

# Single IRB for Cooperative Research

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# Cooperative Research in the Pre-2018 Common Rule

- Each institution engaged in a cooperative research study had to obtain IRB approval of the study
  - Did not require that a separate local IRB at each institution conduct such review
    - IRB Authorization Agreement (IAA)
    - Individual Investigator Agreement (IIA)
- Often resulted in multiple reviews for one study and associated documents (e.g., consent forms)
- Little evidence suggesting that this increased protection of research subjects

# Public Comments to NPRM Proposal

- More than 300 comments
- Research institutions tended to oppose it
  - Majority of these supported the proposal, but opposed a mandate
  - Need for local review
  - Operational issues and increased administrative cost
- Individuals and scientific organizations tended to support it
  - Avoid redundancy
  - Streamline IRB approval

# Cooperative Research in the Revised Common Rule

## Applicability

- U.S. institutions engaged in federally funded cooperative research for the portion of the research conducted in the U.S.

## Not applicable when:

- More than single IRB review is required by law (including tribal law)
- Federal sponsor determines and documents that the use of a single IRB is not appropriate for the particular context

§\_.114(b)

# Compliance date

- Applies to research approved by an IRB on or after January 20, 2020