

## **Tribal Nations – Preliminary Findings from a Review of Responses to the Common Rule NPRM**

### Overview

There were thirteen responses in this category. Comments were predominantly focused on the proposed treatment of biospecimens and mandated use of a single institutional review board (IRB) for multisite studies. Six of the thirteen responses echoed those of the National Congress of American Indians (NCAI), often using the same text.

### Biospecimens (70% support, 30% oppose)

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. Seventy-seven percent (10 of 13) of responses included comments on at least one of the three major proposed changes. Among those responding, 30% (3 of 10) opposed at least one of the proposed changes and 70% (7 of 10) supported them.

### Definition of “Human Subject” (100% support)

Fifty-four percent (7 of 13) of responses included comments on the proposal to expand the definition of “human subject” to include research with non-identified biospecimens. Of these 100% (7 out of 7) supported the proposal. Tribal Governments want to ensure that their culture and beliefs unique to biospecimens are respected, and felt that by expanding the definition these materials would be better protected. A few noted that while some material may be considered “medical waste,” cultural practice and belief identify these materials as sacred and they should therefore have the same protections as any other human subjects research. Concerns were also raised about identifiability.

### Broad Consent (100% oppose)

On the topic of broad consent, 77% responded, of which 100% (10 of 10) were opposed to broad consent. Opposition to broad consent was largely due to the proposed exclusion of secondary research use of biospecimens from IRB review if broad consent is obtained using the proposed Secretary’s template. In particular, concern was expressed about future secondary research not being endorsed or reviewed by tribes, potentially causing harm to the individual or the tribe as a whole. Concern was also expressed about not having the opportunity to opt-out.

“...a broad consent for future, unspecified research use of biospecimens challenge[s] the ongoing ability of both tribes and individuals to choose to remove their data from research.”

“Without specific provisions in a revised Common Rule that address the authority of Tribal Nations to provide research oversight in relation to the use of biospecimens in federally supported research, NCAI and the Choctaw Nation of Oklahoma do not support the use of biospecimens being included in any exclusion category.”

“...secondary research is part of an egregious past with research for AI/AN tribes.... We do not support this proposed revision...”

Waiver of Consent (100% support)

Forty-six percent of responses, those responding in step with NCAI, included comments on proposed restrictions to IRB waiver of consent. Of these, 100% of responses (6 of 6) supported the proposed change to make use of waiver “rare,” suggesting that consent should be required and that IRBs should not have the authority to waive consent.

“NCAI asserts that there is no circumstance in which it would be appropriate to waive the requirement to obtain consent.”

Single IRB (100% oppose)

Eight-five percent (11 of 13) of responses included comments on the proposal to mandate use of a single IRB. Of these, 100% (11 out of 11) indicated strong opposition to a proposed mandate.

Tribal nations are particularly sensitive to past atrocities committed against tribal people with regard to research projects. This group sees a single IRB of record at the grantee institution as a loss of control, a loss of voice, and a significant vulnerability. They voiced detailed concerns over non-tribal IRB’s lack of knowledge of tribal cultural practices.

“By promoting the use of a single IRB in cooperative and multi-site research, these proposed revisions do not foster community-based governance and oversight of research that has the potential to improve outcomes for tribal and minority populations.”

“There should not be a requirement for only one IRB of record for multi-site studies....one may consider a study minimal risk while the tribe considers it to be a significant risk.”

“...Tribal IRB should always be considered the IRB of record when any tribal individuals are included as part of the research...”

Overarching Concerns

Six responses (46%), those echoing the NCAI, suggested that the NPRM should be revised and republished. Tribal groups do not feel they were adequately engaged and seek “specific provisions acknowledging the authority and role of tribal nations in overseeing research that happens on their lands and with their citizens.”