

# **Advance Notice of Proposed Rulemaking: Summary of Comments**

**Edward E. Bartlett, PhD**  
Office for Human Research Protections

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# Disclaimer

- *The views expressed in this presentation are solely those of the presenter, and do not represent the official position of the U.S. Department of Health and Human Services or the Office for Human Research Protections.*

# Federal Register Notice

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- July 26, 2011 - Advance Notice of Proposed Rule Making (ANPRM) was published in the Federal Register

# Questions

- ANPRM included 74 questions
- Most of the 74 questions had sub-questions, so actual number of questions is 155
- Questions were developed with input from a range of federal agencies
- Many questions were written in an open-ended format, in order to stimulate discussion

# Organization of Questions

Questions were organized into 7 broad areas:

- 1) Refinement of the existing risk-based regulatory framework
- 2) Use of a single IRB review of record for domestic sites of multi-center studies
- 3) Improvement of consent forms and the consent process
- 4) Establishment of mandatory data security and information protection standards for all studies that involve identifiable or potentially identifiable data
- 5) Establishment of an improved, more systematic approach for the collection of information on unanticipated problems and adverse events
- 6) Extension of Federal regulatory protections to all human subjects research, regardless of funding source, conducted at institutions in the U.S. that receive some federal funding for human subjects research
- 7) Improvement in the harmonization of regulations and related agency guidance

# Responses

- Deadline: October 26, 2011
- Over 1,100 responses received
- Some responses addressed most of the 155 questions
- A few submissions exceeded 100 pages in length
- Most submissions were thoughtful and reasoned, some erudite.

# Challenges Encountered in Processing Comments

- Some suggestions in the ANPRM did not have corresponding questions, so commenters responded to questions that were peripherally related to the concept
- Some comments fell outside the scope of topics addressed by the ANPRM
- Some comments were highly nuanced and difficult to interpret
- Some commenters made suggestions about needed *guidance*, when the question was specific to *regulatory* changes
- Some commenters gave identical answers to multiple questions to highlight their concerns
- Some persons submitted identical comments in multiple submissions
- Some organizations organized campaigns to their members, resulting in multiple commenters providing identical answers