



Not My Study... Challenges of Clinical Trial Disclosure at an Academic Medical Center

Office of Research Compliance and
Quality Assurance

Yolanda P. Davis
Sr. Research Compliance Officer



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

Overall Purpose

To Bring Awareness of the importance of Clinical Trial Disclosure and enable the University to be compliant with Current Regulations, Requirements, and Policies.

Objectives

- Participants will have an increased awareness of Clinical Trial Disclosure using ClinicalTrials.gov and its' impact on the University of Miami.
- Encourage researchers to register their Protocols and Report their results on ClinicalTrials.gov in order to become more compliant with the regulations and requirements associated with Clinical Trial Disclosure.
- To remove perceived barriers associated with Clinical Trial Disclosure, Protocol Registration and Result Reporting utilizing ClinicalTrials.gov.

Glossary of Terms

<u>FDAAA</u>	Food and Drug Administration Amendment Act; Section 801; 2007
<u>FDAMA</u>	Food and Drug Administration Modernization Act; Section 110; 1997
<u>RP</u>	Responsible Party <i>Identification of RP</i> <ul style="list-style-type: none">• Sponsor – Organization that initiates the study or• Principal Investigator (PI) – Only if designated as the RP by the Sponsor Organization or• Sponsor-Investigator – Individual who both initiates and conducts
<u>ICMJE</u>	International Committee of Medical Journal Editors
<u>NCT #</u>	National Clinical Trial Number
<u>CMS</u>	Centers for Medicare & Medicaid Services
<u>RCQA</u>	Office for Research Compliance and Quality Assurance

What is Clinical Trial Disclosure?

The act of making clinical trial information (protocol registration and protocol results) known and/or available publicly.

Why is Awareness so important?

- Continue to be known as a World Renowned Research University
- Garner the Trust of our Surrounding Community
- Maximize Publication Potential
- Research Participant Safety
- Achieve and Maintain Compliance with Federal Regulations

Failure to Embrace the Concept

- What happens if we don't embrace becoming more transparent
 - Civil Penalties up to \$10,000/day from FDA if found to be non-compliant
 - Inability to keep Current and Obtain Future Grant Funding from Federal Agencies
 - Inability to publish articles in 1000+ Journals that have adopted the ICMJE Requirement
 - Non-Payment for Qualifying Services performed during a Clinical Trial, Clinical Study or Registry by CMS

What is ClinicalTrials.gov

- Operated by the National Library of Medicine (NLM)
- ClinicalTrials.gov can be searched in real time to find enrolling and completed studies
- Created to increase research transparency and to help people find trials

