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Proposed Changes to ClinicalTrials.gov

Reporting Requirements
Elizabeth Massey Gendel, PhD

On 11/19/14, HHS and NIH released 2 proposals for ClinicalTrials.gov reporting requirements: (1) the Notice of Proposed Rulemaking (NPRM) and (2) draft NIH policy. Both documents are open for a 90-day public comment period ending on 2/19/15.

Notice of Proposed Rulemaking (NPRM)

The mandate to register Applicable Clinical Trials (ACTs) and submit results to ClinicalTrials.gov has been in place for several years, as described in the Food and Drug Administration Amendments Act of 2007 (FDAAA). The purpose of the NPRM is to clarify the FDAAA requirements and propose a few changes. Notable changes are listed below:

- Based on information entered at the time of registration, an algorithm would determine whether a study is an ACT.
- Results information would be required for all ACTs that are required to register, not just ACTs in which the drugs or devices are approved, licensed, or cleared.
- Additional data elements would be required for registration and results submission, listed here.
- Some data elements would have to be updated more frequently, detailed here.
- Responsible parties would be required to correct any errors within 15 days.

Draft NIH Policy

The purpose of the proposed NIH policy (detailed in NOT-OD-15-019) is to promote the dissemination of information from NIH-funded clinical trials.

The policy would extend the FDAAA requirements to all clinical trials funded by NIH, whether or not the trials are subject to FDAAA. In other words, registration and results submission would be required for NIH-funded clinical trials of all phases (phase 1 and pilot projects would not be excluded, as in FDAAA) and for all NIH-funded interventional trials (not just studies of drugs or devices, as in FDAAA). Compliance with the new policy would be a term and condition in the Notice of Grant Award.

Note that NIH has recently revised its definition of a clinical trial (see NOT-OD-15-015).

Links to Further Resources

Summary of proposed changes
Key changes proposed in the NPRM
NPRM at a glance
News release
NIH viewpoint in JAMA

For assistance with ClinicalTrials.gov registration or results submission, contact Elizabeth Massey Gendel at Elizabeth.M.Gendel@uth.tmc.edu or 713-500-3587.
ClinicalTrials.gov Improvements
Elizabeth Massey Gendel, PhD

Have you noticed? ClinicalTrials.gov has changed their user interface and added some resources.

Changes are detailed at this link and include:

- A new "Draft Receipt (PDF)" link that allows review of the record before it is released to ClinicalTrials.gov. The draft receipt now reflects the current working version of the record, rather than the last version Released (submitted) to ClinicalTrials.gov. A link to the PDF is found on the Record Summary page.

- New and improved Help pages, which include examples, data entry tips, and review criteria.

- Results Data Preparation Checklists, which are found on the Help pages in the Results Section. These new checklists are intended to summarize the data needed before starting results data entry.

For assistance, contact Elizabeth Massey Gendel at Elizabeth.M.Gendel@uth.tmc.edu or 713-500-3587.

Why Do I Need to Register my Trial at ClinicalTrials.gov?
Elizabeth Massey Gendel, PhD

Studies that are considered to be applicable clinical trials (guidance here) are required to be registered at ClinicalTrials.gov.

Why do I need to register my study?

- It’s required by law (FDAAA 801)
- It’s required for journal publication (ICMJE)
- It’s required by UTHealth (HOOP 168)
- It’s mandatory for Medicare claims* (CMS Change Request 8401, MLN Matters SE1344)

*Beginning January 2015, it will be mandatory to report a ClinicalTrials.gov NCT number on Medicare claims for items/services provided in clinical trials that are qualified for coverage. Note that MHHS approval of any qualifying trial is contingent upon registration to ClinicalTrials.gov.

For help in determining whether your study requires registration or for help with any aspect of ClinicalTrials.gov registration and results submission, contact Elizabeth Massey Gendel at 713-500-3587 or Elizabeth.M.Gendel@uth.tmc.edu.
Clinical Research Finance Lunch and Learn
Clinical Research Finance Team

Please **bring your lunch** and join the Clinical Research Finance (CRF) team for the new monthly Lunch and Learn sessions.

These sessions are opportunities for the research community to ask CRF questions that they have about Coverage Analysis, budgeting, and billing, as well as account close outs.

The sessions will be held on the 2nd Wednesday of each month in MSB 2.135 from 11:30am to 12:30pm, so mark your calendars to join us!

The first few sessions will focus on Coverage Analysis and the upcoming NCT # requirements; however, we want these to be open forums for the community to ask any questions that they may have.

So that we may better serve you and know how to tailor the sessions, please send your questions and/or topic suggestions to CRF at crf@uth.tmc.edu ahead of time.

We look forward to seeing you there!

If you have questions, contact Heather Cody at 713-500-3983 or Heather.Cody@uth.tmc.edu.

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**New Requirement for CMS Pre-Approval for Reimbursement of IDE Study Services**
*Elizabeth Massey Gendel, PhD*

As a result of changes to CMS regulations found in 42 CFR 405 Subpart B, pre-approval for reimbursement of IDE study services will be centralized, and requests for review and approval of IDE studies should be submitted directly to CMS, rather than through the local Medicare Administrative Contractor (MAC) Novitas.

This new requirement applies to studies with FDA approval letters dated January 1, 2015 or later. IDE studies approved by MACs prior to January 1, 2015 will continue to be administered by the MAC.

Further information is found at this [link](#).

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**Upcoming Certification Testing Dates**

**CCRP certification**: For those of you interested in becoming a Certified Clinical Research Professional, the next test date in Houston, TX is at The Methodist Hospital on January 17, 2015 with a registration deadline of December 5, 2014. You can find more information [here](#).

**CCRC certification**: The next exam dates for certification as a Clinical Research Coordinator (CRC) are in March 2015. Applications are due by February 1, 2015, and you can find more information [here](#).
Upcoming Training

**Study Coordinator Monthly Forum**

**Objective:** Discuss best practices in clinical research management and network with administrators and staff from various research groups within UTHealth.

**Date:** December 2, 2014; January 27, 2015

**Time:** 11:30 am – 1:00 pm

**Location:** MSB 2.135

*Lunch provided for the first 45 participants.*

Registration is not required. Information [here](#).

**Clinical Research Education Program**

**Objective:** Promote excellence in clinical trial management for research nurses, study coordinators, and other research staff. Days 1 and 2 focus on clinical trial management, and day 3 focuses on clinical trial finance and contracting.

**Date:** April 21 – 23, 2015

**Time:** 8:00 am – 4:00 pm

**Location:** Cooley University Life Center

Registration is required and will open soon.

**iRIS Training**

**Objective:** Provide hands-on training in the iRIS system, which is used to submit research protocols to UTHealth’s CPHS and AWC.

**Date:** December 3, 2014

**Time:** 1:30 pm – 4:00 pm

**Location:** UCT 1160

*Parking will be validated.*

Registration is required. Register [here](#).

**Grants 101**

**Objective:** Provide an overview of the process of preparing and submitting a grant application from UTHealth, as well as the review process by funding agencies. Target audiences are junior investigators and administrative support staff.

**Date:** January 22 – 23, 2015

**Time:** 8:30 am – Noon

**Location:** Cooley University Life Center

Registration is required. Register [here](#).

About the Clinical Trials Resource Center

It is the mission of the Clinical Trials Resource Center (CTRC) to provide a single portal of expertise and best practices for study teams in order to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT 790. Please visit [www.uthouston.edu/ctrc/](http://www.uthouston.edu/ctrc/) for more information.

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