# IRB NEWS

A monthly newsletter brought to you by the Harvard University Area IRB,
Committee on the Use of Human Subjects


## The Revised Common Rule is Coming!

The Final Rule published by the U.S. Department of Health and Human Services on January 19, 2017 does not contain the sweeping changes that were previously proposed. However, the Final Rule does provide some helpful revisions to provide the clarification and reduce administrative burden. Implementation of Final Rule by the feds is slated for January 19, 2018. To prepare the Harvard research community for these upcoming changes, the IRB office will be holding one and a half hour drop-in training sessions in the Forum Room, Lamont Library on the following days/times:

- **Tuesday, December 19, 11:30 am**
- **Tuesday, January 2, 9:30 am**
- **Thursday, January 4, 3:30 pm**
- **Monday, January 8, 2:30 pm**
- **Thursday, January 11, 1:00 pm**

## ESTR Upgrade to Incorporate Revised Rule Changes

Our online sub**m**ission system, ESTR, will be upgrading shortly to accommodate the Revised Rule changes that are to take place. Our System Administrator will be holding one hour sessions to provide an overview of the system changes and discuss how they affect IRB submissions and review. The sessions will be held at **Story Street** in the **first floor conference room** on the following days/times:

- **Thursday, January 4, 11:00am**
- **Monday, January 8, 11:00 am**

- **Tuesday, January 16, 2:00 pm**
- **Monday, January 22, 3:00 pm**

To sign up for one of these sessions, please visit **this webpage.**

## Receiving NIH Funds

As part of the NIH initiative to improve the quality and transparency of NIH supported research, a suite of initiatives have been launched. These initiatives include dedicated funding opportunity announcements for clinical trials, Good Clinical Practice training, enhanced registration and results reporting on ClinicalTrials.gov and required use of single IRBs for multi-site studies. Determining whether these initiatives apply to your research largely depends on whether your research meets the NIH definition of a clinical trial. The NIH has also boiled down this definition to some basic questions researchers need to ask, and answer. These questions are:

- Is your research funded by NIH?
- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

If the answer to all four questions is yes, then NIH considers your research a clinical trial. Don't fret—the Harvard University Area IRB Office is here to help! Please drop us a line!

## Like Our New IRB Newsletter?

We hope you enjoyed receiving our IRB Newsletter. Each month, we will be providing you new information on topics pertaining to items in the IRB world, the IRB office, and the local research community. If you would rather not receive our IRB Newsletter, just click on the unsubscribe link below. And, please know that you can always check out our website for all of the latest information!

**Harvard University Area IRB, Committee on the Use of Human Subjects (CUHS)**

Smith Campus Center, 1350 Massachusetts Ave, Suite 935 Cambridge, MA 02138