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HOW TO COMMENT ON DHHS ANPRM TO THE COMMON RULE

Date: 2011-09-26

Brief Overview: Advanced Notice of Proposed Rulemaking (ANPRM) for Revisions to the Common Rule



The Secretary of Department of Health and Human Services (DHHS) in coordination with the Office of Science and Technology Policy (OSTP) announced on July 26, 2011 its ambitious effort to update the regulations overseeing research on human subjects. The proposed changes can be found in an [Advance Notice of Proposed Rulemaking \(ANPRM\), Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators](#), published in the July 25 Federal Register (92 pages). Before making any revisions to the regulations, which have been in place since 1991 and are often referred to as the Common Rule, the government is seeking the public's input on an array of issues related to the ethics, safety, and oversight of human research. A [DHHS Summary Table](#) of the 19 proposed revisions is also available.

The deadline for comments to DHHS has been extended to October 26, 2011 by 5pm, EST!

Summary of Aspects of Common Rule Being Re-Examined

The government has **two overarching goals** with respect to the revisions it is considering to the Common Rule: (1) to enhance the protection of research subjects and (2) to improve the efficiency of the review process. To accomplish these goals, **seven possible regulatory reforms** are envisioned and described in the ANPRM:

- Revising the existing risk-based framework to more accurately calibrate the level of review to the level of risk.
- Using a single Institutional Review Board review for all domestic sites of multi-site studies.
- Updating the forms and processes used for informed consent.
- Establishing mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable data.
- Implementing a systematic approach to the collection and analysis of data on unanticipated problems and adverse events across all trials to harmonize the complicated array of definitions and reporting requirements, and to make the collection of data more efficient.
- Extending federal regulatory protections to apply to all research conducted at U.S. institutions receiving funding from the Common Rule agencies.
- Providing uniform guidance on federal regulations.

Request for Formal Commentary on the Proposed Changes

It is very important that the opinions and comments of the UCLA research community be added to the national discussion. The proposed changes are the most extensive since the Department of Health, Education and Welfare published proposed rules for the protection of human subjects involved in research in 1979. Though these rules have been updated, there remain questions about whether the current regulatory framework is appropriate and adequate for human research activities occurring now in the 21st century.

Many researchers agree that the goals of the ANPRM revisions are laudable. However, the specific details about how these goals would be achieved have resulted in a national debate reflecting widely divergent opinions. You might want to check with your professional society to see if it has prepared comments for your field of research. Please take the time to add your opinion, as described below.

What UCLA IS Doing

The OHRPP has prepared the following:

- [UCLA OHRPP ANPRM Survey](#) to elicit feedback to the proposed revisions. The survey includes all 19 proposed revisions and seeks your opinion as well as requests examples of how these changes may positively or negatively affect your research.
- [UCLA Summary Table](#) with the 19 proposed revisions and the corresponding questions directly from the [ANPRM](#). The [DHHS Summary Table](#) is also available, as noted above.
- [List of the 74 Questions in the ANPRM](#) in a more readable format.

The OHRPP welcomes and encourages your feedback and will use your responses in developing a response to the DHHS.

Please submit all comments by Friday, October 14th.

What UCOP Is Doing

The UCOP Research Policy Analysis and Coordination (RPAC) unit of the Office of Research & Graduate Studies invites your input to help develop a UC system wide comment letter. **UCOP asks that your comments be submitted as soon as possible** in order for them to incorporate your input to the system wide comment letter that is due to HHS by October 26, 2011.

You may e-mail your ANPRM comments to [Jeff Hall](#) as soon as possible.

What You Can Do

You may submit your individual comments as follows:

- **UCLA OHRPP:** Via the [UCLA OHRPP ANPRM Survey](#) or directly by October 14, 2011.
- **UCOP:** E-mail your comments to [Jeff Hall](#) as soon as possible.
- **DHHS:** Directly to DHHS by October 26, 2011 by 5pm, EST. To submit individual comments directly to DHHS, identified by docket ID number HHS-OPHS-2011-0005, following one of the methods below:
 - [Federal eRulemaking Portal](#): Enter the above docket ID number in the "Enter Keyword or ID" field and click on "Search". On the next web page, click on "Submit a Comment" action and follow the instructions.
 - Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions) to: Jerry Menikoff, MD, JD, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to the [Federal eRulemaking Portal](#).