University
of Miami

New Principal Investigator Training

Policy Sections

- **Policy Statement**
- **Reason for Policy**
- **Who Should Know This Policy**
- **Definitions**
- **Procedures**
- **Approval**

Effective Date: August 3, 2015

Revision History (dates of amendments): August 3, 2012

Responsible University Officers: Vice Provost for Research & Executive Director for Research, Research Education & Innovative Medicine

Responsible Offices: CRORS

Policy Statement

This policy applies to all Principal Investigators (PI) who are conducting their first clinical research studies at the University of Miami. It also applies to all PIs who are conducting their first clinical trials involving INDs or IDEs.

Non-adherence with policy requirements will result in withholding of IRB study approval, pending satisfactory completion of required training.

Reason for Policy

To ensure that PIs new to clinical research and/or new to clinical research conducted under an IND or IDE at the University of Miami are fully aware of their responsibilities to satisfy Federal regulations and University policies and procedures.

Who Should Know This Policy

Sponsor-Investigators, Principal Investigators, Study Coordinators, Research Administrators, Miller School of Medicine Office of Research, Office of Research Administration, Vice Provost for Research, IRB and HSRO

History

Amended: August 3, 2012; October 08, 2012

Effective: August 3, 2015

Definitions

CRORS	**Clinical Research Operations & Regulatory Support**
HSRO	Human Subjects Research Office
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
IRB 7	Electronic Protocol Submission and Tracking System
Principal Investigator	An individual who actually conducts a clinical investigation; i.e., under whose immediate direction the test article is administered, dispensed or used.
Sponsor	A person who initiates, but does not actually conduct, the investigation; that is, the investigational drug or device is administered, dispensed or used under the immediate direction of another individual.
Sponsor-Investigator	An individual who both initiates and conducts a clinical investigation and under whose immediate direction the investigational drug or device is being administered, dispensed or used.

Procedures

The office of Clinical Research Operations & Regulatory Support (CRORS) will receive automatic notifications from the IRB 7 system indicating that:

- a Principal Investigator (PI) has submitted his/her first clinical research protocol for IRB approval at the University,
- a PI has submitted his/her first clinical research protocol for a study involving an IND or IDE at the University,
- a protocol amendment has been submitted to the IRB indicating that a new PI is assuming the role of PI for an existing IRB-approved protocol, and this is the new PI's first clinical research protocol or first clinical research protocol for a study involving an IND or IDE at the University.

  Note: The IND or IDE may be held by the PI or by another sponsor.

Following this notification, CRORS will contact the PI to schedule a training session.

CRORS will provide training to these PIs and their study teams at the University of Miami, prior to the start of their studies.

Note: The definition of first-time PI includes those who have previously served as PIs in other institutions.

Training provided will consist of an overview of Good Clinical Practices and associated responsibilities. CRORS can be contacted by phone at (305) 243-6381 or email at CRORS@med.miami.edu for assistance.

Approval

Name	Title	Signature	Date
John Bixby, Ph.D.	Vice Provost for Research	*On File*	7/15/15
Omaida Velazquez, M.D.	Executive Dean, Research and Innovative Medicine	*On File*	7/15/15