted strictly as approved by the IRB. No changes to study procedures, instruments, or consent processes may occur without prior IRB authorization, except where necessary to eliminate apparent immediate hazards to subjects.
- **Reportable Events and Unanticipated Problems:** PIs must report to the IRB, in writing at irb@jsu.edu, any unanticipated problems involving risks to subjects or others, adverse events, protocol deviations, or potential noncompliance with this policy, the approved protocol, or 45 CFR Part 46. Events involving actual harm to a subject must be reported immediately upon the PI becoming aware. All other reportable events must be reported within five (5) business days of the PI becoming aware.
- **Cooperation with Compliance Review:** PIs must provide the IRB, upon request, with access to research records, data, and documentation associated with the approved protocol, including access to original source systems where applicable, to support the IRB's ongoing oversight responsibilities (45 CFR 46.109(a), (g)).
- **Continuing Renewal:** Research requiring review by the convened IRB (full board review) must undergo continuing review at least annually, unless the research qualifies for an exception under 45 CFR 46.109(f). Federal regulations do not permit the IRB to waive this requirement or grant an extension for full board studies. If the protocol is not reviewed and approved by the expiration date, all aspects of the human participants' research must stop until the continuing renewal application is submitted, reviewed, and approved by the IRB. Research eligible for expedited review does not require annual continuing review unless the IRB determines otherwise for that specific study. Exempt research does not require continuing review.
- **Amendments or Changes to Approved Research:** A modification is defined as any change to a protocol from what was previously approved during the period for which approval has already been given. Changes of any kind in research procedures, the recruitment process, the recruitment instruments, the informed consent/assent process, and/or to the consent/assent document cannot be initiated by the investigator prior to IRB review and approval, except where necessary to eliminate apparent immediate hazards to human participants (45 CFR 46.108(a)(3)(iii)). Please notify the IRB immediately if there are any changes to the approved protocol at irb@jsu.edu.

- **Study Completion:** Research subject to continuing review under this policy must be closed out with the IRB prior to expiration of approval, by written notification confirming that all approved procedures have concluded and indicating the disposition of any identifiable data or biospecimens retained. Research not subject to continuing review may be allowed to lapse; the IRB will administratively close such studies upon expiration of the approval period. Please notify the IRB in writing once the study concludes at irb@jsu.edu.

REPORTING AND RECORDS

IRB policies, application materials, and annual reports are publicly available on the JSU IRB website. The JSU Institutional Review Board (IRB) maintains all required documentation associated with protocol review and oversight, including research applications, consent materials, correspondence, meeting minutes, amendments, and reportable events; this documentation is retained for the period required by federal regulations and institutional policy. Under federal Common Rule guidelines (45 CFR 46) and FDA regulations (21 CFR 56.115), IRB records must be retained for a minimum of three years after a study's closure, or longer when required by sponsor contracts or state law. When research involves protected health information (PHI), HIPAA requires that relevant compliance documentation be retained for at least six years from the date of creation or last effective date. Because multiple regulatory frameworks may apply simultaneously, most IRB records at JSU are retained for a minimum at least six years after study closure, or longer where required by regulation, sponsor, or state records schedules. Records will be accessible for inspection and copying by authorized federal representatives (45 CFR 46.115(b)).

POLICY VIOLATIONS

The IRB has authority to review, approve, require modifications to secure approval, or disapprove all research activities covered by this policy (45 CFR 46.109(a)). The IRB has authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects (45 CFR 46.113).

As part of its ongoing oversight responsibilities, the IRB Chair may request access to any records, data, correspondence, or other documentation associated with an IRB-approved protocol, including original source records, at any time during or after the conduct of the research, to assess compliance with the approved protocol, this policy, or 45 CFR Part 46. Investigators must provide requested records and reasonable access to underlying source systems promptly upon request (45 CFR 46.109(a), (g)).

If the IRB Chair determines that research participants are at risk, or that the integrity of an investigation could be compromised, while a noncompliance review is pending, the Chair may direct the investigator to suspend some or all research activities pending resolution of the matter. Any interim suspension referred to by the convened IRB will be reported at its next meeting, along with the basis for the action.

- **Reporting.** Any individual who becomes aware of a possible violation of the approved protocol, this policy, or 45 CFR Part 46 must report the matter promptly to the IRB Chair or the IRB Office at irb@jsu.edu. When a report is made by someone other than the investigator, the confidentiality of the reporter's identity will be maintained and will not be disclosed to the individuals involved in the matter, except where disclosure is necessary to conduct the investigation or is otherwise required by law.
- **Investigation.** Upon receipt of a report, the IRB Chair will conduct an initial assessment and depending on the complexity of the matter, may investigate directly or convene a subcommittee to do so. The IRB Chair's investigation report and any supporting documentation will be provided to the convened IRB for its review.
- **Minor Noncompliance**. If the IRB Chair determines that a matter constitutes minor noncompliance, the Chair may resolve the matter directly with the investigator, including requiring corrective action, without referral to the convened IRB. The investigator will be notified in writing of the determination and any required corrective action. If the investigator disputes the determination, or if the Chair determines the matter should receive further review, the matter will be referred to the convened IRB under the procedure below.

