Review of the Common Rule Comments – Initial Findings

Council on Governmental Relations Meeting

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COGR

Participants

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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

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- 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

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- 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.