

# Revising the Common Rule: AAMC Member Feedback on Proposed Changes to ***IRB Review of Multisite Trials***

Heather H. Pierce, JD, MPH  
Senior Director, Science Policy  
Regulatory Counsel  
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Association of  
American Medical Colleges

## Today's Goals

- Brief overview and orientation to proposed changes
- Tell AAMC:
  - What aspects of the proposal make sense to you?
  - What proposed changes are concerning? What is the effect on institutions? Investigators? Research subjects?
  - What data might be persuasive?
  - How do the proposals advance or hinder the stated goals of:
    1. Increasing human subjects' ability and opportunity to make informed decisions
    2. Reducing potential for harm and increasing justice
    3. Facilitating current and evolving types of research
      - Reducing ambiguity in interpretation
      - Increasing efficiencies
      - Reducing burden on investigators

# Input Opportunities

Direct Input to AAMC – by November 2

- Heather Pierce: [hpierce@aamc.org](mailto:hpierce@aamc.org), 202-478-9926

Conversations with AAMC on Specific Proposals

- Informed Consent – October 13, 2015
- Categorization and IRB Review of Research – October 14, 2015
- Research with Biospecimens – October 21, 2015
- **The Single IRB Mandate – October 22, 2015**
- Find slides and more resources at [www.aamc.org/commonrule](http://www.aamc.org/commonrule)

Send Your Comments to HHS – by December 7

- [www.regulations.gov](http://www.regulations.gov) (HHS-OPHS-2015-0008)

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# Overview of the NPRM

80 Fed. Reg. 53933-54061 (September 8, 2015)

- Executive Summary (p. 53933)
- Discussion of Major Proposals (p. 53942)
- Regulatory Impact Analysis (p. 53993)
- Summary of ANPRM Comments (p. 54033)
- Regulatory Text (p. 54044)

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## **ANPRM – July 26, 2011**

Public comment is requested on the feasibility, advantages, and disadvantages of mandating that all domestic sites in a multi-site study rely upon a single IRB as their IRB of record for that study.

This proposal would only affect which IRB would be designated as the IRB of record for institutional compliance with the IRB review requirements of the Common Rule.

It would not relieve any site of its other obligations under the regulations to protect human subjects. Nor would it prohibit institutions from choosing, for their own purposes, to conduct additional internal ethics reviews, though such reviews would no longer have any regulatory status in terms of compliance with the Common Rule (and could be discouraged).

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## **Draft NIH Policy on the Use of a Single IRB**

Issued December 14, 2014

- Generally requires all domestic sites of multisite NIH-funded studies to have a single IRB of record
- Responsibilities
  - Single IRB: compliance with regulatory requirements for IRBs such as providing initial and continuing review of the research
  - Participating Sites: other regulatory obligations, such as obtaining informed consent, overseeing the implementation of approved protocols, and reporting unanticipated problems and adverse events

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-026.html>

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# Proposed Changes to the Review of Multisite Research

1. All cooperative research must be overseen by a single IRB
2. Federal jurisdiction would extend over independent IRBs
3. Documentation of each organization's responsibilities would be required

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## Questions raised by ANPRM (and the NPRM answers)

- What types of research and how many sites?
  - All types, more than one site conducting research in the United States
  - “Cooperative research projects are those projects covered by this policy that involve more than one institution.”
- How would the IRB be selected?
  - Funding agency would select
  - If no funder, the lead institution selects

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## Questions raised by ANPRM (and the NPRM answers)

- How would the roles and responsibilities be defined to address liability and logistic concerns?
  - New jurisdiction over unaffiliated IRBs
  - Institution and IRB should establish and follow procedures
  - “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.”
- How would local context issues need to be addressed?
  - If required by law or deemed that a single IRB is not appropriate, multiple IRBs may be used
  - Local review could be limited to those questions
  - Most issues can be addressed through mechanisms other than IRB review

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## Cooperative Research (§\_\_\_.114(b); pp. 53981-84, 54052)

Proposal: Require all institutions in the U.S. engaged in cooperative research to rely on a single IRB as the reviewing IRB for that study

- Foreign sites do not need to rely on the single IRB
- Reviewing IRB will be selected by the funding agency
- Does not apply to research for which more than single IRB review is required by law (e.g., FDA-regulated device trials)
- Does not apply to research for which the 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 study

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## **Documenting Institutional Responsibilities (§\_\_\_.103(e); pp. 53984, 53991, 54048)**

Proposal: When an institution is relying on another IRB's oversight, that reliance and the allocation of responsibilities must be documented by both institutions

- (e.g., in a written agreement between the institution and the IRB, or by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution)

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## **Extending Jurisdiction over IRBs (§\_\_\_.101(a); pp. 53983, 54045)**

Proposal: To give Common Rule departments and agencies the authority to enforce compliance directly against unaffiliated IRBs that are not operated by an assured institution.

- “The entities that must comply with this policy are institutions that are engaged in research described in paragraphs (a)(1) or (2) of this section, and **institutional review boards (IRBs) reviewing research that is subject to this policy.**”

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## Mandated Single IRB of Record: Questions Asked in the NPRM

74. Is mandated single IRB review for all cooperative research a realistic option at this time? **Please provide information about the likely costs and benefits to institutions.** Will additional resources be necessary to meet this requirement in the short term? Should savings be anticipated in the long run?
75. What areas of guidance would be needed for institutions to comply with this requirement? Is there something that OHRP could do to address concerns about institutional liability, such as the development of model written agreements?

