

Revising the Common Rule:

AAMC Member Feedback on Proposed Changes to the ***Categorization and IRB Review of Research***

Heather H. Pierce, JD, MPH
Senior Director, Science Policy
Regulatory Counsel
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Today's Goals

- Brief overview and orientation to proposed changes
- Your input:
 - What aspects of the proposal make sense to you?
 - What proposed changes are concerning?
 - Why? What is the effect on institutions? What is the effect on research subjects?
 - What data do you have (or evaluation needs that you have identified) that 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, 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

Send Your Comments to HHS – by December 7

- www.regulations.gov (HHS-OPHS-2015-0008)

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)

Major Changes to the Categorization of Research

Excluded Activities (§__.101(b)(1)) - NEW

- Activities that are not research (6)
- Activities that are low risk and already subject to independent controls (4)
- Activities that are low risk and do not meaningfully diminish subject autonomy (1)

Exemptions (§__.104(d), (e), and (f)) - MODIFIED

- Low-risk, must be recorded (4)
- Sensitive information, not biospecimens, recorded, must apply standards for protection (2)
- Biospecimens or identifiable private information, recorded, protection standards, informed consent, limited IRB review (2)

Excluded activities

Category 1 (§__.101(b)(1)); pp. 53947-50, 54045

- An institution's operational monitoring and program improvement
- Oral history, journalism, biography, historical scholarship
- Criminal justice activities
- Quality assurance or improvement activities involving the implementation of an accepted practice to improve health care delivery
- Public health surveillance
- Defense and national security activities

Excluded activities

Category 2 (§___.101(b)(2)); pp. 53950-54, 54045-46

- Tests, surveys, interviews or observation, if subjects cannot be identified OR disclosure would not put subjects at risk OR subject to the Paperwork Reduction Act of 1995/Privacy Act of 1974 (*previous exempt category 2*)
- Collection or study of information gathered for non-research purposes if the sources are publically available OR not identifiable (*previous exempt category 4, modified*)
- Research conducted by a federal department or agency on information collected for non-research purposes
- Certain activities covered by HIPAA

Questions 9-24 in the NPRM

Category 3 (§___.101(b)(3)); pp. 53944-45, 54046

- Secondary use of non-identified biospecimens “to generate information about an individual that already is known” (including validation tests, assays)



Excluded: Program Improvement (§___.101(b)(1)(i))

Data collection and analysis, including the use of biospecimens, for an institution’s own internal operational monitoring and program improvement purposes, if the data collection and analysis is limited to the use of data or biospecimens originally collected for any purpose other than the currently proposed activity, or is obtained through oral or written communications with individuals (e.g., surveys or interviews).

- Survey of hospital patients on meal quality would satisfy this exclusion
- Analysis of comparative effectiveness of two different standard of care treatments would not satisfy this exclusion

Questions 6-7 in the NPRM (p. 53948)



Excluded: Quality Assurance/Quality Improvement (§__.101(b)(1)(iv); pp.53948-49)

Quality assurance or improvement activities involving the implementation of an accepted practice to improve the delivery or quality of care or services (including, but not limited to, education, training, and changing procedures related to care or services) if the purposes are limited to altering the utilization of the accepted practice and collecting data or biospecimens to evaluate the effects on the utilization of the practice. This exclusion does not cover the evaluation of an accepted practice itself.

No questions in the NPRM

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Exempt Research Categories

1. Low-risk Interventions (§__.104(d); pp. 53957-61, 54048)
 - Privacy/security standards do not apply
 - **Questions 34-42 in NPRM**
 - Commonly accepted educational settings, normal educational practices
 - Federal projects evaluating public benefit or service programs
 - Benign interventions with data collection from adults if not identifiable as recorded or disclosure would not be damaging
 - Taste and food quality evaluation

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Exempt Research Categories

2. Collection of Sensitive Information (§__.104(e); pp. 53961-63, 54049)
 - May not include biospecimens
 - Privacy/security standards apply
 - **Questions 43-53 in NPRM**
 - Research involving tests, surveys, interviews, or observation if subjects can be identified
 - Secondary research use of identifiable private information from non-research purposes with notification and use only for specified research

3. Storage of biospecimens or data obtained in other research or non-research context OR research on such stored biospecimens (§__.104(f); pp. 53965-68, 54049)
 - Broad informed consent needed
 - Limited IRB review
 - Privacy/security standards apply
 - **Questions 54-56 in NPRM**

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Exempt Research Determination

- Determination of whether research is exempt accomplished through HHS-developed “decision tool” (§__.104(c); pp. 53955-57, 54048)
 - Exemption determinations made by “an individual who is knowledgeable about the exemption categories and who has access to sufficient information to make an informed and reasonable determination, or by the investigator ... who enters accurate information ... into the decision tool”
 - **Questions 27-33 in the NPRM**
- “Safe harbor”: If information entered into tool is accurate, determination made by tool assumed by federal agencies to be appropriate
- Retention of completed decision tool will meet recording requirements

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Continuing Review of Research (§___.109(f); pp. 53984-85)

- Proposed circumstances under which continuing review will not be required:
 1. Research eligible for expedited review
 2. Research that only involves data analysis and/or accessing follow-up clinical data from standard of care procedures
 3. Research that has undergone “limited review”
 - Limited review implements exemption for “storage or maintenance for secondary research use of biospecimens or identifiable private information”
 - IRB must determine only that:
 - broad informed consent procedures were followed
 - privacy and information protection standards are satisfied if there is a change in storage or maintenance
- **No questions in the NPRM**

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Expedited Review of Research and Definition of Minimal Risk (§___.110,); pp. 53985-87)

- Secretary of HHS will publish a list of studies that may be expedited unless reviewers determine it involves more than minimal risk
 - If presumption is overridden, IRBs must document their rationale
- Definition of minimal risk is unchanged
- Secretary of HHS will publish a list of activities that should be considered minimal risk
- **Questions 79, 80 in NPRM**

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Important reminders

- The NPRM is not a final rule
- Your input matters to AAMC
- 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



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