Clinical Research News You Can Use...

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New ClinicalTrials.gov Requirements
On 9/16/16, the US DHHS issued a final rule that has 2 aims: 1) to set forth changes to the legal requirements for registration and results submission at ClinicalTrials.gov and 2) to clarify requirements that were previously set forth by the law. Additionally, the NIH issued a notice of a revised ClinicalTrials.gov policy.

Key Changes to the Law Described in the Final Rule
• Additional registration and results information must now be submitted to ClinicalTrials.gov (i.e., the full protocol must be submitted at the time of results submission).
• Trials involving FDA-regulated products that have not yet been approved, licensed, or cleared by the FDA are now required to submit results to ClinicalTrials.gov.

Compliance with Final Rule Expected by 4/18/17
The final rule will become effective on 1/18/17, and trials that are required by law to be registered (defined by FDAAA as “applicable clinical trials”) must be in compliance with the final rule by 4/18/2017. The new registration requirements described in the final rule will apply to trials initiated on or after 1/18/17, and the new results submission requirements of the final rule will apply to trials that reach their primary completion date on or after 1/18/17.

Key Changes to NIH Policy
The NIH policy is in most ways similar to the final rule, except that NIH now requires that all NIH-funded clinical trials register and submit results, whether or not the trial is required to register by law. Thus, the NIH policy now covers more types of trials than the law, including phase 1 studies, small feasibility studies, and trials that do not involve any FDA-regulated product, such as trials involving only behavioral interventions.

Compliance with NIH Policy Expected by 1/18/17
The NIH policy is effective 1/18/2017, and expectations for compliance will be included in the terms and conditions of NIH awards. This policy does not apply to NIH-funded clinical trials initiated before the effective date of 1/18/17.

Financial Penalties May Begin in 2017
Not only do these changes introduce new requirements, but as NIH director Francis Collins has suggested, issuance of the final rule gives FDA and NIH more “clout” to enforce compliance, and both agencies may start to enforce compliance via financial penalties sometime in 2017.

Links to Resources
• News release on changes to law and NIH policy
• Summary of changes to law and NIH policy
• Table of changes to law and NIH policy
• Paper describing changes to law
• Paper describing changes to NIH policy
• Series of 3 free, live webinars on changes to law

Contact
Elizabeth Massey Gendel, PhD can help study teams understand and navigate these changes (713-500-3587 or Elizabeth.M.Gendel@uth.tmc.edu).
**The Clinical Trials Resource Center (CTRC) has Two New Graduate Assistants!**

**Chaitra Mahesh Muthalgiri, MBBS**

We are pleased to welcome Chaitra Mahesh Muthalgiri, MBBS to CTRC. Chaitra is currently a graduate student in epidemiology at UTHealth’s School of Public Health. She earned her MBBS degree from India and has clinical experience in Emergency Medicine. She’s also in the past worked with UTHealth’s Dr. Shreela Sharma on the Healthy Eating Active Living (HEAL) project. Chaitra will provide support in the CTRC as a graduate assistant. Welcome, Chaitra!

**Noopur Singh, BSE**

We are delighted to welcome Noopur Singh, BSE to CTRC. Noopur is currently a graduate student in biostatistics at UTHealth’s School of Public Health. She earned a Bachelor of Engineering degree from the University of Michigan and has been working in health technology and data analytics for the past 10 years. She has experience providing data management support for epidemiological studies and surveys at research, non-profit, and government organizations in India, Nepal, and the US. She is a part-time research coordinator at Baylor College of Medicine’s Children’s Nutrition Research Center and will also be providing support in the CTRC as our newest graduate assistant. Welcome, Noopur!

**Upcoming Certification Testing Dates**

CCRP certification: For those interested in becoming a Certified Clinical Research Professional, the next exam in Houston is at Methodist Hospital on February 4, 2017 with a registration deadline of December 23, 2016. You can find more information [here](#).

CCRC certification: The next exam dates for certification as a Clinical Research Coordinator (CRC) are in February and March of 2017. Applications are due by February 1, 2017, and you can find more information [here](#).
New NIH Policies Related to Clinical Research

In addition to the revised policy on ClinicalTrials.gov requirements described on page 1, the NIH released two other new policies on 9/16/16, both described below.

**GCP Training** ([NIH notice this link](#))
Effective 1/1/17, NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials are required to receive training in Good Clinical Practice (GCP), and the GCP training received must be consistent with principles described in section 2 of the [International Conference on Harmonisation’s (ICH’s) E6 GCP guidance](#). This required training is in addition to the existing requirement that NIH awardees receive [training on protections for human research participants](#). GCP training must be completed every 3 years, and recipients of GCP training are expected to retain documentation of their training. More information will be forthcoming on options for GCP training.

**One FOA for All Clinical Trials** ([NIH notice this link](#))
NIH will require that all applications involving one or more clinical trials be submitted through a Funding Opportunity Announcement (FOA) specifically designed for clinical trials. This means that the NIH will no longer accept clinical trial applications through FOAs that are not specifically designed to accept clinical trials. The purpose of this policy is to improve NIH’s ability to identify proposed clinical trials, ensure that key pieces of trial-specific information are submitted with each application, and uniformly apply trial-specific review criteria. The target effective date is 9/27/17.

*At the following links, NIH provides resources to help you determine if your study is a clinical trial:*
- [NIH Definition of Clinical Trial](#)
- [Decision Tree](#)
- [Case Studies](#)
- [Q&A](#)

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**Space is Still Available for the Annual Clinical Research Education Program!**

*October 4 – 6, 2016*
8:30 am – 4:30 pm

*Register [here](#).*
Upcoming Training

Clinical Research Finance Lunch and Learn
Objective: Provide staff members guidance on research financial topics (e.g., budgeting, billing, and coverage analysis). Also, a forum to introduce or update financial matters and to present questions or concerns for discussion in an open setting with peers.
Date: October 12, 2016
Time: 11:30 am – 12:30 pm
Location: MSB 2.135
Feel free to bring your lunch.
Registration is not required.

NEO Training for Clinical Research Finance
Objective: A hands-on workshop that will cover the processes for billing, coverage analysis, building a research budget, and reconciliation.
Date: October 25, 2016
Time: 1:30 pm – 4:00 pm
Location: MSB 2.135
Registration is required. Register here.

Clinical Research Education Program
Objective: Promote excellence in clinical trial management for research nurses, study coordinators, and other research staff. This three day program focuses on clinical trial management, good clinical practice, and efficient trial conduct.
Date: October 4 – 6, 2016
Time: 8:30 am – 4:30 pm
Location: Cooley University Life Center
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 https://www.uth.edu/ctrcl/ for more information.

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