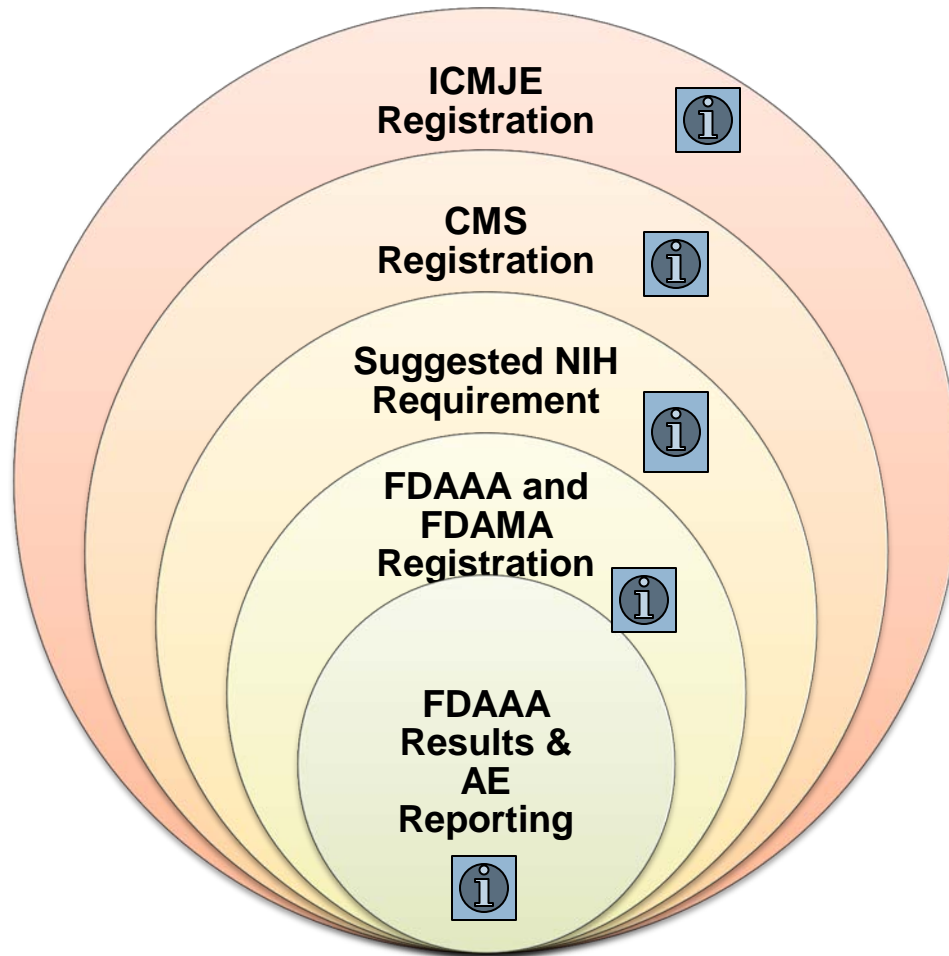
What is ClinicalTrials.gov

- University of Miami has an institutional account
 - Individual investigators/employees are given user profiles on that account
- Each study gets only one record, regardless of number of sites
- Each study should be registered by the Responsible Party (RP)
 - Each user can have access to many records/studies under his/her profile
 - While users can edit such records, only the RP can release it
- Type of information in ClinicalTrials.gov
 - Protocol Registration
 - Results
 - Adverse Events

Challenges Faced in Academia

- Variety of Research
- Variety of Funding
- Variation of how data is collected
- Nuances of Academic Research vs. FDAAA requirements
- Different requirements – FDAMA, FDAAA, CMS vs. ICMJE
- Who is the Responsible Party
- Volume of Trial Registrations
- Volume of Registration System Users
- Infrequent Use of Protocol Registration System
- Lack of Understanding of the Need for Disclosure

Clinical Trial Disclosure Requirements



Clinical Trial Disclosure

How will we deal
with the Challenges
at the University of
Miami

Implementing a Clinical Trial Disclosure Compliance System at an Academic Medical Center

Implementation Approach

RCQA

Operations

Awareness

Training

Admin.
Oversight

Support

C
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Data Entry
[Registration /
Results]

Timeline
Management

Change
Control

Implementing a Clinical Trial Disclosure Compliance System at an Academic Medical Center

- **Awareness**

- ListServ emails, Grand Round Discussions, Targeting Those most Affected,

- **Training**

- Robust Planned Training, Q & A Sessions where the Participants Direct the Training Expected

- **Administrative Oversight**

- Policy Creation, Identifying Needed Process Improvements, Implementing Technology to facilitate compliance, Tracking Legal and/or Clinical Research Guidances and Requirements

Implementing a Clinical Trial Disclosure Compliance System at an Academic Medical Center

- **Support**

- SOP Templates, Interactive Tool to help determine if Proposed Study meets the requirements for Registration, Readily Available FAQ Document, Links to Education Material, Helpful hints documents, Courtesy Notifications and Reminders of upcoming tasks, Peer Coaching to Increase internal Capabilities to Comply with Clinical Trial Disclosure

- **Compliance**

- Audit Clinical Trial Disclosure Tasks, Produce and analyze metrics, and quality of submissions, Evaluate and report on trends and identify areas for improvements

