Document Number:	RCQA-709-01	Effective Date: 18 Apr 2017
Page No.	Page 1 of 6	Author: Y. Davis
Title:	Protocol Registration of UMACTs for Investigator Initiated Trials	

1. PURPOSE

The purpose of this document is to outline the registration process of University of Miami Applicable Clinical Trials (UMACTs) for studies initiated by University of Miami Investigators.

2. DEFINITIONS

CTD	Clinical Trial Disclosure
FDAAA	Food and Drug Administration Amendment Act of 2007
FDAMA	Food and Drug Administration Modernization Act of 1997
ICMJE	International Committee of Medical Journal Editors
NCT #	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.
Principal Investigator (PI)	An individual who actually conducts a clinical investigation (i.e. under whose immediate direction the test article is administered or dispensed to a subject
PRS	Protocol Registration and Result Reporting System
PRS Review	Under review by (ClinicalTrials.gov) QA reviewers
RCQA	Research Compliance and Quality Assurance
Responsible Party	The term used by FDAAA 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.
Study Team	Principal Investigator, Sponsor-Investigator, Research Coordinator, Study Coordinator, etc.

University of Miami Applicable Clinical Trial (UMACT)

Business Rule #1 – Legal Requirement (FDAAA. FDAMA, and 42 CFR § 11)

Criteria Group 1.1

- Study involves a Drug, Device, or Biologic; AND
- It is Phase 2-4; AND
- Study Start Date is as of September 2007 forward (*not programmed)*; AND
- Involves at least 1 U.S. Site; AND
- PI is the Sponsor-Investigator

Criteria Group 1.2

- Study involves a Drug, Device, or Biologic; AND
- It is Phase 2-4; AND
- Study Start Date is as of September 2007 forward (*not programmed)*; AND
- Involves at least 1 U.S. Site; AND
- PI is the Responsible Party

Criteria Group 1.3

- Study involves a Drug, Device, or Biologic; AND
- Study Start Date is as of September 2007 forward (*not programmed)*; AND
- Involves at least 1 U.S. Site; AND
- Involves a Serious or Life-Threatening Disease
- PI is the Sponsor-Investigator

Criteria Group 1.4

- Study involves a Drug, Device, or Biologic; AND
- Study Start Date is as of September 2007 forward (*not programmed)*; AND
- Involves at least 1 U.S. Site; AND
- Involves a Serious or Life-Threatening Disease
- PI is the Responsible Party

Business Rule #2 – Federal Funding Requirement (NIH Policy on the Dissemination of Clinical Trial Information for Federally Funded Studies)

Criteria Group 2.1

- Study involves a Drug, Device, or Biologic; AND

- It is Phase 2-4; OR
- Study involves a Behavioral Interventions, Dietary Changes, Process of Care Changes, Surgical Procedures , or Physical Therapy; AND
- Study Start Date is as of September 2007 forward; AND
- Involves at least 1 U.S. Site; AND
- Federal Funding; AND
- PI is the Responsible Party;

Business Rule #3 – CMS Mandate Requirement

Criteria Group 3.1

- Study involves a Drug, Device, or Biologic; OR
- Study involves a Behavior, Dietary Changes, Process of Care Changes, Surgical Procedures, or Physical Therapy; AND
- PI is the Responsible Party; AND
- Clinical Study/Registry/Clinical Trial; AND
- Medicare Billing

Criteria Group 3.2 (Sponsored Studies)

- Study involves a Drug, Device, or Biologic; OR
- Study involves a Behavior, Dietary Changes, Process of Care Changes, Surgical Procedures, or Physical Therapy; AND
- Sponsor/Collaborative Group/Other Institution; AND
- Clinical Study/Registry/Clinical Trial; AND
- Medicare Billing

Business Rule #4 – ICMJE Requirement

Criteria Group 4.1

- PI is the Responsible Party; AND
- Interventional Study wanting to Publish

Business Rule #5 – Requirement for Result Reporting

Criteria Group 5.1

- Study involves a Drug, Device, or Biologic; AND
- It is Phase 2-4; AND
- Study Start Date is as of September 2007 forward; AND
- Involves 1 U.S. Site; OR Study is Federally Funded Interventional Study

3. RESPONSIBILITY

3.1. **CTD Compliance Officer or Designee**

3.1.1. Create PRS account
3.1.2. Assist with protocol registration, if applicable
3.1.3. Review record for consistency and regulatory compliance, if applicable

3.2. **PI and/or Study Team**

3.2.1. Obtain PRS Account
3.2.2. Register protocol in ClinicalTrials.gov if applicable
3.2.3. Record NCT number in Velos

4. PROCEDURE

ID	*Step*	*Description*	*Responsible*	*Timeline*
4.1. Protocol Registration of UMACTs of Investigator Initiated Trials				
4.1.1.	Obtain PRS Account *if applicable*	If the PI and/or study team do not have a PRS account, they should email ctgovum@miami.edu with CT.gov in the subject line and the following information: • Preferred Username (preferably CaneID) • Full Name • Title • Department • Phone Number • Email address	PI and/or Study Team	Upon notification to register study
4.1.2.	Schedule assistance with registration *if applicable*	PI and/or study team may request one on one assistance of RCQA CTD team with registering their protocol within the PRS by clicking the link, located within their welcome to PRS email (or the link is available at https://uresarch.miami.edu)	PI and/or study team	Prior to enrollment of first participant

ID	Step	Description	Responsible	Timeline
4.1.3.	Contact CTD Ancillary Committee if in disagreement with determination *If applicable*	PI may contact CTD Ancillary committee by emailing ctgovum@miami.edu to request an additional review of their protocol submission	PI and/or study team	Prior to enrollment of first participant
4.1.4.	Register protocol within PRS	PI and/or study team will register the study on https://register.clinicaltrials.gov, by entering the eProst ID number associated with the study as the Unique Protocol ID within PRS. Studies that are federally funded, in whole or part should list the grant number as the secondary ID and the name of the associated agency granting the funds as a collaborator.	PI and/or Study team	Prior to enrollment of the first participant
4.1.5.	Request review of registration *if desired*	PI and/or study team member may contact RCQA CTD team and request review of their record for consistency and regulatory requirements.	PI and/or study team	Prior to submitting record for PRS review
4.1.6.	Review of registration record	CTD team will review record for consistency with current approved protocol and confirm that regulatory requirements have been met	CTD Compliance team member or designee	Prior to PI submitting record for PRS review
4.1.7.	Record NCT number in Velos	Once NCT number has been obtained, PI or designee will enter the NCT number in Velos. *Refer to "Instructions on Entering an NCT Number in Velos."*	PI or designee	Prior to enrollment of first participant

5. DOCUMENTATION

N/A

6. REFERENCES

HSR-P-101 Clinical Trial Disclosure Protocol Registration
Food and Drug Administration Amendment Act Section 801: 2007
Food and Drug Administration Modernization Act Section 113: 1997
42 CFR § 11: Clinical Trial Registration and Result Reporting
NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
Instructions for entering an NCT Number in Velos

7. TEMPLATES/FORMS/TOOLS

N/A

8. REVISION HISTORY

N/A

9. SIGNATURES

Prepared by: Signature on File Date: 18 Apr 2017
Yolanda P. Davis, BS, CCRP
Clinical Trial Disclosure Manager, RCQA

Approved by: Signature on File Date: 18 Apr 2017
Johanna Stamates, RN, MA, CCRC, CHRC
Executive Director, RCQA