

Single IRB Review Under the Revised Common Rule

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Disclaimer

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



Revision of the Common Rule

- Revised rule was published in January 19, 2017
- Revisions needed to meet the challenges of the rapidly changing landscape of research
- Goals:
 - To better protect research subjects
 - To reduce administrative burdens so that IRBs can better serve their role
- General implementation date: January 19, 2018
- **Implementation date for the single IRB review provision: January 20, 2020**



Implementation of the Transition Provision

Transition date for revised Common Rule

Pre-2018 Rule applies to all studies

Studies initially “approved” before January 19, 2018:

- Presumption: Pre-2018 rule applies
- Institution may elect to apply the revised Common Rule. IRB must document this in writing.

Studies initially “approved” on or after January 19, 2018:

The revised Common Rule applies

January 19, 2018

Implementation date for single IRB review in cooperative studies: **January 20, 2020**

Requirement for Single IRB Review

- U.S. institutions engaged in **cooperative research** must rely on a single IRB for the portion of the research conducted in the U.S.
- **Cooperative research** is research that involves more than one institution
- Reminder: implementation **January 20, 2020**

§__.114(a),(b)(1)

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Who Selects the Reviewing IRB?

- The Federal department or agency supporting or conducting the research, or
- The lead institution supporting the research, subject to the acceptance of the funding Federal department or agency



What are the Documentation Requirements?

- The relying institution and the organization operating the IRB shall document the institution's reliance on the IRB and the responsibilities of each entity
- Flexible options to meet this requirement include:
 - Describing it in the research protocol
 - Implementing through an institution-wide policy directive
 - Creating a written agreement between the institution and the IRB

§__.103(e)

(7)



Exceptions to the Single IRB Review Requirement

- When more than single IRB review is required by law (including tribal law)
- Whenever 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 – flexibilities allowed

§__.114(b)(2)

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Differences from the NIH Single IRB Review Policy

- Differences in scope and language of the exceptions but generally compatible
 1. NIH policy refers to multi-site studies conducting the **same protocol**; Final Rule refers to **cooperative research** (sites do not have to conduct the same protocol to be subject to the mandate)
 2. NIH allows for additional exceptions – when single IRB is prohibited **by policy**. Requests for exceptions **with compelling justification** will also be considered
- Information on NIH single IRB review policy:
<https://www.nih.gov/about-nih/who-we-are/nih-director/statements/single-irb-policy-streamline-reviews-multi-site-research>

Can Institutions Not Subject to the Mandate Choose to Rely on Single IRB Review?

Yes!

The current ability to voluntarily enter into joint review arrangements is unchanged!

§__.114(c)

(10)



Companion Provision Regarding IRB Accountability

- IRBs not operated by an FWA-holding institution will be directly responsible for compliance
- OHRP will exercise its authority directly over such reviewing IRBs

§__.101(a)

(11)



Please refer to the text of the revised Common Rule available on [OHRP's website](#) for a complete and accurate description of the regulatory requirements



Questions About the Revisions?



- OHRP will be developing resources to explain the revised Common Rule. Check out www.hhs.gov/ohrp
- Submit your questions to OHRP@hhs.gov

THANK YOU FOR YOUR ATTENTION

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