- **Serious or Continuing Noncompliance**. If the IRB Chair determines that a matter may constitute serious or continuing noncompliance, or if there is uncertainty about the appropriate classification, the matter will be referred to the convened IRB. Before the matter is presented to the convened IRB, the investigator will be given written notice describing the concerns and no fewer than ten (10) business days to submit a written response, and will be invited to attend the convened IRB meeting at which the matter is reviewed.
- **Determination.** The convened IRB will determine whether the matter constitutes serious or continuing noncompliance. Upon such a finding, the IRB may take any action reasonably calculated to protect the rights and welfare of subjects and bring the research into compliance, including requiring corrective action, modifying the terms of approval, or suspending or terminating approval of the research. Any suspension or termination will include a statement of the reasons for the action and will be reported promptly to the investigator, appropriate institutional officials, and the department or agency head, as applicable (45 CFR 46.113).
- **Corrective Action.** Any corrective action required under this section, whether by the IRB Chair for minor noncompliance or by the convened IRB for serious or continuing noncompliance, will include a defined timeframe for implementation. The investigator is responsible for ensuring the corrective action is completed within that timeframe and for providing documentation to the IRB confirming completion. Failure to complete the required corrective action within the specified timeframe may result in further review by the convened IRB and additional action, including suspension or termination of approval.
- **External Reporting.** The IRB Chair will ensure prompt reporting of any unanticipated problems involving risks to subjects or others, any serious or continuing noncompliance, and any suspension or termination of IRB approval to appropriate institutional officials and, where required under JSU's Federalwide Assurance, to the Office for Human Research Protections and the relevant funding agency or sponsor (45 CFR 46.108(a)(4)).
- **Conflicts.** Conflicts of interest arising in the course of a noncompliance review are addressed under the Conflict of Interest section of this policy.

- **Referral to Other Processes.** Where an investigation under this section identifies information suggesting possible research misconduct or a violation of academic integrity, the matter will be referred to the appropriate office under JSU's Scholars' Code, Code of Student Conduct, or Misconduct in Research and Other Scholarly Activities Policy (II:06), as applicable. Such referral is independent of, and does not require completion of, IRB review under this section, and findings under this policy are limited to human subjects protections.
- **Appeal.** An investigator who disagrees with the determination under this section may appeal in writing to Human Protections Administrator within ten (10) business days of receiving notice of the determination. The appeal must identify the specific finding or action being appealed and the basis for the appeal.

CONFLICT OF INTEREST

IRB members and the Human Protections Administrator must disclose any real or perceived conflict of interest related to a study under review. Members with a conflict may provide information or answer questions at the request of the IRB but will not participate in review of the application and must leave the meeting during final discussion and vote (45 CFR 46.107(e)). For purposes of IRB member recusal, a conflict exists under the criteria below regardless of whether the interest meets the Significant Financial Interest threshold in Policy I:01:15.

- The member or an immediate family member or business interest may benefit financially from the research.
- The member is an immediate family member or close colleague of the principal investigator.
- The member is the principal investigator or is otherwise involved as part of the research team.
- The member serves as a supervising faculty member for a student investigator on the study.

Investigators must disclose significant financial interests related to proposed human subjects research in accordance with JSU Policy I:01:15 (Financial Conflict of Interest for Sponsored Projects). The IRB may require disclosure of investigator conflicts to participants during the consent process, independent oversight, or other management measures as a condition of approval. Investigator financial conflicts identified during IRB review will be referred to the Office of Sponsored Programs.

Other potential conflicts of interest outside the scope of this policy will be considered on a case-by-case basis by the IRB chair, and the Human Protections Administrator, if necessary. If the IRB Chair and/or Human Protections Administrator has a conflict of interest, an experienced member, to be designated by the IRB Chair or HPA, will lead the review. Consultants with conflicts of interest are prohibited from participating in the review of the affected study.

STUDENT RESEARCH

Student research and the use of students as research participants require special consideration under this policy. Because this policy applies to all activities that meet the definition of research involving human subjects at JSU, it applies equally to student-led projects.

