



United South and Eastern Tribes, Inc.

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Submitted via regulations.gov

Jerry Menikoff, M.D., J.D.
Office for Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Re: NPRM (Docket ID # HHS-OPHS-2015-0008) Comment Submission

Dear Dr. Menikoff,

On behalf of the United South and Eastern Tribes, Inc. (USET), we are pleased to provide the Department of Health and Human Services (HHS) Office for Human Research Protections with comments in response to the Notice of Proposed Rulemaking (NPRM) to revise the Federal Policy for the Protection of Human Subjects (the "Common Rule").

USET is a non-profit, inter-tribal organization representing 26 federally recognized Tribal Nations from Texas across to Florida and up to Maine¹. USET is dedicated to enhancing the development of federally recognized Indian Tribes, to improving the capabilities of Tribal governments, and assisting USET Member Tribal Nations in dealing effectively with public policy issues and in serving the broad needs of Indian people. This includes advocating for the rights of Tribal Nations to oversee and regulate any research conducted on their citizens or lands, as well as the protection of American Indian and Alaska Native (AI/AN) human subjects as they participate in studies.

Impact of Common Rule Revisions on AI/AN Community

With an eye toward the recent past in which researchers committed ethical violations against our communities and our people, the NPRM will most certainly have strong implications for Tribal Nations and their citizens. While USET agrees that updates to the Common Rule are critically necessary, we urge HHS to consider the history between research and Tribal Nations, as well as opportunities to ensure that past abuses never happen again. In its present form, USET, and many others across Indian Country, does not believe the NPRM provides adequate protections for AI/AN human subjects and their biospecimens nor does it ensure that the governments of Tribal Nations (through Tribal institutional review boards or otherwise) are able to properly regulate research. With this in mind, USET extends its strong support to the extensive and well-informed comments submitted by the National

¹ USET member Tribes include: Alabama-Coushatta Tribe of Texas (TX), Aroostook Band of Micmac Indians (ME), Catawba Indian Nation (SC), Cayuga Nation (NY), Chitimacha Tribe of Louisiana (LA), Coushatta Tribe of Louisiana (LA), Eastern Band of Cherokee Indians (NC), Houlton Band of Maliseet Indians (ME), Jena Band of Choctaw Indians (LA), Mashantucket Pequot Indian Tribe (CT), Mashpee Wampanoag Tribe (MA), Miccosukee Tribe of Indians of Florida (FL), Mississippi Band of Choctaw Indians (MS), Mohegan Tribe of Indians of Connecticut (CT), Narragansett Indian Tribe (RI), Oneida Indian Nation (NY), Passamaquoddy Tribe at Indian Township (ME), Passamaquoddy Tribe at Pleasant Point (ME), Penobscot Indian Nation (ME), Poarch Band of Creek Indians (AL), Saint Regis Mohawk Tribe (NY), Seminole Tribe of Florida (FL), Seneca Nation of Indians (NY), Shinnecock Indian Nation (NY), Tunica-Biloxi Tribe of Louisiana (LA), and the Wampanoag Tribe of Gay Head (Aquinnah) (MA).

Congress of American Indians (NCAI). We encourage HHS to pay particular attention to the words of NCAI and others in Indian Country as rulemaking proceeds.

Need for Additional Tribal Consultation

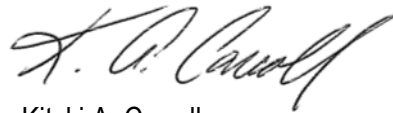
Similarly, USET urges the Agency to establish a process for Tribal consultation on the Common Rule. While the revision process and call for federal comments has been ongoing since at least 2011, HHS has conducted extremely limited consultation with Tribes. USET is aware of only one opportunity for Tribes consult with the federal government on the NPRM---a teleconference that was scheduled for one day prior to the comment submission deadline. Given the potential for the NPRM's serious impacts in Indian Country and on AI/AN people, USET urges the Agency to provide additional opportunities for consultation with Tribal Nations.

USET appreciates this opportunity to provide comments on proposed revisions to the Common Rule. Should you have any questions or require additional information, please do not hesitate to contact Ms. Liz Malerba, USET Director of Policy and Legislative Affairs, at (202) 624-3550 or by e-mail at lmalerba@usetinc.org.

Sincerely,



Brian Patterson
President



Kitcki A. Carroll
Executive Director

CC: USET member Tribes
Wanda James, USET Deputy Director

"Because there is strength in Unity"