

Independent IRBs and Affiliated Advisors and Associations - Preliminary Findings from a Review of Responses to the Common Rule NPRM

There were twelve responses in this category, including responses from four independent IRBs, one of which submitted 6 separate responses, each on a specific topic. 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

We reviewed three major proposals specific to biospecimens including the proposal to expand the definition of a 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. Twenty-five percent (3 of 12) of responses included comments specific to biospecimens. Seventeen percent (2 of 12) of responses included comments on the proposal to expand the definition of “human subject” to include non-identified biospecimens. One group opposed the change and one supported it with qualifiers. Regarding the proposal to mandate broad consent for future unspecified research use of biospecimens, 25% of responses included comments on this topic. Of these, 67% (2 of 3) opposed the proposed change and 33% (1 of 3) supported it. Seventeen percent of responses included comments on proposed restrictions to IRB waiver of consent, both (2 of 2; 100%) opposed the proposed change.

Single IRB

All but one independent response included comments on single IRB with 83% (5 of 6 comments), including all independent or commercial IRBs, in support of the proposed change.

Additional Areas of Concern

Seventeen percent of responses (2 of 12) included comments in support of extending the Common Rule to all clinical trials (one offered qualified support) and one response supported proposed data security safeguards. Regarding the proposal to post clinical trial consent forms to a federal website, 25% (3 of 12) of responses included comments with two opposed and one in support of the proposed change.