

# Agencies Extend Comment Period on Proposed Changes to Clinical Research Rules

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Those wishing to comment on revisions to the Federal Policy for Protection of Human Subjects (known as the “Common Rule”) could add a 30-day comment period extension to the things they were grateful for at this year’s Thanksgiving dinner. On Wednesday, November 25th, the 16 federal agencies involved in updating the Common Rule **announced** an extension of the comment period for the September 8, 2015, **notice of proposed rulemaking** (“NPRM”). The agencies granted the 30-day extension based on requests for additional time to fully review the NPRM and provide comments.

As we’ve **previously reported**, the NPRM makes some significant changes to the Common Rule. The changes include:

- expanding the scope of the applicability of the Rule to cover all clinical trials conducted at U.S. institutions that receive federal funding for non-exempt human subjects research (even if the research itself is not federally funded);
- updating the IRB review process to a more risk-based framework;
- creating new exemptions from the Common Rule for certain types of research; and
- improving and streamlining the informed consent process.

The Department of Health & Human Services has provided a **succinct summary** the changes and the Office of Human Subject Research Protections has created a six-part webinar series available on YouTube with more detail about the changes (links to all webinars are available **here**).

Persons interested in commenting on the NPRM must now submit comments by January 6, 2016.

## Authors