



Division of Research University Policy

SUBJECT: Account Set-up for Projects Involving Human Subjects, Animal Subjects, and/or Biohazardous Materials	Effective Date: 08/01/2019	Policy Number: 10.2.1	
	Supersedes: 10-13-2014 01-09-2013 01-19-2012	Page 1	Of 3
	Responsible Authorities: Assistant Vice President for Research, Sponsored Programs Assistant Vice President for Research, Research Integrity		

I. Background

Engaging in human subject research (Institutional Review Board – IRB), animal research (Institutional Animal Care and Use Committee - IACUC), or research involving biohazardous materials (Institutional Biosafety Committee - IBC) without the proper Institutional Board/Committee approvals can violate federal regulatory policy as well as have serious ethical implications for the Principal Investigator(PI) and the University. Faculty, staff and students are required to secure IRB, IACUC, and/or IBC approval prior to initiating any data collection.

II. Policy

It is the policy of Florida Atlantic University that all sponsored research that involves human subjects, animal subjects, or biohazardous materials have IRB, IACUC, or IBC approval on file prior to a Workday account being initiated. The University’s policy states that non-compliance may result in, among other things, suspension or termination of the study; and/or suspension of research privileges at the University.

Faculty, staff and students are advised that actions could include, but are not limited to:

- The Division of Research will not initiate Workday accounts for projects lacking necessary IRB, IACUC or IBC approvals.
- Funding may be withheld: Federal sponsors and most private sponsors require IRB, IACUC, and/or IBC approval(s) as a condition of an award. Sponsors

may postpone review of proposals or initiation of a grant award notification if proof of committee approval is not provided upon Sponsor's request.

- An IRB fee is charged for industry-funded research involving human subjects which are reviewed by an external, for-profit IRBs.
- Journal articles should not be published without the appropriate committee approval. Most peer reviewed journals require evidence of IRB, IACUC, and/or IBC approval when considering articles for publication.
- The University does not support research conducted without the appropriate compliance committee approval. Data secured before such approval may be disapproved for use by the IRB, IACUC, and/or IBC.
- The University has the authority to suspend all research activities for a specified time frame as a disciplinary measure.

Workday accounts may be initiated for projects that include research involving human subjects, animal subjects, or biohazardous materials when the following are applicable:

- When a substantive, scientifically justified request is submitted by the PI, and when an IRB, IACUC, and/or IBC protocol has been submitted and is already under committee review; and
- When the PI provides written assurance that no human subjects, animal subjects, and/or biological research will be initiated without the appropriate protocol approvals having been secured.

For example, Workday accounts may be initiated ahead of final protocol approval for the purpose of equipment purchase, payroll, or other justifiable expense.

To request a Workday account ahead of final protocol approval, the Principal Investigator must submit a request to the Assistant Vice President, Research Integrity and Assistant Vice President, Sponsored Programs for review. (See Exhibit A - Request for Workday Account on Projects Involving Human Subjects, Animal Subjects, and/or Biohazardous Materials). * In certain circumstances, granting of such an exception will be contingent upon the approval from the Vice President for Research.

Liability issues arising from unapproved research become the responsibility of the principal investigator. Persons conducting unapproved research are deemed to be acting outside the scope of authority granted to them by the University. The University may not, therefore, provide a principal investigator of an unapproved project the resources to answer a liability complaint.

POLICY APPROVAL

Initiating Authority

Signature: Date:

Name:


Daniel Flynn, Vice President for Research

Exhibit A

Date:

To: Assistant Vice President, Research Integrity
Assistant Vice President, Sponsored Programs
Cc: Dean/ Department Chair
From: Principal Investigator
RE: **Request to Initiate a Workday Account on Projects Involving Human Subjects, Animal Subjects, or Biohazardous Materials**

Project Title:
Sponsor:
Project Period:

I have reviewed the Policy for Account Set-up for Projects Involving Human Subjects, Animal Subjects and/or Biohazardous Materials policy and request an exception to the account set up policy based on the following detailed justification. I have also included a timeline detailing when the documentation will be submitted for the appropriate committee approval.

Examples include: [Provide details surrounding the applicable justification]

- A) The research being conducted involves _____ animals, _____ human subjects, or _____ biohazardous material at a later stage in the research; and/or
- B) A protocol has been submitted to the appropriate committee and is currently pending (Protocol #_____).

I further assure the Division of Research that I will not engage in any human subject research, animal subject research, and/or use of biohazardous material without first securing the appropriate committee approval. I understand that engaging in human subjects research, animal subject research, and/or research involving biohazardous materials without the appropriate approvals violates federal regulatory policy that could result in findings of non-compliance and/or result in the suspension of this Workday account.

Principal Investigator: _____ Date: _____

Printed Name: _____ Date: _____

- *Note: In certain circumstances, this exception to the policy must be approved by the Vice President for Research. (Institutional Official)*