Want To Learn More

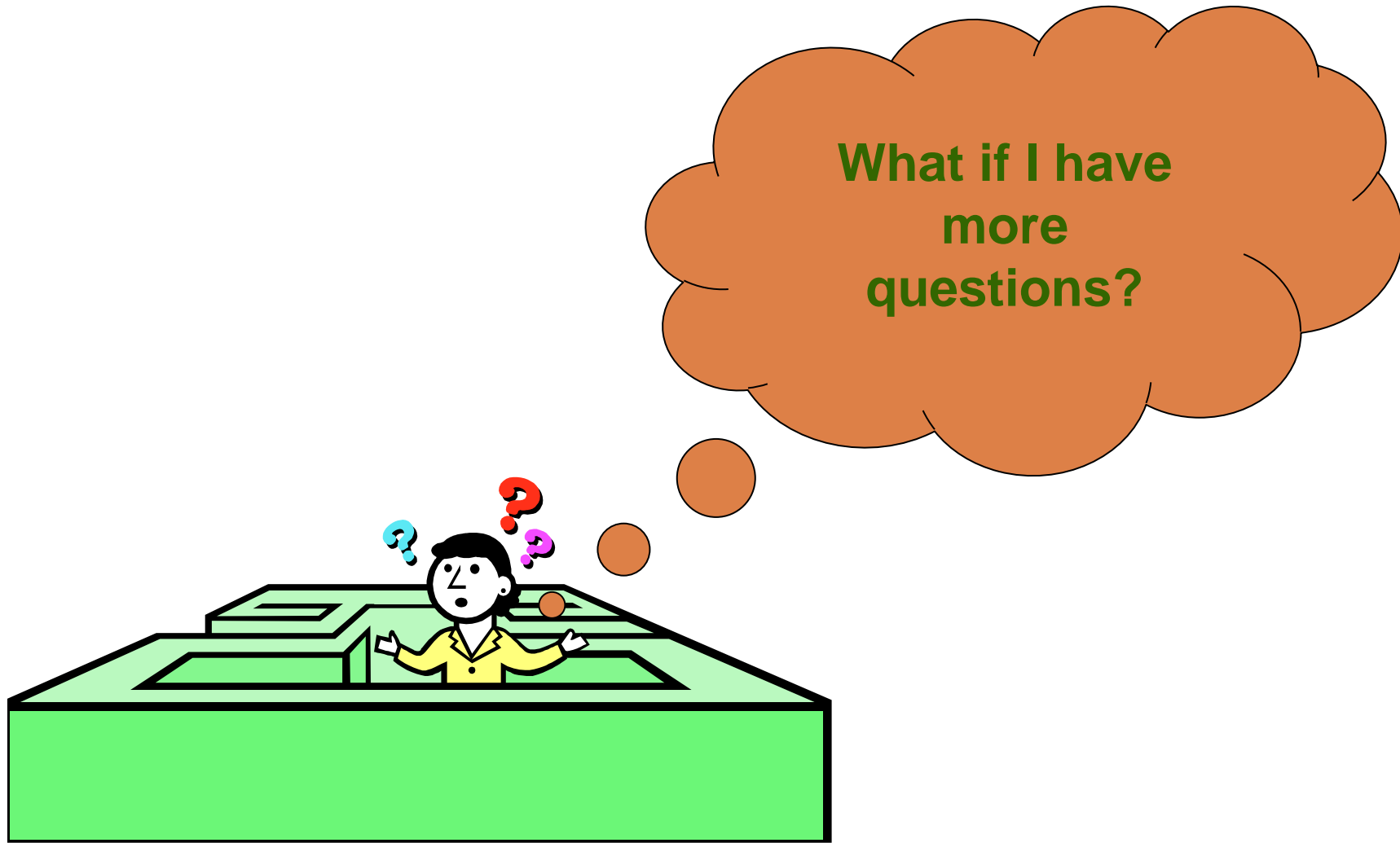
- **Look for these trainings Related to Clinical Trial Disclosure in ULearn**
 - **Introduction and Overview of Clinical Trial Disclosure**
 - **Protocol Registration on ClinicalTrials.gov** (must have taken the Introduction and Overview of Clinical Trial Disclosure Course)
 - **Result Reporting on ClinicalTrials.gov** (must have taken Introduction and Overview of Clinical Trial Disclosure and Protocol Registration on ClinicalTrials.gov)
 - **Managing your Record on ClinicalTrials.gov** (must have taken the Introduction and Overview of Clinical Trial Disclosure and Protocol Registration on ClinicalTrials.gov course)
 - **Is Your Protocol Registration Ready**

Feedback

- Please complete the survey at the following URL:

https://umiami.qualtrics.com/SE/?SID=SV_39GXrUVmfstfoG1

You will receive an email with a reminder. Thanks in advance for your participation.



