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Submitted via the Federal eRulemaking Portal at: http://www.regulations.gov

Re: Comments concerning the Notice of Proposed Rulemaking (NPRM) to revise the Federal Policy for the Protection of Human Subjects (the “Common Rule”)
Docket ID: HHS-OPHS-2015-0008

Halito, Dr. Menifoff:

The Choctaw Nation of Oklahoma is a Tribal Nation located in 10 ½ counties of southeastern Oklahoma that has had a federally-registered IRB since August 2004. It is the third largest tribe in the United States, and has successfully partnered with academic institutions on research projects, ranging from pre-eclampsia and pediatric diabetes to language ideologies and cultural perceptions of technology related to heritage preservation.

The Choctaw Nation’s IRB echoes many of the comments proposed by the National Congress of American Indians (NCAI). Central to several of our comments is the documented mistrust of research by American Indian/Alaska Native (AI/AN) people and communities, and that without specific provisions acknowledging the authority and role of tribal nations in overseeing research that happens on their lands and with their citizens, this trust will be further undermined – especially given that these proposed revisions are to the most significant research policy in the nation.

Proposed changes to create excluded and expand exempt categories of research will potentially remove research protections for activities involving sensitive information in tribal research contexts. Often tribal research review extends the scope of examination beyond individual-level protections to enact community-level protections important for maintaining the integrity of culturally significant information and practices. Some tribal research review boards do not currently include exempt or expedited processes, preferring to review all proposed research activities with full-board review. Most tribal IRBs and research review boards also require the review of presentations and publications before they can be disseminated to an audience outside the tribe or the research group. Primarily, this is to ensure that the research proposed is the same as the outcomes published (historically a problem some tribes have encountered). This requirement for the return of
research information to tribes can, however, also serve as a means by which tribal populations receive a benefit to balance their participation in the research.

In our work and with that of other Tribal Nations, we see the need for oversight to monitor and enforce the ethical and appropriate practice of research after initial IRB approval is obtained. The proposed changes generate concern about the continuing tribal ability to treat federal regulations governing human research protections ‘as the floor, not the ceiling’. Statements within the NPRM like, “By reclassifying certain research activities from being exempt to being excluded, the proposed rule would eliminate the need for any administrative or IRB review” (p. 53950), are particularly worrisome.

Of even greater concern is the position Tribal Nations that do not have their own regulatory bodies for human research protections are put in. Changes to excluded and exempt categories of research and the elimination of some continuing review requirements, especially with no clear mechanism for additional tribal oversight and input, leave these communities with external groups deciding what constitute risks and benefits for them.

In prior comments submitted in response to the 2011 ANPRM and 2013 Genomic Data Sharing Policy, NCAI outlined the need for active tribal approval for research involving tribal data as well as the inclusion of tribal IRBs and other research review processes in any revisions to federal policy. Explicit policy language indicating the need for tribal oversight will provide clear guidance for researchers and institutions engaged in research-related activities with Tribal Nations, rather than relegating this important process to the navigation of loopholes or dependence on the goodwill of others. In many AI/AN communities, well-designed, ethical research is vitally important for addressing the health and wellbeing of tribal citizens. Clear language regarding tribal oversight within revisions of the federal policy will eliminate confusion, facilitate more timely review of research, and allow tribes to negotiate aspects of community consent and protection that are not provided within the current focus on individual-level protections in the Common Rule.

The above comments are submitted in relation to the following specific questions in the NPRM:

- **Question 1**: Public comment is sought on whether the proposed changes will achieve the objectives of (i) decreasing administrative burden, delay and ambiguity for investigators, institutions, and IRBs, and (ii) strengthening, modernizing, and making the regulations more effective in protecting research subjects.

- **Question 15**: Public comment is requested on the extent to which excluding any of these research activities from the Common Rule could result [in] actual or perceived reduction or alteration of existing rights or protections provided to human research subjects. Are there any risks to scientific integrity or public trust that may result from excluding these research activities from the Common Rule?
More broadly, the Choctaw Nation of Oklahoma believes approaching the rulemaking process in a way that places the protection of research participants at odds with scientific progress is not fitting. Specifically, reliance on "majority rule" in the determination of research policy revisions, rather than a method where minority voices can be heard, especially given the ethical implications and foundations of the original policy, does not seem appropriate. Throughout the proposed revisions, 28 separate references are made to the "majority" of comments received at various points in the process of amending the Common Rule. We continue the call of the NCAI for transparency in the process of establishing federal research policy, federal responsibility for monitoring the impact and outcomes of these policies, and a commitment to tribal consultation on policies with significant tribal implications.

According to the rationale presented for "modernizing the Common Rule" on page 53938 of the NPRM, advances in technology create much of the need for these proposed revisions: "Evolving technologies, including imaging, mobile technologies, and the growth in computing power have changed the scale of information collected in many disciplines......The sheer volume of data that can be generated in research, the ease with which it can be shared, and the ways in which it can be used to identify individuals were simply not possible, or even imaginable, when the Common Rule was first adopted".

This, in itself, should have us all more cautiously approaching meaningful human protections, rather than promoting a policy that is in any way advocating "removal of burden". Historically, ethical violations and harm to human research subjects has taken place as a result of compromising protections in the name of science and innovation. Such actions of the research community are what, in fact, prompted the very policy that we now aim to revise.

