FLORIDA INTERNATIONAL UNIVERSITY

OFFICIAL UNIVERSITY POLICY

Human Subjects Research Approval and Registration/Publication of Clinical Trial Results # 2370.015

INITIAL EFFECTIVE DATE:	LAST REVISION DATE:	RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT
February 11, 2004	November 24, 2020	Office of Research and Economic Development

POLICY STATEMENT

Research involving human subjects, may not commence prior to the principal investigator's receipt of written approval or written exemption from the IRB. All required IRB approvals must be in place before ORED will set up a new project ID, continuation or temporary release of sponsored project funds. All NIH sponsored clinical trials must be registered on ClinicalTrials.gov prior to the enrollment of the first subject.

SCOPE

University Community (faculty, staff and students) that conduct research with human subjects.

REASON FOR POLICY

To ensure that IRB approval or IRB exemption is obtained for all research involving human subjects prior to commencement of those projects.

DEFINITIONS

TERM	DEFINITIONS
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.
IRB	The Florida International University Institutional Review Board
NIH	The National Institutes of Health
ORED	The Florida International University Office of Research and Economic Development

PI	The Principal Investigator
RESEARCH	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge.

ROLES AND RESPONSIBILITIES

Principal Investigator Responsibilities - Principal investigators are responsible for adhering to all applicable federal and state laws and all FIU policies and procedures regarding human subject research and for monitoring the welfare of the human subjects involved in their projects. Specific guidelines and procedures for conducting projects involving human subjects are detailed in the IRB policies and procedures. The Principal investigator shall not allow any individual to work on the project as Co-PI or other key personnel unless and until that individual has gone through the required training and the individual has been approved by the IRB to participate on the project. Principal investigators and all persons working on projects involving human subjects should consult the IRB policies and procedures to ensure that they are in compliance with all requirements.

RELATED RESOURCES

- FIU IRB Policies and Procedures
- 45 CFR Part 46, Protection of Human Subjects
- ORED Policy - Sponsored Award Project Set-up
- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information - Notice Number: NOT-OD-16-149

CONTACTS

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HISTORY

Initial Effective Date: April 16, 2020
Review Dates (*review performed, no updates*): N/A
Revision Dates (*updates made to document*): April 22, 2020, November 24, 2020

FLORIDA INTERNATIONAL UNIVERSITY

OFFICIAL UNIVERSITY PROCEDURE

Human Subjects Research Approval and Registration/Publication of Clinical Trial Results # 2370.015a

INITIAL EFFECTIVE DATE:	LAST REVISION DATE:	RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT
February 11, 2004	November 24, 2020	Office of Research and Economic Development

PROCEDURE STATEMENT

Principal Investigators ("PI") must submit protocols for research projects' involving human subjects to the Florida International University IRB in accordance with the IRB's policies and procedures, prior to commencement of the project. The IRB's policies and procedures are posted on the ORED website on the Human Research (IRB) page. The link(s) to the policies are also found on the Document Details page of this policy abstract online. Those policies and procedures govern the IRB process and conduct of human subject research from the initial protocol application through the close-out of the project. If the activities are funded, once the IRB has approved the protocol, ORED will process the award and issue a project ID for the project or process the temporary release of sponsored project funds or the continuation, as appropriate.

All NIH sponsored clinical trials must be registered on ClinicalTrials.gov prior to the enrollment of the first subject. The Principal Investigator for each clinical trial is responsible for that registration. Clinicaltrials.gov also allows voluntary reporting of other studies that:

1. Are in conformance with any applicable human subject or ethics review regulations (or equivalent) and
2. Are in conformance with any applicable regulations of the national (or regional) health authority (or equivalent). Investigators may choose to register a study that is not an applicable clinical trial as a condition to publish study results in a journal. FDA regulations require reporting of results from registered trials.

The Principal Investigator must generally report results on ClinicalTrials.gov no later than 12 months after the trial completion date. Results must include participant baseline characteristics, participant flow diagram, outcomes, and adverse events. Instructions for study registration and submitting results are available at ClinicalTrials.gov. FDA also requires sponsors or investigators to certify compliance with ClinicalTrials.gov registration when submitting certain applications to the FDA. The Principal Investigator is responsible for certifying that compliance using Form FDA 3674 and the Principal Investigator shall provide a copy of the form that he/she submits to the FDA to ORED. Please note that fines of $10,000 per occurrence and $10,000 per day can be assessed if a ClinicalTrial.gov record does not comply with the registration and reporting requirements. Responsibility for assessed penalties will rest with the PI and the PI's Department and College.