NPRM Update

Summary of Public Comments

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Public Comments

- 2,100+ public comments on the NPRM
  - For comparison: 1,100+ on the ANPRM in 2011
- A majority of the comments (80%) from people writing in their individual capacity
  - Most of these individuals did not include information about their affiliation (e.g., if they were writing from the perspective of an research professional, HRPP professional, or patient)
- Official institutional comments: Majority from medical institutions (including medical schools) and academic institutions

General Themes

Concern about:

- Overall complexity and length of the NPRM
- Lack of availability of key deliverables (e.g., exemption tool, broad consent template, Secretary's list of privacy safeguards)
- Proposals being internally inconsistent
- Proposals giving investigators too much leeway to determine if their research falls under the rule


3

General Comments

Sample quotation:

"The urgency to approve a final revised Common Rule prior to the end of the 2016 is deeply concerning and has resulted in a premature, rushed document that is replete with deficiencies, contradictions, areas of conflict or overlap with other federal requirements, undefined processes, categories or lists and yet to be developed forms and templates. The lack of availability of these items at this late stage in the rule making process makes commentary particularly challenging."


4

Methodology

- Each comment read and analyzed for:
  - Which NPRM proposals discussed
  - Extent to which comment supported or opposed the proposals discussed in the comment
- Tracked the following:
  - General demographic information about commenters
  - Reasons for/against various proposals
  - Alternative proposals and other ideas not proposed or discussed in the NPRM
  - "Form letters," other types of coordinated campaigns, extent to which comments "endorsed" by other commenters

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5

Most Commented on NPRM Proposals (1)

1. Inclusion of non-identified biospecimens in the definition of human subject (~ 55% of comments)
2. Stringent waiver criteria for biospecimens (~ 45% of comments)
3. Broad consent (~ 25% of comments)

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6

Preliminary Assessment of Comments
Biospecimen Expansion

- Strong majority of commenters oppose these proposals
- Most comments from patients and public
- Opposition across all subgroups:
  - Patients
  - General public
  - Research-affiliated organizations and individuals


7

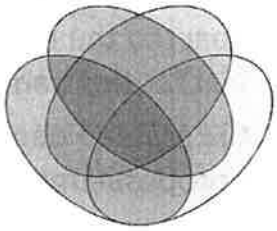
Preliminary Assessment of Comments
Biospecimen Expansion

- Patients: Concern about restricting access to biospecimens and slowing research
- General public: Most supportive, but oppose broad consent and any waiver of consent
- Research affiliation: Overwhelmingly oppose


8

Most Commented on NPRM Proposals (2)

4. Single IRB review mandate (~ 15% of comments)
5. Exemption determination tool (~ 10% of comments)
6. Improving informed consent (~ 10% of comments)



Preliminary Assessment of Comments **Single IRB Review Mandate**

- Comments supporting and opposing the proposal were mixed
  - Institutions tended to oppose the proposal
  - Individuals, not commenting in their official institutional capacity, tended to support the proposal

Preliminary Assessment of Comments
Single IRB Review Mandate

Opposing comments:

- Noted the value of local IRB review (e.g., provides additional protections for subjects, maintains institutional accountability)
- Cited increases in burden and inefficiency, due in part to the need for more agreements among institutions and IRBs
- Expressed need for more data and studies before proposal implemented


11

Preliminary Assessment of Comments
Exemption Decision Tool

- Public comment was generally mixed, with approximately half supporting and half opposing this proposal.
- A strong majority felt unable to adequately respond to this proposal without seeing the decision tool first.


12

Preliminary Assessment of Comments
Exemption Decision Tool

- Comments on investigators' use the exemption determination tool included the following concerns:
  - ➢ It is inappropriate and a conflict of interest
  - ➢ Proposed exemptions categories were so nuanced that substantial guidance would be needed for investigator to input accurate information


13

Preliminary Assessment of Comments
Improving Informed Consent

- A strong majority supported the proposal for a "core" consent form, providing essential information first


14

Preliminary Assessment of Comments
Improving Informed Consent

Comments opposing the proposal included the following concerns:

- A "core" consent form and appendices would not improve subject understanding
- The required elements of consent would not always be sufficient to enable an informed decision
- Guidance, not regulatory requirements, would be more appropriate
- The length and complexity of forms would not be reduced


15

Preliminary Assessment of Comments
Posting Informed Consent Forms

- Public comment on the posting of the forms was mixed
- Some of the favorable comments viewed posting as a means of education and improving forms, while others saw little or no value
- Some commenters expressed concern about the timing of the posting


16

Public Response to Other Major NPRM Proposals

- Exclusions and exemptions
- Elimination of continuing review in certain circumstances
- Clinical trial expansion
- Privacy safeguards


17

Preliminary Assessment of Comments **Exclusions and Exemptions**

- Numerous public comments expressing concern about the approach, including:
  - ➢ Too complex
  - ➢ Exclusions add a new step to decision-making, with different categories and no documentation requirement


18

Preliminary Assessment of Comments
Eliminating Some Continuing Review

- A strong majority supported this proposal
- Supporting comments indicated it would alleviate IRB administrative burden without diminishing protections for human subjects
- Opposing comments were concerned that continuing review is important for periodically re-evaluating a research study's benefits, risks, methods, and procedures


19

Preliminary Assessment of Comments
Extending Coverage to Clinical Trials

- Comments were mixed
- The majority supporting the proposal did not provide a rationale
- Concerns expressed by those opposing the proposal included:
  - Would encompass many minimal risk social and behavioral studies
  - Would be covered by the single IRB review mandate without federal funds to implement the requirement
  - Would be complicated to implement given institutions' changing funding status


20

Preliminary Assessment of Comments
New Privacy Safeguards

- The majority of comments were supportive
- Many opposing the proposal objected to any standardized privacy safeguards, and noted that the HIPAA standards were too severe for many social and behavioral research activities
- Both those who supported and opposed the proposal indicated that it was difficult to comment on the adequacy of privacy standards that are yet to be developed


Questions?