Industry/Pharma/Trade Groups – Preliminary Findings from a Review of Responses to the Common Rule NPRM

Overview

There were 31 total responses in this group. Those responding overwhelmingly commented on proposed changes specific to biospecimens and mandated use of a single institutional review board (IRB), but many also commented on other areas we queried, including extending the Common Rule to all clinical trials; proposed data security safeguards; and the proposal to post clinical trial consent forms to a federal website.

Definition of "Human Subject" (100% oppose)

Eighty-four percent of responses included comments on the proposal to expand the definition of "human subject" to include non-identified biospecimens. Among those commenting, 100% (26 of 26) opposed the proposed change.

Since most members of these organizations use biospecimens for research to develop new drugs, devices, and biological products, they expressed concern that secondary research use of biospecimens should "strike an appropriate balance between protecting the privacy and autonomy of human subjects and facilitating scientific advances that can benefit future patients." Two organizations suggested Alternative A - expanding the definition of "human subject" to include whole genome sequencing - and one suggested Alternative B - classifying certain biospecimens used in particular technologies as meeting the criteria for "human subject" - as the best approach if the definition of "human subject" was to include non-identified biospecimens. Three responses indicated that none of these approached were acceptable.

> "We are concerned that the NPRM has unnecessarily classified all biospecimens as de facto identifiable with little or no benefit to the public. We strongly believe that identifiability should remain the Common Rule's determining factor as to whether a research study is conducted with human subjects, and that OHRP should continue to explore ways to harmonize the Common Rule's and HIPAA's definitions of identifiability."

Broad Consent (47% oppose, 53% support with qualifiers)

Of the seventeen comments on broad consent, 53% (9 of 17) of organizations offered qualified support for broad consent for future research, stating that they are concerned about how this will be implemented. Forty-seven percent (8 of 17) oppose broad consent. Four supported notice as an alternative to consent and four a "opt-out" approach rather than "opt-in" to maximize opportunities for specimen donation. One comment expressed opposition to proposed restrictions to IRBs ability to waive consent.

> "The proposed requirement for broad consent for all future collection of biospecimens, regardless of identifiability may have a profound and damaging effect on the availability for research of samples collected in a treatment setting."

Single IRB (7% oppose, 67% support, 26% support with qualifiers)

Forty-eight percent of responses included comments on mandated use of a single IRB. Of those, 67% (10 of 15) support single IRB as a way to reduce burden, 26% (4 of 15) offered qualified support and 7% (1 of 15) opposed the proposed measure. One institution offering qualified support indicated the following:

> "We feel strongly that the use of single IRBs should not be mandated, but instead encouraged. We believe that, in the name of human subjects protection, institutions should still be allowed flexibility as needed."

Posting Consent Forms (89% oppose, 11% support with qualifiers)

Very few organizations directly addressed other parts of the NPRM; however of the nine organizations (29%) commenting, 89% (8 of 9) expressed the concern that the proposed requirement to make consent forms publically available will not improve consents (one offered qualified support).

> "The public posting of these consents adds no value and could potentially lead to ill-informed second-guessing of the work of the IRB and even speculative or spurious litigation. In addition, the consent forms from industry-sponsored trials may give competitors detailed information about an investigational drug and/or research program beyond that available in a public registry posting, including safety and efficacy information and/or preclinical data considered to be confidential by the sponsor. The premature release of such information could compromise the ability of the sponsoring company to secure patent rights and hence compromise their ability to bring the drug or device to market in the United States."

One organization stated that it would "not serve its intended purpose to make consent forms more patient friendly and could, in fact, have the unintended effect of exacerbating the problem by making consents lengthier and more legalistic."

Additional Areas Queried

Of the 13% (4 of 31) commenting on the topic of mandating standardized data protection requirements 75% (3 of 4) were opposed and 25% (1 of 4) supported the proposed measure. Another organization was concerned that the extension of the Common Rule to cover all studies conducted by domestic institutions that receive federal funding could drive companies to conduct more trials outside of the United States.

Beyond analyzing responses to the particular NPRM elements elaborated above, we also looked at more general assessments of the status of the NPRM. Two organizations (6%) suggested the NPRM should be revised and republished. One echoed SACHRP's comments that OHRP "consider releasing a revised, simplified set of proposals for notice and comment before finalizing any changes to the Common Rule."