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PROTECTING RESEARCHERS AND RESEARCH SUBJECTS
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Major Proposed Changes on Subject Protection Rule Will Impact IRBs

It's here. After a little more than four years since issuing the Advance Notice of Proposed Rulemaking (ANPRM) on changing the existing Common Rule on the protection of human research subjects, the federal government has issued the subsequent Notice of Proposed Rulemaking (NPRM). On the Web, access to the NPRM is at http://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf.

Although we occasionally note how often Institutional Review Boards (IRBs) are cited in regulatory proposals, we won't bother in this case. Suffice it to say that they are cited over 100 times.

Before proceeding, we are asking our readers to do some things we've never requested before. **First**, you don't even have to examine the 128 pages of the FEDERAL REGISTER notice initially. We estimate that those 128 pages contain approximately 140,000 words -- including 30 tables. An example of the tables is Table 30 ("Estimated Annual Reporting Burden" on page 54029). That federal reporting estimate is an annual total of 12,155,926.14 reporting hours for IRBs and others, which does not include the additional burdens if one of the notice's many proposals becomes final; i.e., to expand applicability of the Common Rule to studies not now covered.

We Need More Time! 90 Days Is Not Enough

Second, instead of reviewing the proposed changes first, we urge you to submit -- as soon as possible -- your request to extend the comment deadline from what we consider to be an astoundingly unacceptable December 7 of this year, to at least March 7 of 2016 (about 180 days) -- if not longer. Several ways of submitting comments are explained on page 53933 of the notice, in the 2nd column. One of the most common methods is to access the Web address at http://www.regulations.gov, referring to Docket ID Number HHS-OPHS-2015-0008.

Note that the government's own "Guide to the Rulemaking Process" (on the Web at https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf) states that "For complex rulemakings, agencies may provide for longer [public comment] time periods [i.e., longer than 30 - 60 days], such as 180 days or more."

Third, don't hesitate to point out to federal agencies that it took them four years to review a few hundred comments on the previous ANPRM and related developments to come up with the new NPRM. And the research compliance community gets only 90 days to review about 140,000 words that could affect most, if not all, of their human studies? This makes sense?

Fourth, we ask that you contact colleagues (including elected officials or others with respected reputations) and ask them to also submit the same request

NOTE #1: Quoted materials in this newsletter appear exactly as originally published in source documents, including any misspellings, grammatical errors, missing words, etc.

NOTE #2: Articles may be continued in subsequent issues.

ALSO IN THIS ISSUE

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