



SUBJECT: Account Set-up for Projects Involving Human and Animal Subjects	Effective Date: 10-13-14	Policy Number: 10.2.1	
	Supersedes: 1-9-13 1-19-12 6-21-2010 11-1-2008	Page 1	Of 2
	Responsible Authorities: Vice President for Research Director, Sponsored Programs		

I. Background

Engaging in human subject research without Institutional Review Board (IRB) approval or engaging in animal subject research without Institutional Animal Care and Use Committee (IACUC) approval not only violates federal regulatory policy but can also have serious ethical implications for the researcher. Faculty, staff and students are required to submit IRB or IACUC approval prior to initiating any data collection.

II. Policy

It is the policy of Florida Atlantic University that all sponsored research that involves human or animal subjects have IRB or IACUC approval on file prior to a grant 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 and Staff are advised that actions could include, but are not limited to:

- The Division of Research will not initiate grant accounts for projects lacking necessary IRB or IACUC approvals.

- Funding may be withheld: Federal sponsors, and most private sponsors, require IRB or IACUC approvals as a condition of an award. Sponsors may postpone review of proposals or initiation of a grant award notification if proof of committee approval cannot be provided to them on request.
- An IRB fee is charged for industry-funded human subjects research.
- Journal articles cannot be published without the appropriate committee approval. Most professional journals require evidence of IRB or IACUC 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 or IACUC.
- The University has the authority to suspend all research activities for a specified time frame as a disciplinary measure.

Grant accounts may be initiated for projects that include research with animals or human subjects when the following are applicable:

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

For example, grant accounts may be initiated ahead of final protocol approval for the purpose of equipment purchase, payroll or other justifiable expense. The Principal Investigator must submit the request to the Director, Research Integrity and Director, Sponsored Programs for review. (See Exhibit A - Request for Grant Account on Projects Involving Animal or Human Subjects). * 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 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 an investigator of an unapproved project the resources to answer a liability complaint.

POLICY APPROVAL

Initiating Authority

Signature:  _____ Date: 10/9/14

Name: John W. Newcomer, M.D., Interim Vice President for Research

Exhibit A

Date:

To: Director, Research Integrity
Director, Sponsored Programs
Cc: Dean/ Department Chair
From: Principal Investigator
RE: **Request to Initiate a Grant Account on Projects Involving Animal or Human Subjects**

Project Title:
Sponsor:
Project Period:

I have reviewed the Policy for Account Set-up for Projects Involving Human and Animal Subjects 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 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/ We further assure the Division of Research that I/ we will not engage in any human or animal subject research without first securing the appropriate committee approval and I/ we understand that engaging in human subjects research or animal subject research without the appropriate protocol approvals violates federal regulatory policy that could result in findings of misconduct and / or result in the suspension of this grant 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)*