
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

# The Single IRB Requirement in the Revised Common Rule (45 CFR 46.114)

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# 45 CFR 46.114 of the new rule

(a) Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

(b)(1) Any institution located in the United States that is engaged in cooperative research **must rely upon approval by a single IRB for that portion of the research that is conducted in the United States**. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

(2) The following research is not subject to this provision:

(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

# New rule studies subject to the single IRB requirement

- *To be subject to the single IRB requirement, a study must meet all of the following criteria:*
  - The study is subject to the new rule. This could be because:
    - ✓ (1) the study was initially approved by the IRB on or after January 21, 2019; or
    - ✓ (2) an institution determined and an IRB or institution document that a study initially approved under the old rule would instead be subject to the new rule
  - The study is non-exempt human subjects research
  - The study meets the definition of cooperative research (i.e., projects covered by 45 CFR part 46 that involve more than one institution)
  - The study (or a portion of the study) is supported or conducted by HHS

# Compliance date for the cooperative research provision

## Studies Subject to the Old Rule

- Single IRB of record in cooperative research is optional

## Studies Subject to the New Rule

- Single IRB of record in cooperative research is generally required on and after January 20, 2020 (unless the study qualifies for an exception)

# Implication of the 114(b) compliance date for studies that an institution has transitioned to comply with the revised common rule

- **Transition Principle:**
  - The new rule applies prospectively in transitioned studies (i.e., with respect to actions taken on or after a study's transition date)

- **What does this mean for cooperative research projects that were initially approved under the old rule but have since been transitioned to the new rule?**
  - A single IRB is ONLY needed with respect to regulatorily required IRB actions taken on and after a study's transition date (i.e., the date that an institution or IRB documents that a study originally approved by an IRB under the old rule will instead be subject to the new rule) *[see draft guidance on the transition provision]*

# Questions About the Revisions?

- Submit your questions to OHRP@hhs.gov
- Check out the OHRP website at www.hhs.gov/ohrp for resources on the revised Common Rule