University
of Miami

POLICY 101 – CLINICAL TRIAL DISCLOSURE: PROTOCOL REGISTRATION

Policy Sections

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

Effective Date: 16 Jun 2014

Revision History (dates of amendments): N/A

Responsible University Officers: Vice Provost for Research

Responsible Offices: Office of the Vice Provost for Research and Office of Research Compliance and Quality Assurance

Policy Statement

The University of Miami's policy requires registration of **all Clinical Trials** (all phases and intervention types) on ClinicalTrials.gov before enrollment of the first participant**,** where the University of Miami – Principal Investigator has initiated, sponsored or been designated the Responsible Party for registering such Clinical Trial .

For purposes of this policy, the University of Miami defines Clinical Trials as those trials which are Principal Investigator initiated, Principal Investigator sponsored or where the Principal Investigator is the Responsible Party and which include one or more health related interventions that evaluate the effects on health outcomes by modifying a biomedical or health-related outcome. Health-related interventions include:

- Drugs (e.g. IND and IND Exempt)
- Surgical Procedures (e.g. arthroscopic procedure)
- Biologics (e.g. vaccine)
- Devices (e.g. pacemaker)
- Behavioral Treatments (e.g. Music Therapy)
- Dietary interventions (e.g. high fat high fiber consumption)
- Process-of-care changes (e.g. health education)
- Physical Therapeutics, Rehabilitation and Exercise (e.g. motor stimulation)

Failure to comply with this policy may result in the following: inability to publish; civil monetary penalties levied against the University; suspension of protocol approval from the IRB; loss of additional or continued funding from federal agencies and other entities.

Reason for Policy

University of Miami's policy on Clinical Trial Disclosure (CTD) meets the requirements and/or suggestions of FDAAA, FDAMA, CMS, NIH, and ICMJE.

FDAAA Section 801; 2007:	http://clinicaltrials.gov/ct2/manage-recs/fdaaa
FDAMA Section 113: 1997:	http://www.gpo.gov/fdsys/pkg/PLAW-105publ115/pdf/PLAW-

	105publ115.pdf#page=16
CMS:	http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8401.pdf
NIH:	http://grants.nih.gov/ClinicalTrials_fdaaa/steps.htm
ICMJE:	http://www.icmje.org/journals.html

Who Should Know This Policy

Sponsor-Investigators, Principal Investigators, Principal Investigators designed as the Responsible Party, Study Coordinators, Study team members, Research Administrators, Miller School of Medicine Office of Research, Office of Research Administration, Department Chairs, Division Chiefs, Vice Provost for Research, RCQA, IRB and HSRO

History

Amended: N/A

Effective: 16 Jun 2014

Definitions

CMS	Centers for Medicaid and Medicare Services
FDAAA	Food and Drug Administration Amendment Act of 2007
FDAMA	Food and Drug Administration Modernization Act of 1997
HSRO	The University of Miami Human Subject Research Office
IND	Investigational new drug application; a request for authorization from the FDA to administer an investigational drug or biological product to humans
IRB	Institutional Review Board
Principal Investigator (PI)	An individual, who actually conducts a clinical investigation under whose immediate direction the intervention is administered, dispensed or used.
RCQA	The University of Miami Research Compliance and Quality Assurance office
Responsible Party	The term used by FDAAAA to designate the entity or individual responsible for the clinical trial and for the submission of clinical trial information. This can mean: • The sponsor of the clinical trial, or • The principal investigator if so designated
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

- During initial protocol submission into the IRB7 system, the Principal Investigator or study team member will answer a series of questions related to the University of Miami criteria for Clinical Trial Disclosure.
- Answers to the designated questions will determine whether the protocol meets the requirements for Protocol Registration under the University of Miami Policy.
- The Principal Investigator and/or designated study team member will receive an automated email from the system advising him/her to register the protocol.
- The Principal Investigator and/or designated team member should promptly take the necessary steps to register the protocol at ClinicalTrials.gov.

Approval

Name	Title	Signature	Date
Dr. John Bixby	Vice Provost for Research	*Signature on file*	6/13/2014