Disease Registries – Preliminary Findings from a Review of Responses to the Common Rule NPRM

Overview

Responses identified as Disease Registries, six in total, included large national registries for cancer and joint replacement, a cancer registry professional, and a physician coalition that sponsors registries that analyze clinical outcome data. 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.

Biospecimens (75% oppose, 25% support)

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. Sixty-seven percent (4 of 6) of responses included comments on at least one of three major proposed changes. Among those responding, 75% (3 of 4) opposed one or more of the proposed changes and 25% (1 of 4) supported the changes.

Definition of "Human Subject" (100% opposed)

Fifty percent (3 of 6) of responses included comments on the proposal to expand the definition of "human subject" to include deidentified biospecimens. Of these, 100% (3 of 3) opposed the proposed change citing the potential impact on science and medicine as well as the cost implications. One response indicated a preference for Alternative Proposal A – expanding the definition of "human subject" to include whole genome sequencing. Overwhelmingly this group identified the rationale that this would severely limit scientific breakthroughs and not grant additional autonomy.

> "With precision medicine now a mandated national priority, there is tremendous focus on the development of targeted therapies which requires the identification of representative sets of biospecimens for research. While research could, in theory, be performed utilizing biospecimens for which consent was obtained, the inherent limitations of such a restriction could negatively bias efforts in cancer research in this field."

Broad Consent (100% oppose)

Thirty-three percent (2 of 6) of responses included comments on the proposal to mandate broad consent for unspecified secondary research use of biospecimens, of which 100% (2 of 2) opposed the proposed change. Both supported notice as an alternative to broad consent. Those commenting expressed concern about the ability of small hospitals to comply, resulting in a large proportion of the population not being represented in registries.

> "If this additional informed consent is required, the implementation [should] include a well-funded effort to support hospitals and surgical centers across the United States to comply. Otherwise, samples available for research applications will come solely from a limited number of research centers, resulting in selection bias that may often make research conclusions invalid once applied in the broader clinical setting."

Waiver of Consent (75% oppose, 25% support)

Sixty-seven percent (4 of 6) commented on the proposed restrictions to IRB waiver of consent, of which 75% (3 of 4) opposed the proposed change and 25% (1 of 4) supported it. The registries were particularly opposed to potential changes to the waiver regulations for archived tissues.

> "It is crucial that the spirit of this consent process be addressed but pursued in a way that assures that the population-based biospecimens identified by central cancer registries remain available for research."

Single IRB (25% oppose, 75% support)

Sixty-seven percent (4 of 6) of responses included comments on the proposal to mandate a single IRB for multisite studies, of which 75% (3 of 4) supported the measure and 25% (1 of 4) opposed it. The responses generally supported this effort to reduce research review time burden. One respondent opposed the proposed measure and expressed concern regarding the additional infrastructure needed to implement the central IRB process.

> "We strongly support the concept of centralized IRB for cooperative research."

> "Without central IRB review, participants' involvement in clinical data registries can be significantly delayed due to processing time for local IRB approval and/or waivers. IRBs vary in processing time, and if an institution's IRB is extremely backlogged, that may substantially delay the hospital's ability to participate in the registry. Mandating central IRB review and approval will allow many hospitals to join clinical data registries without these undue delays.

Additional Areas Queried

Two responses (33%) opposed the proposal to extend 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 and one opposed the proposal to post clinical trial consent forms to a public federal website. Disease Registries did not comment on the proposed data security safeguards.