



UNIVERSITY POLICY SR-10.00-04/26

TO: The University of West Florida Community

FROM: President Manny Diaz, Jr.

SUBJECT: Protection of Human Research Subjects

RESPONSIBLE OFFICE: Research Administration and Engagement

I. Purpose:

The University is committed to safeguarding the rights, safety, and welfare of all human subjects participating in research engaged by the University.

II. Definitions:

Engaged in Human Subjects Research – The University is considered engaged in human subjects research when University faculty, staff, students, or agents for the purposes of the research obtain: (1) data about human participants of the research through intervention or interaction with them; (2) identifiable private information about the human participants of the research; or (3) the informed consent of human participants for the research. The University follows the Office for Human Research Protections guidance to apply this definition.

Human Subject: A living individual about whom an investigator conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses studies or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes or, generates identifiable private information or identifiable biospecimens.

Human Subjects Research: Any activity that is “Research” and that involves “Human Subjects” as these terms are defined below and under applicable federal law. Any questions about whether an activity meets the regulatory definition of human subjects research should be referred to the UWF IRB office which will provide a determination. Determinations that human data is not identifiable are made by the UWF Institutional Research Board (IRB) for Human Research Participant Protection.

Research: 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, regardless of whether 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.

III. Policy:

- A. The Human Research Protection Program (HRPP) includes the University Institutional Review Board (IRB) and other duly constituted relied-upon IRBs. All human subjects research in which the University is Engaged in, must undergo review and approval by the University's IRB before the research can commence. No human subjects research may begin or continue at the University, without all necessary institutional approvals. If IRB approval lapses, all research activity, including analysis of identifiable data, must stop unless the termination of study procedures creates a safety concern or ethical issue.
- B. Recruitment of University faculty, staff, and students as potential participants by external investigators must first receive approval by the University IRB.
- C. In the review and conduct of research involving human participants, actions by the University will be guided by the principles of respect for persons, beneficence, and justice as set forth in the Belmont Report (Ethical Principles and Guidelines for the Protection of Human Subjects of Research) and other applicable guidelines and human research standards. The actions of the University will also conform to applicable federal, state, and local laws and regulations.
- D. The Associate Vice President of Research Administration and Engagement serves as the Institutional Official for the University's Federalwide Assurance and is responsible for oversight and the compliant operation of the HRPP.
- E. The University Institutional Official may, under exceptional circumstances, independently review any research protocol and, if deemed necessary because of previously unforeseen risks to subjects or noncompliance with applicable regulations, has the authority to disapprove the implementation of a research protocol even if it has been approved by the IRB. However, no University official(s) may approve the implementation of any research protocol in lieu of IRB approval, nor may they override IRB decisions that disapprove of a research protocol.
- F. Anyone who knows that, or has reason to believe that human subjects research is being conducted in a manner that is not in compliance with the HRPP must report the matter promptly to either the Research Compliance Officer, the AVP of Research Administration and Engagement, or anonymously through the University's Integrity Helpline. All reported matters will be reviewed in a timely manner and, to the extent possible, will be handled confidentially. Where appropriate, sanctions will be considered and imposed. Any attempt to retaliate against a person for reporting possible non-compliance with the HRPP may itself be considered a violation of the HRPP.
- G. Infractions of federal regulations or University policies and procedures for human subjects research by University researchers may result in suspension or termination of the research by the IRB. The IRB will investigate and determine the necessary corrective action regarding any infraction of which it has received notice, either through third-party allegation or self-disclosure. Sponsors of the human participant research will be notified as required by regulation, statute, or contract. The IRB will inform the University officials of the results of the investigation and may recommend additional investigation and/or administrative action under other applicable University policies, and procedures.
- H. To implement this policy, the IRB shall adopt procedures detailing its responsibilities and actions, consistent with federal, state, and local regulations and statutes. These procedures shall govern the conduct and review of all human research conducted under this policy.

Any adoption and modification of these procedures require approval by the IRB, the Institutional Official.

Approved by:  _____
President Manny Diaz, Jr.

Date: 6/10/26

Authority: 45 CFR 46, 21 CFR 56

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Last Review: