FLORIDA INTERNATIONAL UNIVERSITY

OFFICIAL UNIVERSITY PROCEDURE

Human Subjects Approval Prior to Award Processing and Registration/Publication of Clinical Trial Results #2370.015a

INITIAL EFFECTIVE DATE:	LAST REVISION DATE:	RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT
February 11, 2004	March 30, 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. Additionally PIs of NIH-sponsored clinical trials are required to register and publish results on ClinicalTrials.gov.

SCOPE

University Community (faculty, staff and students)

REASON FOR PROCEDURE

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

DEFINITIONS

TERM	DEFINITIONS
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.

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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.

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.

RELATED RESOURCES

- Florida International University Institutional Review Board 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
- 2370.015 Human Subjects Approval Prior to Award Processing and Registration/Publication of Clinical Trial Results policy.

CONTACTS

- Office of Research Integrity, Florida International University, 11200 S.W. Eighth Street – MARC 430, Miami, Florida 33199, Telephone: (305) 348-3024

HISTORY

Office of Sponsored Research Administration Faculty/Staff Guide for the Administration of Externally Funded Projects, INTERIM VERSION; **Effective Date: February 11, 2004; Revision Date:** September 19, 2013. ClinicalTrials.gov Requirement Update June 6, 2018, March 30, 2020