Additional Resources

- General ClinicalTrials.gov information:
<http://clinicaltrials.gov/ct2/about-site>
- FDAAA related information: <http://clinicaltrials.gov/ct2/manage-recs/fdaaa>
- For specific questions or comments: register@clinicaltrials.gov.
- Office of Extramural Research (OER):
http://grants.nih.gov/Clinialtriasl_fdaaa/
- Frequently Asked Questions for NIH Grantees:
http://grants.nih.gov/ClinicalTrials_fdaaa/faq.htm
- *Instructions for Authors* sections of ICMJE journals all have information regarding clinical trial registration
- **Local Contacts:**
 - University of Miami, Yolanda P. Davis at y.p.davis@med.miami.edu or 305.243.0494

Clinical Trial Disclosure

References

- FDAAA Section 801 (2007)
- FDAMA Section 113 (1997)
- ICMJE Statement 2004
- An Academic Medical Center Perspective, DIA_Clinical Trial Disclosure: Moving Towards Clinical Trial Transparency. October 1 – 2, 2013; Bethesda, Maryland
- Teden, P (2010). Clinical Trial Registration and Results Disclosure; Business Process Considerations. Drug Information Journal, 243 – 252
- Zarin, D.A., & TSE, T. (2008 March 7: 319(5868)). Moving Towards Transparency of Clinical Trials. Science, 1340 – 1342

Clinical Trial Disclosure

Questions?



Contact Information

Office of Research Compliance and Quality Assurance

Yolanda P. Davis: y.p.davis@med.miami.edu

- <http://www.uresearch.miami.edu>
- Telephone: (305) 243 0494
- Fax: (305) 243 6160
- E-mail: RSQA@med.miami.edu

To report a problem or concern:

www.canewatch.ethicspoint.com

FDAAA – Results Submission

Required for:

- Applicable Clinical Trials
- In which the study product is approved (for any use) by FDA

When:

- Within 12 months of Primary Completion Date (final data collection for primary endpoint)
- If product not approved by Primary Completion Date but is approved later, then results due 30 days after approval
- Delays are possible, primarily for manufacturer or under limited special circumstances
 - Pending publication is NOT considered a good cause for delay



<http://clinicaltrials.gov/ct2/manage-recs/fdaaa>

FDAAA 2007

- **FDA Amendments Act of 2007 (FDAAA)**

- Most prospective clinical trials involving regulated drugs, biological products, and devices must be registered on ClinicalTrials.gov. (The law also requires reporting of results and adverse events for a subset of these studies.)

To learn more about FDAAA 801 Requirements, visit:

<http://clinicaltrials.gov/ct2/manage-recs/fdaaa>



NIH – Requires and Encourage


- NIH grantees must take specific steps to ensure compliance with NIH implementation of FDAAA.
 - Studies that meet the FDAAA definition of Applicable Clinical Trial **MUST** be registered,

The NIH encourages registration and results reporting for **all NIH-supported clinical trials**, regardless of whether or not they are subject to FDAAA.

Source: http://grants.nih.gov/ClinicalTrials_fdaaa/steps.htm



CMS Requirement

- Effective January 1, 2014, it will be mandatory to report a clinical trial number on claims for items/services provided in clinical trials, clinical studies and registries that are qualified for coverage as specified in the Medicare National Coverage Determination (NCD) Manual, Publication 100-03, section 310.1. 

CMS Guidance on including NCT on Medicare claims: <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8401.pdf>

ICMJE Requirement

International Committee of Medical Journal Editors (ICMJE)

- Requires registration in a publicly available, searchable system.
- Scope is broader than FDAAA (i.e. clinical trials).
- Includes 1000+ journals that have adopted the ICMJE policy, such as BMJ, JAMA, and NEJM.

Source: <http://www.icmje.org/journals.html>

