

<b>SUBJECT:</b> Human Subjects Research (HSR) Determinations	<b>Policy Number:</b> 10.3.2	<b>Effective Date:</b> May 2, 2022
	<b>Supersedes:</b> October 31, 2018 October 9, 2015 October 21, 2011 May 14, 2010	<b>Pages:</b> 4
	<b>Responsible Authorities:</b> Vice President for Research Assistant Vice President, Research Integrity Institutional Review Board	

I. Background

Human subjects research (HSR) is defined as a systematic investigation designed to develop or contribute to generalizable knowledge that involves obtaining information about living individuals through intervention or interaction. This definition is based on the Department of Health and Human Service (DHHS) regulations [45CFR 46.102].

Additionally, the Food and Drug Administration (FDA) considers any clinical investigation involving a human subject to be human subjects research [21CFR50, 21CFR56, 21CFR312 and 21CFR812].

II. Purpose

The purpose of this policy is to set forth the regulations which define human subjects research, and to codify Florida Atlantic University's position that any HSR conducted under its auspices, whether funded or not, must undergo appropriate ethical review.

III. General Statement

The IRB has jurisdiction over the ethical review of Human Subjects Research. Any research involving human subjects (as defined by HHS regulations or the Food and Drug Administration (FDA) Regulations,) that is conducted under the auspices of FAU, must be submitted to the FAU Institutional Review Board, or other appropriate IRB, for ethical review.

When a FAU researcher seeks approval to analyze de-identified data or biospecimens of a vulnerable population collected by another institution, ethical guidelines should still be considered. Researchers should make an effort to ensure that appropriate ethical guidelines were followed when the data/biospecimen was collected. Specifically, the original data or sample collection should have been collected under board review (IRB or equivalent). The data should have been collected using active and informed consent and assent as applicable. Appropriate letters of authorization and collaboration should be available from the source of the dataset.

IV. Definitions

**About Whom** as listed in the HHS specific definitions below, means the investigator is soliciting individual specific information about the person, not a program, service, or product.

**Human subjects research** means the proposed study meets the definition of both human subjects and research as defined per HHS regulations 45CFR46.102.

**Secondary Use Research** means research with data that was collected for non-research purposes including, but not limited to: data collected from medical, school, or employment records, or publicly or privately available datasets.

**Secondary Research** means research involving data collected for the purposes of a research project. For example, performing research on a dataset from active or inactive research project(s), regardless of whether the data is identifiable or de-identified.

### 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

Any research involving human subjects as defined by HHS regulations or the Food and Drug Administration (FDA) Regulations and is conducted under the auspices of FAU, must be submitted to the FAU Institutional Review Board, or other appropriate IRB, for ethical review.

VI. Accountability

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

Ensuring that any proposed study that meets the definition of HSR is submitted to the FAU Institutional Review Board, or other appropriate IRB, in a timely fashion for ethical review, prior to beginning the study.

VII. Procedures

- For secondary use research that requires access via password, approval process, data use or data security agreement, submit a Human Subjects Research Determination (Form 106) to the FAU Human Research Protection Program (HRPP) for review. Include a copy of the required terms of use (if available), data agreement, and/ other documentation required by the data custodian.
- All projects that meet the definition of secondary research or are funded must submit a Human Subjects Research Determination (Form 106) to the FAU HRPP for review. For secondary research, provide a copy of the original consent document (if one was used).
- If a project does not meet either of the above criteria, determination whether an FAU employee, student, or collaborator is engaged in HSR , can be made by the Principal Investigator by reviewing the regulations and associated decision aids at <http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c1>.
- If the investigator is still unsure, they may either complete the Human Subjects Research Determination (Form 06) and submit it via IRBNet to the FAU HRPP for a formal determination. Determinations of engagement in human subjects research will

not be made via phone or webrtc and must be documented in writing.

- Once a Human Subjects Research Determination (Form 106) is submitted, an HRPP staff will review the document and supporting material to provide a written determination:
  - 1) *Not Research*: The project does not meet the definition of research per federal regulations and IRB review is not required.
  - 2) *Research not involving human subjects (NHRS)*: The project meets the federal regulatory definition of research, but does not involve human subjects. IRB review is not required for these projects.
  - 3) *Project involving human subjects*: If the study meets the definition of human subjects research, then a formal IRB application package should be submitted to the IRB.

VIII. Policy Renewal: As needed

IX. References

45 CFR 46.102  
21 CFR 50  
21 CFR 56  
21 CFR 312  
21 CFR 812

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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)