Biorepositories, Affiliated Organizations and Consultants – Preliminary Findings from a Review of Responses to the Common Rule NPRM

Overview

Responses from those identified as biobanks, affiliated organizations and consultants, 13 in total, primarily consisted of large banking networks or groups that support biospecimen research, but also included consultants and international representatives that collaborate with U.S. physicians. As such, the responses focused primarily on the proposed changes that impact biospecimen research. A few of the respondents cited the inconsistent expectation of how biospecimens and data are used for research, stating that "A compelling rationale has not been provided for this differential treatment."

Biospecimens (67% oppose, 25% support, 8% support with qualifiers)

We reviewed three major proposals specific to biospecimens including the proposal to expand 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. Ninety-two percent (12 of 13) of responses included comments on at least one of the three proposed changes. Among those responding, 67% (8 of 12) opposed the proposed changes, 25% (3 of 12) supported them and 8% (1 of 12) offered qualified support.

Definition of "Human Subject" (86% oppose, 14% support)

Fifty-eight percent (7 of 12) of responses included comments on the proposal to expand the definition of "human subject" to include non-identified biospecimens, of which 86% (6 of 7) opposed the proposed changes citing the potential impact on science and medicine and concerns about costs. Fourteen percent (1 of 7) supported the proposal. Of those opposed, three indicated support for Alternative Proposal A – expanding the definition of "human subject" to include whole genome sequencing.

> "Respecting autonomy at the expense of patient lives is a significant ethical concern."

Broad Consent (55% oppose, 27% support, 18% support with qualifiers)

Eighty-five percent (11 of 13) of responses included comments on the proposed mandate for broad consent for future unspecified research use of biospecimens. Of these, 55% (6 of 11) opposed broad consent, 27% (3 of 11) supported it and 18% (2 of 11) supported it with qualifiers. Of those that opposed broad consent, the main concern was regarding the logistics and cost for smaller hospitals and the potential loss of specimens from certain populations.

> "It's not clear who will pay for the cost of seeking consent for the future research use of specimens collected during the course of routine care. The costs will only be covered by grant funds when there is a specific project for which specimens will be collected and/or

> used. Will implementing [a] hospital wide process for all clinically collected specimens (many of which may never be used for research) raise the cost of health care? The end result may be 1) increases the costs of health in a non-transparent way or 2) most hospitals and clinics will simply not implement institution-wide consent processes or 3) consent will obtained in a pro-forma approach."
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> "The NPRM places too much reliance on broad consent and not enough attention to governance and oversight of the research on biospecimens"

Waiver of Consent (80% oppose, 20% support)

Thirty-eight percent (5 of 13) of responses included comments on proposed restrictions to waiver of consent by the IRB. Of those, 80% (4 of 5) opposed the proposed changes and 20% (1 of 5) supported them. The registries did not support the changes to the waiver regulations for archived tissue. Many of the comments described scenarios where specimens are collected for clinical care and it is not known at that time whether they may be used for research.

> "The NPRM proposal creates a high bar and is also ambiguous."
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> "How will the IRB know whether other biospecimens are available for the proposed research or how compelling the scientific reasons for the research are?"

Additional Areas of Concern

Biorepositories and affiliated organizations did not respond to other areas we queried, including mandated use of a single IRB, extending the Common Rule to all clinical trials and the proposal to post clinical trial consent forms to a federal website. One response addressing data security safeguards opposed the proposed changes.