COGR-APLU Analysis of the Common Rule NPRM Comments

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COGR
Council On Governmental Relations

Association of Public & Land-grant Universities

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Common Rule NPRM Comments

2,186 comments were submitted to Regulations.gov

Public (906)
Patients and Representatives (245)
Researchers/Practitioners (401)
Research Institutions, Medical Centers, Affiliated IRBs, Employees (204)
Industry/Pharma/Trade Groups (31)
Tribal Governments (13)
Advisory and Related Groups (6)
Independent IRBs (12)
Health Departments/Officials, Municipal Governments, Epidemiologists (17)
Biorepositories (13)
Disease Registries (6)
Professional Associations and Societies (86)
Advocacy Groups (60)
Withdrawn, Duplicate, Extension Request, Etc. (186)

Common Rule Comments - Biospecimens

76% of respondents commented on at least one of the major proposals specific to non-identified biospecimens:

- 74% opposed the proposed changes

Patients and the research community overwhelmingly opposed the proposed changes.

- 96% of patients, researchers/practitioners, universities and medical centers and industry respondents opposed the proposed measures.

Findings are consistent with the HHS Office for Human Research Protections analysis which found that a “strong majority of commenters oppose these proposals” and there was “opposition across all subgroups.”

Common Rule Comments - Biospecimens

- Significant reduction in the availability of biospecimens;
- Disproportionate reduction in specimens from disadvantaged groups;
- Disproportionate impact on research into rare diseases;
- Significant negative impact on medical advances.

Common Rule Comments – Single IRB

15% of responses included comments on the proposal to mandate use of a single IRB for multisite studies.

- 51% opposed the proposed change and 48% supported it
- Advocacy groups, professional societies, disease registries and independent (commercial) IRBs tended to support the proposed change.
- Universities and Tribal Governments were generally opposed
- SACHRP, AAHRPP and PRIM&R opposed the proposed changes
- OHRP reported similar findings

Common Rule Comments – Single IRB

Support:

- Streamline operations and reduce delays.

Opposed:

- Will not reduce delays or decrease cost and administrative work in many instances.
- Not appropriate for all studies, including social and behavioral studies, studies with a different focus and protocol at different sites, studies with few sites and studies involving special populations.

Common Rule Comments – Extending the Common Rule to All Clinical Trials

4% of responses included comments on extending the Common Rule to all clinical trials regardless of funding source at institutions that receive federal funding for non-exempt and non-excluded human subjects research.

- 52% (39 of 75) oppose the change, 48% supported it
- OHRP reported mixed findings
- Universities and medical centers, professional associations and advocacy groups provided the majority of comments. Universities generally opposed the changes.
- Universities already apply the rules to all clinical trials. Under the current rule universities can reduce administrative burden while maintaining equal protections.

Common Rule Comments – Data Security Safeguards

6% of responses included comments on the proposed Secretary's security safeguards.

- 33% opposed the proposed change and 67% supported it. Support from researchers was expressed primarily through an form letter.

Common Rule Comments – Posting Consent Forms to a Federal Website

Approximately 4% of responses included comments on the proposal to post clinical trial consent forms to a public website.

- 84% opposed the proposed change, 17% supported it.
- OHRP suggested that responses were “mixed”
- Those opposed suggested that the proposed change would not improve consent forms and would increase burden and cost.

Common Rule Comments – Overarching Concerns

5% of all comments suggested that the NPRM did not meet necessary standards or requirements, and called for part or all of the NPRM to be withdrawn, rewritten and republished for comment.

- Includes 25% of responding universities and 15% of professional associations and advocacy groups.

- SACHRP has recommended that “HHS conduct a comprehensive re-write of the NPRM through a concerted effort to simplify the proposed changes and to focus efforts on selected issues for which there is broad support by the public, investigators, IRB professionals, sponsors and other experts.”

Common Rule Comment Analysis

http://cogr.edu/Human-Subjects-and-Animal-Research

- Full Analysis
- Tables
- Summaries by respondent group

Common Rule Comment Analysis

- Outreach
- Next Steps
- Questions?