Review of the Common Rule Comments – Initial Findings

Council on Governmental Relations Meeting
February 25, 2016
Participants

Lois Brako
  Assistant Vice President for Research, Regulatory and Compliance Oversight, University of Michigan

Toni Russo
  Administrative Officer and Policy Analyst, COGR

Genevieve Croft
  Senior Associate, Research Policy, APLU

Lisa Nichols
  Director, Research and Regulatory Reform, COGR
Overview

Approximately 2,190 comments

- ~50 are requests for extensions
- At least 75 are not viable
- 65 or more are specific to exclusions related to oral history and public officials.
Categories

- **A - (n = ~1250)** Patient, Representative or Association (A1); General Public (A2); Presumed Researchers, Practitioners or Affiliates (A3)

- **B - (n = ~460)** Researchers or Associations (B1); Medical/Clinical Practitioners or Associations (B2); Medical Researcher/Practitioner (B3)

- **C - (n = ~180)** Research University/Institution or Association (C1); University Department/Entity (C2); Medical/Clinical Research Institution or Medical Center/Clinic or Association (C3); University or Medical/Clinical Research Institution IRB, IRB chair or IRB employee (C4); and University/entity employee (non-research)(C5)

- **D - (~125)** Industry/Pharma/Trade groups (D1); Tribal governments (D2); Advisory and related groups (D3); Independent IRBs or Individuals Affiliated (D4); Depts. of Health/Health Officials and Municipal Governments (D5); Biobanks/Affiliated Organizations/Consultants (D6); Data Registries (D7)
Areas of Review

- Biospecimens: Expanding the definition of a human subject, Alternative proposals, Requirement for broad consent, Notice, Opt-out, limiting an IRB’s ability to waive consent;
- Mandating a single IRB;
- Extending the Common Rule to all clinical trials;
- Proposed security safeguards and standards;
- Posting informed consent forms.
Universities/Med. Centers/IRBs

180 comments:

- Research universities and associations: 69; University department/entity: 2
- Medical/clinical research institution, or medical center clinic or association: 41;
- University/medical center IRB, IRB Chair or IRB employee: 51;
- University/entity employee (excluding researchers or practitioners): 17;
Findings

- Definition of human subject: 101 responded. 97 opposed. 3 support. 1 supports with qualifiers.
- Alt. proposals: 21 Alt. A – whole genome; 8 None; 1 NPRM
- Broad consent: 116 responses. 107 opposed. 5 support. 4 support with qualifiers.
- Notice – 17 supported the concept of notice as an alternative to broad consent.
- Opt-out – 14 supported the concept of opt-out.
- Waiver – 47 oppose the proposed changes to waiver. 2 support them.
Findings

- Single IRB: 100 oppose mandated single IRB. 7 support it. 4 support it with qualifiers – support generally drawn from medical schools/centers.

- Extending the Common Rule to all clinical trials: 24 oppose it. 3 support. 6 support with qualifiers.

- Safeguards: 25 oppose. 3 support. 2 support with qualifiers.

- Posting consent: 45 oppose. 1 supports.

- 47 suggested that the NPRM was not well-developed and that some or all parts of it should be written, re-written or revised.
Patients/General Public

Approximately 1250 comments:

- 250+ comments from patients with rare cancerous tumors (primarily Desmoid Tumors or Leiomyosarcoma) and their family members.

- 2 patients and one anonymous entry that is “based on a patient's perspective” supported the proposed biospecimen changes. All others oppose them.

- Patients and their family members are predominantly explicit about their opposition to the proposed changes to waiver, but some also address broad consent and biospecimens generally.

- Among the general public responses both for and against the proposed biospecimens changes, but no final count at this time.