

## Revising the Common Rule:

### AAMC Member Feedback on Proposed Changes to ***Informed Consent***

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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

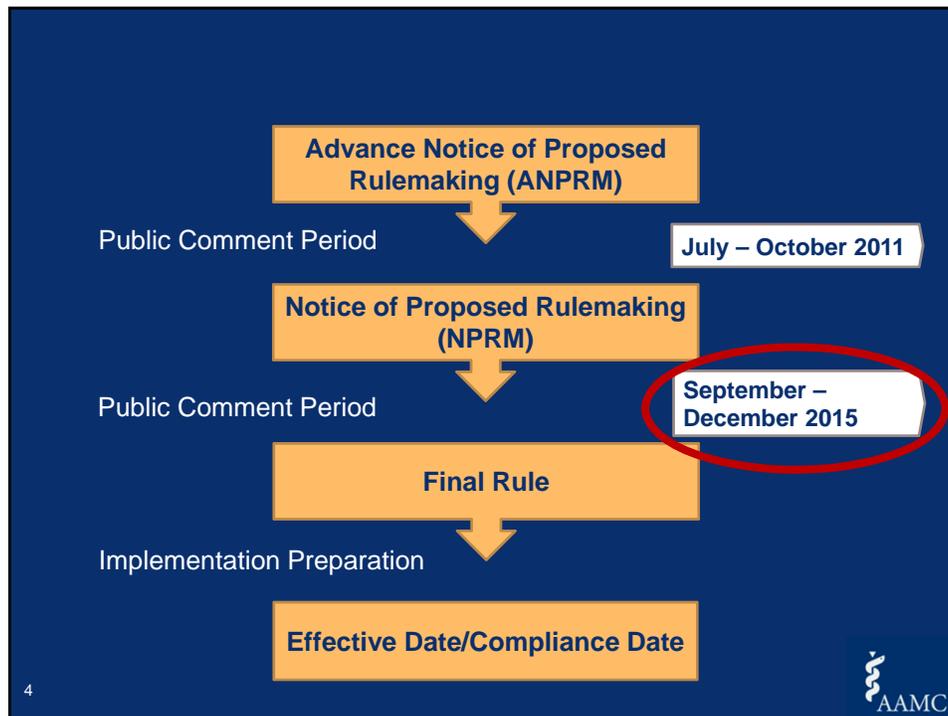
Conversations with AAMC on Specific Proposals

- **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](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)



## Changes to Obtaining, Waiving, and Documenting Informed Consent

Goal: “to facilitate prospective subjects’ decision about whether or not to participate in a research study, thereby enhancing autonomy”

Primary changes:

- Emphasize the need to get essential information to prospective subjects
- Organize document to provide sufficient detail but also facilitate understanding
- Present core information first, including only required elements and including all other information in appendices



## Changes to Elements of Informed Consent (§ \_\_.116; pp. 53969-72, 54052)

Basic elements of informed consent are largely unchanged, with one new element:

- A statement about whether or not the subject's data will be used for future research studies if the identifiers are removed (§ \_\_.116(a)(9))

Additional elements are generally unchanged and three elements have been added (§ \_\_.116(b)(7-9)):

1. Potential for commercial profit
2. Return of results
3. Discussion of recontacting for more data/biospecimens or other research

Only one question in NPRM: Topics for future guidance



## Waivers of Informed Consent (§ \_\_.116; pp. 53975-78, 54054-55)

- New criteria if *identifiable* biospecimens or identifiable information: “research could not **practicably** be carried out without accessing or using identifiers” (§ \_\_.116(f)(1)(iii))
- Two additional criteria for waiver if the research involves biospecimens (§ \_\_.116(f)(2)):
  1. Compelling scientific reasons for the use of the biospecimens
  2. The research could not be conducted with other biospecimens for which informed consent was or could be obtained
- Pay particular attention to questions 65-70 (pp. 53977-78)



## **Waivers of Informed Consent (§§ \_\_.116, 117; pp. 53975-78, 54054)**

- IRB may approve screening, recruiting, or eligibility determinations without consent with assurance of protections (§ \_\_.116(g))
- No waiver possible if broad consent for storage of biospecimens was refused (§ \_\_.116(f)(3))
- Waiver of written informed consent possible if subjects are members of a “community in which signing forms is not the norm” (§ \_\_.117(c)(1)(iii))
- **Pay particular attention to questions 65-70 (pp. 53977-78)**



## **Other Changes to Informed Consent**

- Only required language should be in document, other language in appendices (§ \_\_.117(b)(1))
- Final consent forms would be posted on a federal website (§ \_\_.116(h))



## Broad Consent Requirements (§\_\_.116(c)(1), p. 53972-75, 54053)

- Four elements from the basic elements of informed consent
  1. Reasonably foreseeable risks/discomforts
  2. Benefits
  3. Confidentiality
  4. Contact for questions and concerns
- Three additional elements if applicable:
  1. Potential for commercial profit
  2. Return of results
  3. Discussion of recontacting for more data/biospecimens or other research

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## Broad Consent Additional Requirements (§\_\_.116(c)(1))

1. A general description: types of research conducted and information expected to be generated, types of information or biospecimens that might be used, and the types of institutions that might conduct the research
2. Description of types of biospecimens or information to be collected over what time period
3. How long an investigator can conduct the research
4. Voluntary participation statement
5. If no notification will be provided about future research conducted
6. If applicable, a statement on potential for sharing
7. Institution or institutions where collection will take place
8. If relevant, consent or refusal to include de-identified data in a publicly available database

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## Other Broad Consent Considerations

- Written consent for biospecimen or data *collection* (outside of the research context) “cannot exceed 10 years from the date of consent” (§\_\_.116(c)(1)(ii)(B))
- HHS will develop at least two templates for the broad consent document (§\_\_.116(d)(1))
- Refusal to consent must be documented (§\_\_.116(d)(4))
- Questions 61-64 in the NPRM (pp. 53974-75)

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## A Plea

- 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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## Questions for You

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