Proposed Revisions to DHHS Regulations for Research Involving Human Subjects
“The Common Rule”

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Research Administrators Forum
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DHHS is Proposing Changes to the Common Rule

- Seeking **public comment** on array of issues related to ethics, safety and oversight of human research

- **Historic event**: First proposed changes to the Common Rule since 1991

- Comment period ends **October 26, 2011**
Why Revise the Common Rule?

- Two overarching goals:
  - Enhance the **protection** of research subjects
  - Improve **efficiency** of the review process

- Seven possible regulatory reforms described in Advance Notice of Proposed Rulemaking (ANPRM)
  - On the surface, the changes appear to be really good and well intentioned, but the devil is in the details!
ANPRM Highlights

Proposed revisions (with enhanced research protections in mind):

- Specific data security protections, calibrated to the level of identifiable information collected
- Require written consent for research use of biospecimens, even those that have no identifiers
- Greater specificity about how consent forms are written and what information they contain
ANPRM Highlights

- Proposed revisions (with efficiency in mind):
  - Use of a **single IRB of record** for multi-site studies
  - No IRB **continuing review** of minimal risk research (expedited studies)
  - Revise and simplify **exempt research categories** and the process of exemption
  - Create a single website for **adverse event reporting**, stored in a single database
How to Comment on the ANPRM

- Individually:
  - Go to www.regulations.gov
  - Docket ID# HHS-OPHS-2011-0005

- Part of a group - UCLA and UCOP will be submitting a response
  - UCLA survey will be sent next week
  - Comments can be sent by email to Sharon Friend: sfriend@research.ucla.edu
More Information

Office of Human Research Protection website:
http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html

- Read ANPRM
- View FAQs
- How to submit / browse comments
- View table comparing existing regulation with changes in the ANPRM