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

- Pre-2018 Rule applies to all studies
  - 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

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)
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)
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)
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](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)
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)
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