Departments of Health/Health Officials/Municipal Governments and Epidemiologists – Preliminary Findings from a Review of Responses to the Common Rule NPRM

Overview

There were 17 responses in this category. Responses were largely from state and city health departments as well as public health laboratories, Centers for Disease Control staff, associations representing city and state health officials, a council of state epidemiologists and the California arm of the Newborn Screening in Genomic Medicine and Public Health (NSIGHT) Consortium, a National Institutes of Health funded initiative.

We reviewed comments related to a number of major proposals in the NPRM, including proposals specific to biospecimens, mandated use of a single institutional review board (IRB) for multisite studies; 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. Generally, this group was most concerned about changes to archived biospecimens, since public health work depends heavily on collected samples.

Biospecimens (79% oppose, 7% support, 14% support with qualifiers)

We reviewed three major proposals specific to biospecimens including the proposal to change the definition of "human subject" to include non-identified biospecimens, to mandate broad consent for secondary research use of biospecimens and to restrict IRB waiver of consent for secondary research use of biospecimens. Eighty-two percent (14 of 17) of responses included comments on at least one of the three major proposed changes. Among those responding, 79% (11 of 14) opposed one or more of the proposed changes, 7% (1 of 14) supported the changes and 14% (2 of 14) offered qualified support.

> "The proposed rule may hamper the ability of researchers working with state programs to develop new tests for new diseases and challenges their ability to evaluate and assess test performance, and may not significantly decrease administrative burden."

Definition of "Human Subject" (67% oppose, 33% support, two with qualifiers)

Seventy-one percent (12 of 17) of responses included comments on the proposal to change the definition of "human subject" to include non-identified biospecimens. Of these, 67% (8 of 12) opposed the proposed change, approximately 17% (2 of 12) supported it and 17% (2 of 12) offered qualified support. Of those opposed to changing the definition, two suggested that if a change were made they would prefer Alternative A – expanding the definition to include whole genome sequencing and two expressed support for Alternative B if a change were made – classifying certain biospecimens used in particular technologies as meeting the criteria for "human subject."

Broad Consent (64% oppose, 18% support and 18% support with qualifiers)

Sixty-five percent (11 of 17) of responses included comments on the proposal to mandate broad consent for unspecified secondary research use of biospecimens, of which 64% (7 of 11) opposed the proposed change, 18% (2 of 11) supported it and 18% (2 of 11) offered qualified support. Two (12%) supported notice and six (36%) opt-out as alternatives to broad consent.

> "Requiring broad informed consent for biospecimens collected during clinical encounters will deplete the quantity and diversity of biospecimens available to public health laboratories."

Waiver of Consent (50% oppose, 50% support)

Twenty-four percent (4 of 17) of those responding commented on the proposed restrictions to IRB waiver of consent. Of these, two (50%) opposed the proposed change and two supported it.

Single IRB (50% oppose, 25% support, 25% support with qualifiers)

Twenty-four percent (4 of 17) of those responding commented on the proposal to mandate use of a single IRB for multisite studies. Of these, two (50%) opposed the proposed change, one supported it and one offered qualified support.

Additional Areas Queried

Twelve percent of responses (2 of 17) 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. Of these, one supported the proposed change and one opposed it. Twenty-four percent of responses included comments on data security safeguards, with one opposed, two in support of the proposed safeguards and one offering qualified support. There were no comments on the proposal to post clinical trial consent forms to a federal website.