

## POLICY ON THE SUBMISSION OF HUMAN SUBJECTS RESEARCH TO THE IRB

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Responsible Office: Grants and Sponsored Projects

Effective Date: April 12, 2023

Responsible Official: University Director, Grants and Sponsored Projects

Last Revision:

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### I. Policy Statement

This policy covers the requirement for the submission, review and approval of human subjects research as defined below at Fairleigh Dickinson University. Any project conducted by administration, faculty, staff, and students that meets the below definitions of research and human subjects must be reviewed and approved by the Fairleigh Dickinson University Institutional Review Board and/or designated reviewer before the research can be started.

### II. Scope

This University-wide policy is based on compliance with federal regulations governing human subjects research. It applies to faculty, executives, professional administrators, staff, students, trainees, fellows, interns, and any and all individuals acting as agents of Fairleigh Dickinson, who are affiliated with and may be involved in research at Fairleigh Dickinson University, and all research conducted by such individuals, whether or not conducted on site or federally funded, and protocols for such research, including those undertaken in fulfillment of a course requirement.

### III. Definitions

Research means a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge; (see [45 CFR 46.102\(l\)](#)).

Human subject means 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. (see [45 CFR 46.102.e.1](#))

Both above definitions must be met for submission to the IRB for review and approval.

### IV. Responsibility

Any agent of Fairleigh Dickinson University conducting research as defined above must submit all appropriate documentation for review and approval by the FDU IRB and/or designated reviewer. All instructions, forms and information on the submission process are included on the FDU IRB website which may be found here:

<https://www.fdu.edu/academics/research/grants-sponsored-projects/irb/>

The primary responsibility of the IRB is to review and ensure that appropriate steps are taken

for projects that meet the above definitions, to protect the rights and welfare of humans participating in research. The IRB functions in accordance with guidelines of the Office of Human Research Protection (OHRP) and other federal regulatory agencies.