



|   |   |                                 |
|---|---|---------------------------------|
| <b>SUBJECT:</b><br><br>Account Set-up for Projects Involving Human Subjects, Animal Subjects, and/or Biohazardous Materials | <b>Effective Date:</b><br>06/07/2024  | <b>Policy Number:</b><br>10.2.1 |
|   | <b>Supersedes:</b><br>08-01-2019, 10-13-2014,<br>01-09-2013, 01-19-2012   | <b>Page 1 Of 3</b>              |
|   | <b>Responsible Authorities:</b><br>Associate Vice President, Sponsored Programs<br>Associate Vice President, 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- Journal articles should not be published without the appropriate committee's approval.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 prior to protocol approval 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 IBS 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 Award Administrator in the Office of Sponsored Programs. (See Exhibit A – Request for Workday Account on Projects Involving Human Subjects, Animal Subjects, and/or Biohazardous Materials). All requests will be reviewed and approved by the Associate Vice President, Research Integrity and the Associate Vice President, Sponsored Programs. \*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 with the resources to answer a liability complaint.*

---

The Account Set-up for Projects Involving Human Subjects, Animal Subjects, and/or Biohazardous Materials Policy will be reviewed annually and updated as necessary.

**POLICY APPROVAL**

Initiating Authority

Signature: \_\_\_\_\_  
 Name: Gregg Fields, Interim Vice President for Research

Date: \_\_\_\_\_

**Exhibit A**

Date:  Novelution Proposal No: \_\_\_\_\_

To: Associate Vice President, Research Integrity  
Associate Vice President, Sponsored Programs

CC: Dean/Department Chair

From: Principal Investigator Name:

RE: **Request to Initiate a Workday Account on Projects Involving Human Subjects, Animal Subjects, or Biohazardous Materials**

**Project Title:**

**Sponsor Name:**

**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.

- A) The research being conducted involves: [choose all that apply]  
 Animal subjects,  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 #: \_\_\_\_\_), or  has not been submitted and will be submitted by (Date: \_\_\_\_\_).

**Justification:** [Include additional sheets if necessary]

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 subject research, animal subject research, and/or research involving biohazardous materials without the appropriate approvals violates federal regulatory policy that can result in findings of non-compliance and/or result in the suspension of the Workday account.

Principal Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_ Date: \_\_\_\_\_

**Approved By:**

AVP, Research Integrity

AVP, Sponsored Programs

\_\_\_\_\_  
Name: \_\_\_\_\_ Date: \_\_\_\_\_

\_\_\_\_\_  
Name: \_\_\_\_\_ Date: \_\_\_\_\_