HHS issues a New Common Rule, but is it here to stay?

In January 2017 the Office of the Federal Register published a revised Federal Policy for the Protection of Human Subjects, (aka, the Common Rule). The final version of the updated rule represents extensive work, debate, and revisions dating back to 2011.

While less extensive than the advance proposed rules previously released for public comment, the final will still have broad implications for human subject research. The controversial proposed revisions which added requirements for research with biospecimens are absent in the final rule. Many of the changes that remain are intended to streamline low-risk research.

The ultimate fate of the new rule remains to be seen. A Congressional Review Act provides the new administration with a 60 legislative day review period during which time, any new regulations could be overturned.

If the rule stays, most provisions are scheduled to go into effect January 2018. Interpreting and implementing changes from the 543 page final rule will take time and result in updates to existing policies, forms, guidance and operations related to the UK Human Research Protection Program.

Human Research Update at the January 2017 Center for Clinical & Translational Science (CCTS) Clinical Research Update Series.

At the January 17th CCTS Clinical Research Update program, ORI staff presented information on forthcoming regulatory changes, ongoing IRB initiatives, & evolving operational policies impacting human and clinical research.

If you were unable to attend and would like a copy of the handout, contact ORI education coordinator Belinda Smith (belinda.smith@uky.edu).