


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

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# DISCLAIMER

*The opinions expressed are those of the presenter and do not necessarily reflect the policy of the Department of Health and Human Services.*

# 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 <u>any</u> 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.

# 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)

# *[NEW!]* HHS Exceptions to the Single IRB Requirement (1)

HHS has determined that for HHS cooperative research subject to the 2018 Requirements, and for purposes of 45 CFR 46.114(b)(2)(ii), an institution may continue to use multiple IRBs, in lieu of a single IRB, for the following research:

(1) Cooperative research conducted or supported by HHS agencies other than the National Institutes of Health (NIH), if an IRB initially approved the research before January 20, 2020.

(2) Cooperative research conducted or supported by NIH if either:

   a. the NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, or

   b. NIH excepted the research from its single IRB policy before January 20, 2020.

# *[NEW!]* HHS Exceptions to the Single IRB Requirement (2)

**Remember:**

- These exceptions ONLY apply in research supported or conducted by HHS
  - VA has announced its intention to publish in the *Federal Register* VA specific exceptions to the single IRB policy
- For NIH conducted or supported studies:
  - Even if you think a study qualifies for an exception from the Common Rule's single IRB requirement, the study may still be subject to the NIH sIRB policy
  - If this is an NIH supported or conducted study, it is up to NIH to determine if you are under their sIRB policy
- Exceptions apply to all sites in a cooperative research activity regardless of when sites are added, so long as at least one site meets one of the two exception categories the cooperative research activity as a whole is excepted from the 114 mandate

# IRB/HRPP Operational Issues Related to the revised Common Rule's sIRB Provision

- What happens if/when there are different sIRB exception policies amongst the different Common Rule departments and agencies?
- Are there situations when an institution doesn't need to worry about the revised Common Rule's sIRB mandate for HHS conducted or supported research?
- How should IRBs and institutions handle situations where the IRB of record and one (or more) relying institutions differ in relevant Common Rule determinations (for example, if they differ on determining a study is exempt vs. nonexempt)?
- How does the NIH sIRB policy fit in with the revised Common Rule's sIRB mandate?

# Resources to Review

- "Revised Common Rule Resources" link in the left navigation menu under the "Education and Outreach" tab on the OHRP website
  - Check out the videos and the Q&A's on the revised Common Rule
- "Single IRB Review" link in the left navigation menu under the "Regulations, Policy, and Posting" tab on the OHRP website
- OHRP's guidance and educational material on institutional engagement
  - Mini-tutorial (video) on engagement
  - Engagement guidance
  - Additional non-engaged scenarios
  - Correspondence on survey firms, FWAs, and engagement
- List of Common Rule departments and agencies

# 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