

## POLICY 101 – CLINICAL TRIAL DISCLOSURE: PROTOCOL REGISTRATION

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**Effective Date:** 31 Oct 2017

**Revision History (dates of amendments):** Supersedes HSR-P-101 (effective 16 Jun 2014)

**Responsible University Officers:** Vice Provost for Research

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

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## Policy Statement

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The University of Miami requires registration on ClinicalTrials.gov for **all Clinical Trials** (as defined by NIH), and for all Clinical Studies/Registries with Medicare billing implications, prior to enrollment of the first participant. This applies when the University of Miami Principal Investigator has initiated, sponsored or been designated the Responsible Party for registering such Clinical Trials/Studies. Note that for a study to be considered a Clinical Trial it must involve an **intervention** designed to improve a health-related outcome.

Examples of Interventions are listed below; this list is not inclusive:

- 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.

All investigator initiated trials conducted at the University of Miami must be registered using the UM Institutional Account in the ClinicalTrials.gov Protocol Registration and Result Reporting system (<https://register.clinicaltrials.gov>) and must use the protocol's eProst ID as the Unique Protocol Identifier. The UM institutional account name is: UMiami.

The CTD Ancillary Committee has the final authority in deciding whether a protocol must be registered on ClinicalTrials.gov.

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## Reason for Policy

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University of Miami's policy on Clinical Trial Disclosure (CTD) meets the requirements and/or suggestions of 42 CFR § 11, FDAAA, FDAMA, CMS, NIH, and ICMJE.

42 CFR § 11	<a href="https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission">https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission</a>
FDAAA Section 801; 2007:	<a href="http://clinicaltrials.gov/ct2/manage-recs/fdaaa">http://clinicaltrials.gov/ct2/manage-recs/fdaaa</a>
FDAMA Section 113: 1997:	<a href="http://www.gpo.gov/fdsys/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf#page=16">http://www.gpo.gov/fdsys/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf#page=16</a>
CMS:	<a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8401.pdf">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8401.pdf</a>
NIH:	<a href="https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information">https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information</a>
ICMJE:	<a href="http://www.icmje.org/journals.html">http://www.icmje.org/journals.html</a>

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## Who Should Know This Policy

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Sponsor-Investigators, Principal Investigators, Principal Investigators designated as Responsible Parties, Study Coordinators, Study team members, Research Administrators, Miller School of Medicine Office of Research, Office of Research Administration, Office of Billing Compliance, Department Chairs, Division Chiefs, Vice Provost for Research, CRORs, RCQA, IRB and HSRO

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## History

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**Amended:** 20 Apr 2017

**Effective:** 31 Oct 2017

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## Definitions

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<b>CMS</b>	Centers for Medicaid and Medicare Services
<b>Clinical Trial</b>	<p>A research study<sup>1</sup> in which one or more human subjects<sup>2</sup> are prospectively assigned<sup>3</sup> to one or more interventions<sup>4</sup> (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.<sup>5</sup></p> <p><sup>1</sup>See Common Rule definition of <i>research</i> at 45 CFR 46.102(d).</p> <p><sup>2</sup>See Common Rule definition of <i>human subject</i> at 45 CFR 46.102(f).</p> <p><sup>3</sup>The term “<i>prospectively assigned</i>” refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.</p> <p><sup>4</sup>An <i>intervention</i> is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.</p> <p><sup>5</sup><i>Health-related biomedical or behavioral outcome</i> is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.</p>
<b>FDAAA</b>	Food and Drug Administration Amendment Act of 2007
<b>FDAMA</b>	Food and Drug Administration Modernization Act of 1997
<b>HSRO</b>	The University of Miami Human Subject Research Office
<b>IND</b>	Investigational new drug application; a request for authorization from the FDA to administer an investigational drug or biological product to humans
<b>IRB</b>	Institutional Review Board
<b>NCT</b>	National Clinical Trial (NCT) number, another term for the ClinicalTrials.gov registry number unique to each record. The format for the ClinicalTrials.gov registry number is “NCT” followed by an 8-digit number, e.g.: NCT00000419.
<b>Principal Investigator (PI)</b>	An individual, who actually conducts a clinical investigation under whose immediate direction the intervention is administered, dispensed or used.
<b>RCQA</b>	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 <https://register.clinicaltrials.gov> before enrollment of the first participant.
- Once an NCT number is obtained it must be recorded in Velos.
- For studies that are not yet completed, the study team must at a minimum update the clinicaltrials.gov record every 6 months (within 30 days for recruitment status changes), even if there have been no changes to the record.

## Approval

Name	Title	Signature	Date
John L. Bixby, Ph.D.	Vice Provost for Research	On File	10/31/2017