

<b>SUBJECT:</b> Defining Human Subjects Research (HSR)	<b>Effective Date:</b> October 31, 2018	<b>Policy Number:</b> 10.3.3
	<b>Supersedes:</b> October 9, 2015 October 21, 2011 May 14, 2010	<b>Page 1 of 3</b>
	<b>Responsible Authorities:</b> Vice President, Research Institutional Review Board Associate/Assistant Vice President, Research Integrity	

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 [45 CFR 46.102(d)(f)].

Additionally, the Food and Drug Administration (FDA) considers any clinical investigation involving a human subject to be human subjects research [21 CFR 50, 21 CFR 56, 21 CFR 312 and 21 CFR 812]

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. 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.

V. Definitions

**DHHS Regulations**

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

**Research:** Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities meeting this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. [45 CFR 46.102(d)]

**Human subject:** a living individual *about whom* an investigator (whether professional or student) 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.

(1) **Intervention:** both physical procedures by which data or biospecimens are gathered (for example: venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes.

(2) **Interaction** includes communication or interpersonal contact between investigator and participant.

(3) **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). [45 CFR 46.102(f)]

**Clinical trial:** a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

**FDA Regulations**

**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. [21 CFR 50.3(c), 21 CFR 56.102 (c)] The term does not include nonclinical laboratory studies that are subject to the provisions of 21 CFR 58.

**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. [21 CFR 812.3(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 [21 CFR 50.3 (j)] [21 CFR 56.102 (1)]

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

- Determination of 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, he/she may either complete the Determination of Human Subjects Research Form and submit it to the Research Integrity office via IRBNet for a formal determination, **OR** contact Research Integrity staff directly via email or telephone, to determine whether a formal submission should be made to the IRB.
- If the study is determined to not be human subjects research and does not fall under the purview of an IRB, there is still an expectation that the study will be conducted ethically.
- If the study meets the definition of human subjects research, then a formal IRB application package should be submitted to the IRB via Research Integrity's online system, IRBNet.

VIII. Policy Renewal Date  
NA

IX. References  
45 CFR 46.102(d)(f)  
21 CFR 50  
21 CFR 56

POLICY APPROVAL

*Initiating Authority*

Signature:



Date: 10/29/2018

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

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