Single IRB Review Under the Revised Common Rule

Yvonne Lau, MBBS, MBHL, PhD
Director
Division of Education and Development (DED)
Office for Human Research Protections (OHRP)
Department of Health and Human Services (HHS)

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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.

January 19, 2018

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**

\[\S__.114(a),(b)(1)\]
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
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