Becoming Aware of the Requirements Surrounding Clinical Trial Disclosure (ClinicalTrials.gov)

Office of Research Compliance and Quality Assurance

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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.
## Glossary of Terms

<table>
<thead>
<tr>
<th><strong>ACT</strong></th>
<th>Applicable Clinical Trial</th>
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<tbody>
<tr>
<td><strong>CMS</strong></td>
<td>Centers for Medicare &amp; Medicaid Services</td>
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<tr>
<td><strong>FDA</strong></td>
<td>Food and Drug Administration</td>
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<td><strong>FDAAA</strong></td>
<td>Food and Drug Administration Amendment Act; Section 801; 2007</td>
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<tr>
<td><strong>FDAMA</strong></td>
<td>Food and Drug Administration Modernization Act; Section 113; 1997</td>
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<td><strong>ICMJE</strong></td>
<td>International Committee of Medical Journal Editors</td>
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<tr>
<td><strong>NCT #</strong></td>
<td>National Clinical Trial Number</td>
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<tr>
<td><strong>NIH</strong></td>
<td>National Institute of Health</td>
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<tr>
<td><strong>RCQA</strong></td>
<td>Office for Research Compliance and Quality Assurance</td>
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**RP**

_**Identification of RP**_

- **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
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 could happen 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
HOW AWARE ARE YOU?
How To Vote Respond Texting

1. Standard texting rates only (worst case US $0.20)
2. We have no access to your phone number
3. Capitalization doesn’t matter, but spaces and spelling do
Case Study #1

Effectiveness of Bupropion for Treating Nicotine Dependence in Young People

- Study Design: Multi-center, Randomized, Efficacy Study
- Interventions: Bupropion, Placebo
- Primary Outcome: Smoking Behavior over 6 months
- Study Details: Company ABC is Sponsor, Dr. John Doe is PI
- Study has been registered on ClinicalTrials.gov
**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
Case Study #2

• A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Study of ABCD-1234 in the Treatment of Multiple Sclerosis.
  – Study Design: PI Initiated Trial, IND Exempt
  – Primary Outcome: Proof of Concept
FDAAA - Registration

Required for ‘**Applicable Clinical Trials**’:
- Intervventional studies (drugs, biologics, devices)
- Phase 2 – 4 (not phase 1 drug; not small feasibility device;)
- US FDA jurisdiction (e.g., IND/IDE, IND Exempt, or One US Site)
- Studies initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007

When:
- Within 21 days of enrollment of 1st subject
- Update at least every 6 months (30 days for Recruitment Status and Primary Completion Date)

http://clinicaltrials.gov/ct2/manage-recs/fdaaa
FDAMA - Registration

• Some Phase 1 trials, though they are not Applicable Clinical Trials under FDAAA, are required to register under FDAMA – the earlier law - - which is still in effect.
  – These involve primarily experimental treatments for serious or life-threatening diseases whether using an IND, Group C Cancer drug, or other FDA regulated product.
  – Thus, many studies for cancer and other serious and life-threatening diseases must register regardless of Phase.

For more information:
Case Study #3

- Coping With Adolescent Peer Victimization and Reducing Anxious/Depressed Symptoms
  - Study Design: Interventional, Non FDA Regulated Intervention
  - Primary Outcome: Anxiety Disorder Interview Schedule – Children
  - NIH Funded
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](http://grants.nih.gov/ClinicalTrials_fdaaa/steps.htm)
Case Study #4

Hip Fracture Study

- Method: Compile data from electronic medical record (EMR) over a two year period for 1700 subjects
- Data elements: smoking status, use of alcohol, bone marrow density, weight, and height
- Primary Outcome: Determine the validity of a new hip fracture risk assessment method compared to FRAX, World Health Organization’s fracture risk tool
- Patients Insurance is billed for surgery
CMS Requirement

• Effective January 1, 2014, it became 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.

Case Study #5

Effect of Chronic Sleep Restriction in Young and Older People

• Study Design: Open label, Crossover Assignment
• Interventions: Chronic sleep restriction
• Primary Outcome: Changes in sleep and waking EEG measures, frequent measures of performance, attention, alertness
• Other fact: Two universities collaborating, Dr. A @ AU and Dr. B at BU; Dr. B designed study and wants to contribute to the existing literature, but Dr. A will enroll more subjects
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
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
What if I have more questions?
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/
- 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

Questions?
Contact Information

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To report a problem or concern:

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