Open call to all biomedical researchers: *Tell the federal government how proposed changes to regulations will impact your research – by January 6, 2016*

What is this? “The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have announced proposed revisions to Federal Policy for the Protection of Human Subjects,” known as “The Common Rule.”

What requirements are revised?
- Secondary Use of Biospecimens/Data
- Exemptions
- Elements of Consent
- Waivers of Consent
- Continuing Review
- Minimal Risk Definition/Expedited Review
- IRB Operations
- IRB Review of Grant Applications

What requirements are new?
- Exclusions
- Privacy Safeguards
- Broad Consent
- Public Posting of Consent Forms
- Single IRB Review for Multi-Site Research
- Extend the Common Rule to all Clinical Trials

What do I need to do?
- **Review the details**
  - The UR Office for Human Subject Protection October 27th presentation – [slides & video](#)
  - US Department of Health and Human Services summary and details are found [here](#)
  - Public discussions of the network of Clinical and Translational Science Award (CTSA) hubs

- **Submit feedback** to the federal government before January 6th
  Per HHS.gov, you may submit comments in one of three ways (no duplicates):

  1. **Electronically**, You may submit electronic comments on specific issues in this regulation. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)
     - In another tab or window, access [www.regulations.gov](http://www.regulations.gov):
     - Copy and paste, or just retype, the docket number HHS–OPHS–2015–0008, into the regulations.gov box that is labeled “Search.”
     - The first answer should say “Featured Result.”
     - Click on “Comment Now” button to the right of the notice title.

  2. **By mail**. You may mail written comments (one original and two copies) to the following address ONLY: Office for Human Research Protections (OHRP), 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Please allow sufficient time for mailed comments to be received before the close of the comment period.

  3. **By hand or courier**. If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to the Office for Human Research Protections (OHRP), 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Where can I get more information?