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## Mandated Single IRB of Record: Questions Asked in the NPRM

76. Would it be useful for this requirement to include criteria that Federal departments or agencies would need to apply in determining whether to make exceptions to the use of a single IRB requirement? If so, what should these criteria be?
77. Are the exceptions proposed appropriate and sufficient, or should there be additional exceptions to this mandate for single IRB review than those proposed in the NPRM?
78. Is three years appropriate timing to establish compliance with this provision?

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## Questions to Consider

- Are there certain types of research or number of sites for which the benefits of single IRB review are greater?
- What is the actual cost or burden of establishing a single IRB relationship? How does this balance with the risks or inefficiencies of multiple IRB reviews?
- What components characterize the successful implementation of single IRB review?

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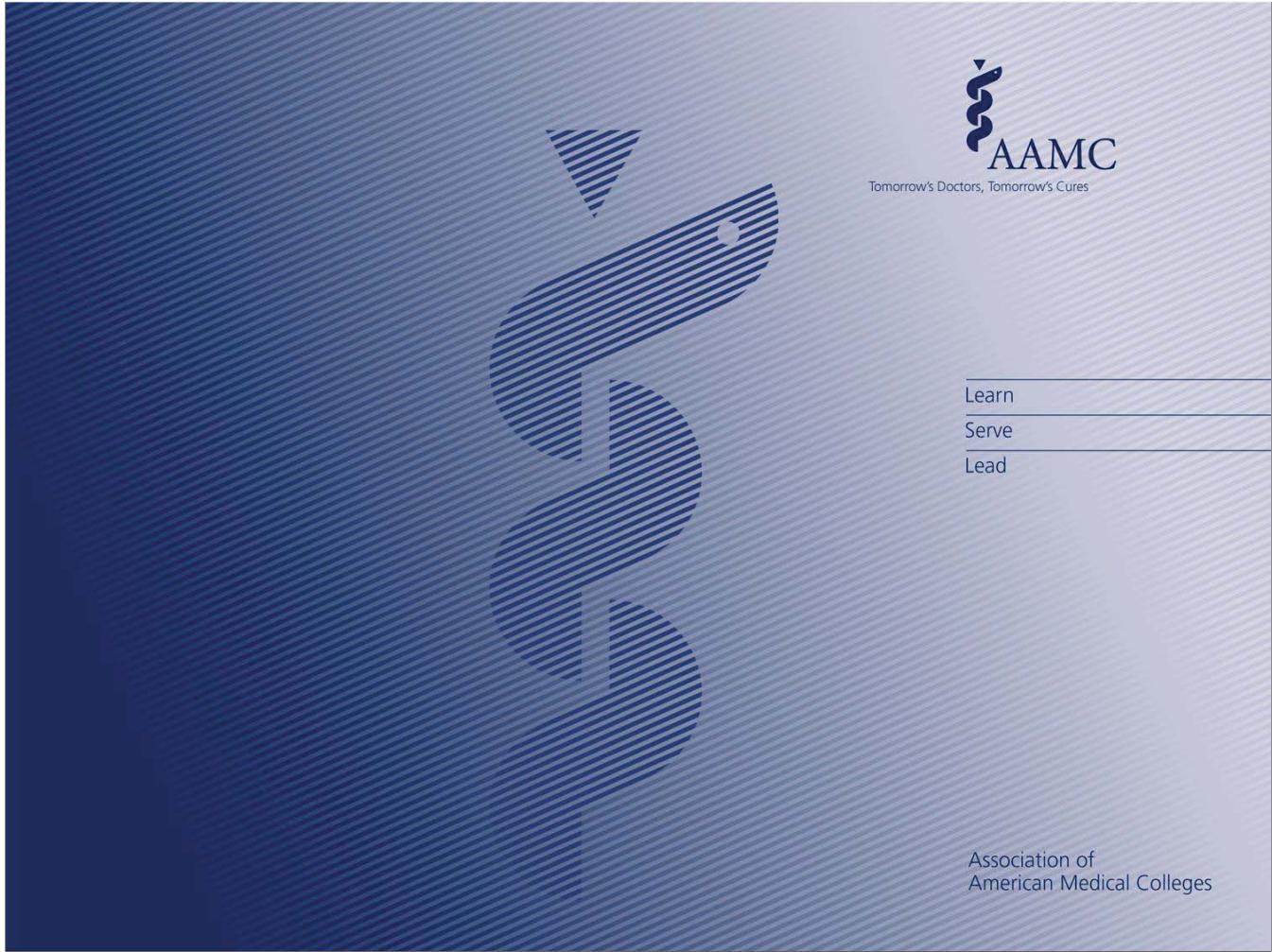


## Important reminders

- The NPRM is not a final rule
- Your input matters to AAMC
  - [hpierce@aamc.org](mailto:hpierce@aamc.org), (202) 478-9926
- Your comments matter to HHS
  - Alternatives are essential
  - Numbers count
  - Data helps
  - It is better to provide some comments on some proposals than not to send comments on any proposals
- More resources at: [www.aamc.org/commonrule](http://www.aamc.org/commonrule)

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