Effective 9/16, a new clinical trial management system (called Research Efficiency Tool, or RE-Tool for short) will be available. RE-Tool provides a central system for tracking research projects and includes functionality for developing clinical trial budgets, preparing coverage analyses, scheduling study visits, automating patient scheduling, and tracking sponsor invoices. RE-Tool has been developed in REDCap, and as such, it is intuitive and relatively easy to use.

Research teams interested in using RE-Tool must complete PI and DMO acknowledgement forms and register for training.

The initial 3-hour training sessions were held in late August. Beginning 9/15, training will be offered on each Thursday. The 9/15 session will be from 9am to 12pm in MSB G.100, and the Clinical Research Finance Team will send out a notification with registration details.

The training sessions will familiarize new users with RE-Tool and will cover:
- Introduction to REDCap and basic functionality
- Overview of RE-Tool
- Use of the Protocol Tracker
- Budget/Coverage Analysis development
- Hands-on practice entering study information to RE-Tool
- Q&A session

If you have any additional questions or concerns, please email RE-ToolHelp@uth.tmc.edu. You may also visit CRF’s webpage on RE-Tool here.

Penalties for ClinicalTrials.gov Noncompliance are Anticipated

As we reported in the January 2016 newsletter, NIH director Dr. Francis Collins intimated that enforcement of compliance with ClinicalTrials.gov results reporting requirements will begin after the government finalizes changes to ClinicalTrials.gov requirements and releases the “Final Rule.” We now know that the release date of this Final Rule is likely November of 2016.

As further evidence that enforcement is imminent, Vice President Joe Biden recently threatened to cut funding to those who don’t report clinical trial results at ClinicalTrials.gov. After Biden’s remarks, Dr. Collins told reporters that the Final Rule would give FDA and NIH “clout” to crack down on institutions and individual investigators who don’t report results. Collins stated, “That final rule is close to appearing,” and once it does, “we can basically say to Harvard, ‘Sorry, we’re not giving you any dollars until this principal investigator who ran a clinical trial deposits the data.’”

You’re not alone! Help is available. You are strongly encouraged to contact Elizabeth Massey Gendel, PhD (Elizabeth.M.Gendel@uth.tmc.edu, 713-500-3587) for one-on-one assistance with ClinicalTrials.gov registration and results reporting.
Upcoming Training

**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:** September 8, 2016
**Time:** 1:30 pm – 4:00 pm
**Location:** UCT 1155 (Parking will be validated)
Registration is required. Register [here](#).

**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:** September 14, 2016 (Developing Coverage Analysis; CRF Team)
**Time:** 11:30 am – 12:30pm
**Location:** MSB 2.135
*Feel free to bring your lunch.*
Registration is not required

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

More information [here](#).
**Date:** September 27, 2016
**Time:** 11:30 am – 1:00 pm
**Location:** MSB 2.135
*Lunch provided for the first 40 participants.*
Registration is not required.

**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](#).

**Orientation for Clinical Research Staff**
**Objective:** Educate new clinical research personnel on clinical trial management, as well as IRB review and Memorial Hermann study start up processes. The program will lead into the Study Coordinator Forum.
**Date:** December 6, 2016
**Time:** 9:00 am – 11:30 pm
**Location:** MSB G.100
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 [https://www.uth.edu/ctrc/](https://www.uth.edu/ctrc/) for more information.

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