FLORIDA ATLANTIC UNIVERSITY

# DIVISION OF RESEARCH

| SUBJECT: Human Subjects Research Protection Training | Policy Number: 10.3.3 | Effective Date: September 21, 2022 |
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| | Supersedes: NA | Pages: 4 |
| | Responsible Authorities:<br>Vice President for Research<br>Assistant Vice President, Research Integrity<br>Human Research Protection Program Staff<br>Institutional Review Board | |

I. Background

Federal Regulations require that personnel conducting research involving human subjects undergo training to improve research subject safety. This includes the Principal Investigator (PI), Co-Investigator, Project Director, and all research personnel who will be interacting with the human subject or that will be handling data (even if they do not directly interact with the human subjects).

II. Purpose

The purpose of this policy is to set forth requirements for training in the protection of human subjects.

III. General Statement

An institution holding an Office for Human Research Protections (OHRP)-approved Federalwide Assurance (FWA) is responsible for ensuring that its investigators conducting HHS-conducted or -supported human subjects research understand and act in accordance with the requirements of the HHS regulations for the protection of human subjects. Therefore, as stated in the Terms of the FWA, OHRP strongly recommends that institutions and their designated IRBs establish training and oversight mechanisms (appropriate to the nature and volume of their research) to ensure that investigators maintain continuing knowledge of, and comply with, the following:

- relevant ethical principles;
- relevant federal regulations;
- written IRB procedures;
- OHRP guidance;
- other applicable guidance;
- state and local laws; and
- institutional policies for the protection of human subjects.

Furthermore, OHRP recommends that investigators complete appropriate institutional educational training before conducting human subjects research. Appropriate and continuous training in the protection of human subjects must be completed by any member of a research team engaged in the following research activities: active recruitment, consenting of participants, assessing inclusion and exclusion criteria, data collection, or viewing, analyzing, maintaining, or sharing research data that either directly or indirectly may identify a research participant.

IV. Definitions

**Human subjects research** means the proposed study meets the definition of both human

subjects and research as defined per HHS regulations 45CFR46.102.

*HHS Specific Definitions*

**Research:** Research is 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. For purposes of this part, 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.

**Human subject:** a living individual 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:** both physical procedures by which data are gathered (for example: venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes.

**Interaction:** includes communication or interpersonal contact between investigator and participant.

**Private information:** information about behavior occurring in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

**Identifiable private information**: 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**: a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

*FDA Specific Definitions*

**Human subjects research** means the proposed study meets the definition of both **human subject** and **clinical investigation** as defined below:

- **Clinical Investigation:** any experiment that involves a test article and one or more human subjects and the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit [21CFR50.3(c), 21CFR56.102(c)]. The term does not include nonclinical laboratory studies that are subject to the provisions of 21CFR58.
- **Human subject:** an individual who is or becomes a participant in research, either as a recipient of a *test article** or as a control. A subject may be either a healthy individual or a patient [21 CFR 50.3(g)]. *For research involving medical devices*, a human subject means a human who participates in an investigation, either as an individual on whom, or on whose specimen an investigational device is used, or as a control. A subject may be in normal health or may have a medical condition or disease. [21CFR812.3(p)]

***Test article:** any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act [21CFR50.3 (j); 21CFR56.102 (1)]

## V. Policy

Persons conducting research involving human subjects must complete and successfully pass training for the protections of human subjects. FAU accepts human subject training through the Collaborative Institutional Training Initiative Program (CITI). This requirement applies to all new IRB protocol submissions and when adding project personnel onto an existing IRB-approved protocol.

## VI. Accountability

**The Principal Investigator (PI) will be responsible for:**

Ensuring all project personnel have satisfied the human subjects protection training requirement when submitting for new projects, continuing reviews, and when adding new personnel.

**Research Team Members will be responsible for**:

Maintaining current human subjects protection training. Training should be completed every three (3) years. Training should correspond to the type of research being conducted; either Social, Behavioral, and Educational or Biomedical and/ or Information Privacy and Security if accessing Protected Health Information for research purposes.

**HRPP Staff will be responsible for**:

Reviewing human subjects protection training completion certificates or reports and informing research team personnel if the completion certificates or reports are outdated, do not correspond with the type of research being conducted, or if the incorrect courses have been completed.

## VII. Procedures

New Users:

- If completing human subjects protection training for the first time, research team personnel engaging in humans subjects research will register an account at citiprogram.org.
- Users should select the training module that most closely corresponds to the type of research in which they will be involved.

- When training has been completed, research personnel should save a copy of their completion certificate or report for their records and provide a copy of the certificate or report as necessary.

Returning Users:

- Refresher courses must be completed every three (3) years.
- When training has been completed, research personnel should save a copy of their completion certificate or report for their records and provide a copy of the certificate or report as necessary.

Existing Users New to FAU:

- If you are new to FAU but have completed human subjects protection training at another institution within the past three (3) years, you may provide a copy of the current certificate or report as necessary.
- New to FAU users are strongly encouraged to affiliate with FAU in the CITI system and update their profile to reflect their current FAU role. This action will allow HRPP staff to locate the user in the CITI system, if needed.

VIII. Policy Renewal: As needed

IX. References

Office of Human Research Protections, Investigator Responsibilities FAQ

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POLICY APPROVAL
*Initiating Authority*

Signature: Date:

Name: Daniel C. Flynn, Ph.D., Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)