Student Projects Not Requiring IRB Review: Course-based projects—including action research, practitioner inquiry, quality improvement plans, professional development projects, and leadership presentations—are not considered research involving human subjects and are not required to undergo IRB review when they meet all of the following conditions:

- **Instructional or Operational Intent:** The project is conducted solely to fulfill a course requirement, demonstrate practical application, or address an internal school, district, or workplace problem (e.g., a school improvement plan or professional development proposal).
- **No External Academic Dissemination:** There is no intent to publish findings in a journal, archive them in a public research repository, or present them at an external academic or professional conference. The project does not contribute to generalizable knowledge.
- **Limited Audience:** Presentations or reports are strictly limited to instructors, classmates, campus symposia, or local workplace stakeholders (such as a local school board, department head, or district in-service) solely for course credit or operational feedback.
- **No Identifiable Data or Direct Interaction:** The activity does not involve direct interaction with, or the collection of identifiable information about, any individual participant. Use of unidentifiable or aggregate data, or a project's occurrence within a setting that includes vulnerable populations (e.g., a K-12 school), does not by itself trigger this condition.
- **Minimal Risk:** The project poses no more than minimal risk to participants and does not collect sensitive, identifiable private information where disclosure could pose legal, financial, employment, or reputational harm.

Instructors may screen whether an activity appears instructional-only, but determinations that a project is non-research or exempt are made by the IRB, not the instructor. Uncertain cases must be routed to the IRB Office.

Student Projects Requiring IRB Review: IRB submission and approval prior to initiating data collection is required if a student project involves identifiable information from, or direct interaction with, participants, elevated risk, sensitive identifiable private data, or an intent to publish, publicly archive, post, or present findings at an external academic or professional conference. Any student project that constitutes research involving human subjects must be submitted to the IRB for formal review and determination prior to data collection, even if the investigator believes the project qualifies for Exempt status.

Exempt status means the project has been determined by the IRB to qualify for exemption from full board review procedures under 45 CFR 46.104 — it does not mean the project is exempt from IRB oversight altogether, or that the investigator may self-determine exempt status.

Research Involving Students or Supervisees: Neither course instructors nor workplace supervisors may directly recruit their own students or direct supervisees without prior IRB review and approval of specific recruitment safeguards. IRB protocol applications involving dual-role relationships must describe how prospective participants will be protected from coercion or undue influence, incorporating measures such as third-party administration of surveys/consent, anonymous data collection, or equal non-research alternatives for course credit.

DEFINITIONS OF TERMS

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(l)). Under federal regulations, research involving human subjects is classified into three distinct categories - exempt, expedited, and convened full board. Detailed criteria and examples for each review category — exempt research (45 CFR 46.104), expedited review (45 CFR 46.110), and full board review conducted at a convened meeting (45 CFR 46.108(b)) — are maintained on the JSU IRB website and updated as needed to reflect current federal guidance. Research involving children is reviewed in accordance with 45 CFR Part 46, Subpart D; review categories (exempt, expedited, or full board) is determined by risk category and regulatory criteria, not participant age alone.

Human subjects are defined as living individuals about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) 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 the investigator and the subject.

Private information includes 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. *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 (45 CFR 46.102(e)(1)–(6)).

Informed Consent is the process by which a participant voluntarily agrees to take part in a study after being provided with clear information about the purpose, procedures, duration, risks, benefits, confidentiality, and the voluntary nature of participation. Consent must be written in language understandable to the participant and must allow time for questions before deciding. Documentation of consent is required unless the IRB approves a waiver or alteration. When research involves individuals who cannot legally provide consent, parental permission and/or participant assent is required in accordance with IRB guidance. Requirements for informed consent, including required disclosure elements, are set out at 45 CFR 46.116; documentation of consent, and any waiver of documentation, are addressed at 45 CFR 46.117.

Minimal Risk in research is defined as harm or discomfort of no greater probability and magnitude than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests (45 CFR 46.102(j)).

Vulnerable Populations are groups of individuals who may have limited capacity to fully understand research participation or to freely provide informed consent due to diminished autonomy, compromised decision-making, increased susceptibility to coercion or undue influence, or heightened risk of harm from research involvement. These groups require additional safeguards to ensure protection of their rights and welfare. The following are recognized as vulnerable populations: children and minors; prisoners; pregnant individuals, fetuses, and neonates; individuals with cognitive or decision-making impairments; and individuals who are economically or educationally disadvantaged (45 CFR 46.111(b); 45 CFR Part 46, Subparts B, C, and D).

Noncompliance is a failure by an investigator or research team member to comply with the requirements of 45 CFR Part 46, institutional policy, or the requirements or determinations of the IRB, including deviation from the terms of an IRB-approved protocol. Noncompliance may result from action or omission and may be minor, serious, or continuing.

Minor Noncompliance is an isolated instance of noncompliance that does not affect the rights or welfare of participants, does not place participants at risk, and does not reflect deliberate disregard of applicable regulations or IRB requirements.

Serious Noncompliance is noncompliance that places participants at more than minimal risk, compromises the rights or welfare of participants, or reflects deliberate disregard of applicable regulations or IRB requirements or determinations.

Continuing Noncompliance is a pattern of noncompliance, whether minor or serious, occurring over time or across research projects, that indicates the noncompliance is likely to continue absent intervention.

RESPONSIBILITY

The Assistant Vice Provost of the Office of Institutional Research and Effectiveness.

EVALUATION

This policy will be reviewed at least every five (5) years.