NEW “COMMON RULE”
IRB REGULATIONS
Effective January 2018

The scheduled date for the majority of the revisions to the New Federal IRB Regulations is quickly approaching. The 125-page policy governing research involving human subjects involves significant changes to improve protections and streamline the IRB review process. While there is a chance of a one-year delay in implementing some of the provisions, IRBs would likely be able to proceed with implementing several “burden-reducing” changes.

The Office of Research Integrity (ORI) is preparing for the upcoming regulatory shift by revising applications, procedure/guidance documents, checklists, and even the new E-IRB submission system to take advantage of regulatory flexibility.

The goal is that the E-IRB system, currently in pilot phase, can be launched campus-wide based on the new rule. This would allow researchers to transition to a version of E-IRB that will closely mirror the future of research oversight.

A few of the changes researchers can anticipate include:
- New Exempt Review Categories for Low-Risk Research
- Streamlined Continuing Review requirement for Expedited Research Protocols
- A New approach to Consent which requires that the “Key Information” essential to decision making receive priority by appearing at the beginning of the consent form and being presented first in the consent discussion.

ORI and the Center for Clinical and Translational Science (CCTS) will continue to provide announcements and education sessions to introduce changes based on implementation of the new regulations.

Randomization Video for Potential Participant Education

The Office for Human Research Protections (OHRP) has released a new video on randomization on its public outreach website About Research Participation at www.hhs.gov/About-Research-Participation. This and other materials on this website are intended to help potential participants understand how research works, what questions they should consider asking, and things to think about when deciding whether to participate in a study. Research staff can also make use of these materials to facilitate the informed consent process.

RANDOMIZATION
This video explains the concept of randomization and what potential participants need to know when volunteering for a study with a randomized design.