Beyond individual privacy issues and the data security of research participants, tribal IRBs and research review boards see potential harm that can occur when Tribal Nations' names are linked to biological specimens, genetic material, or other kinds of data. Many of these issues tie into the discussions of secondary research with biological specimens and the revision including broad consent. Especially if specimens and data are then used for secondary analysis in ways not authorized by the tribe, there is the potential for group harm and stigmatization of the tribe in resulting publications and reports. With this in mind, there is a need for further discussion of ethics in the use of secondary data, both with biological and non-biological data. On its face, the use of secondary data is not unethical if there is a process in place to uphold principles of respect, beneficence, and justice for both individuals and communities; however, secondary research with biological data has violated individual AI/AN and tribal consent in our lifetime. What recourse exists for tribal or other communities if research results in group harms when the concept of tribal consent or group protections does not even have a place in the proposed revisions? Moving
forward with the proposed revisions as-is misses an opportunity to strengthen and modernize the Common Rule in a way that recognizes tribal sovereignty and ensures protection for AI/AN research participants.

Historical legacies of unethical research and the resultant mistrust, make it difficult to understand how broad consent for unspecified future use would be an acceptable revision. Yet, the Choctaw Nation of Oklahoma has allowed a minimal number of protocols to contain future broad consent by ensuring the tribal IRB has authority to review and approve any future secondary studies. We believe this gives individual participants an assurance that tribal regulatory bodies are safeguarding individual and tribal interests as the studies progress. It’s unclear whether this practice could continue under the proposed changes.

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.

The above comments are submitted in relation to the following specific questions in the NPRM:

- **Question 54:** Public comment is sought on whether the NPRM's proposal of exemption §104(f)(2) is the best option, or whether there is a better way to balance respect for persons with facilitating research.

Small tribal populations can more easily result in triangulation of de-identified data. A study protocol deemed low-risk in a non-tribal review would often be an inaccurate assessment of risk at the local level, in view of cultural beliefs and practices. Choctaw Nation believes there is a need for proposed revisions that speak to the essential role tribal governments have in overseeing research on their lands and with their citizens; and therefore, oppose the implementation of the single IRB review mandate within the NPRM. It is critical that populations involved in research have the right to determine for themselves what constitutes benefits and risks. Additionally, we hold the view that the principle of beneficence should encompass a community determining whether proposed research is relevant and valuable to those involved, similar to idea discussed in, “Research Ethics Reconsidered in the Context of Community-Engaged Research: Proposed Revisions to the Belmont Report and Federal Regulations Guiding the Protection of Research Participants”.

Tribal Nations, especially given their sovereignty and nation-to-nation status, should be designated as an exception to single IRB review. In our experience, even respective research projects going through our tribal IRB process have been grateful for the additional review at the tribal level. Researchers regularly gain insights that make their research more relevant and directly applicable to real-world situations. Enrichment is often noted
through engagement with the tribal community and through the guidance given as part of the tribal IRB review process.

Although exceptions are noted in the NPRM for cases where Federal agencies supporting the research do not believe it is appropriate and "for research where local perspectives might be distinctly important (e.g., in relation to certain kinds of vulnerable populations targeted for recruitment)", the Choctaw Nation has to disagree with the statement that "The evaluation of a study's social value, scientific validity, and risks and benefits, and the adequacy of the informed consent form and process generally do not require the unique perspective of a local IRB", (p. 53984).

While it is noted that federal agency policy does not supplant state or local laws and regulations that may otherwise be applicable and that provide additional protections for human subjects, we would call for explicit statements also recognizing the legal jurisdiction of Tribal Nations, their obligations to protect human subjects of research, and the regulations they have created to effectively carry out these responsibilities.

The above comments are submitted in relation to the following specific questions in the NPRM:

- **Question 77**: Are the exceptions proposed appropriate and sufficient, or should there be additional exceptions to this mandate for single IRB review than those proposed in the NPRM? If additional exceptions should be included, please provide a justification for each additional exception recommended.

As one of the largest tribes within the United States and one that has successfully operated a tribal IRB for over 10 years, the Choctaw Nation feels the responsibility to provide public comment on the NPRM to revise the Federal Policy for the Protection of Human Subjects (the "Common Rule"). We thank you for the opportunity to comment on this very important rulemaking effort, but also reiteration the response of NCAI, calling for tribal consultation prior to finalizing the proposals contained in the NPRM:

"As the predominant policy governing research practice and protection of human research subjects in the US, the Common Rule and this set of proposed revisions have significant tribal implications. Per the Memorandum issued by President Barack Obama in 2009, pursuant to Executive Order 13175, there must be a process of consultation with tribes. Consider this language from the 2009 Memorandum, 'The United States has a unique legal and political relationship with Indian tribal governments, established through and confirmed by the Constitution of the United States, treaties, statutes, executive orders, and judicial decisions. In recognition of that special relationship, pursuant to Executive Order 13175 of November 6, 2000, executive departments and agencies (agencies) are charged with engaging in regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications, and are responsible"
for strengthening the government-to-government relationship between the United States and Indian tribes.”

Following the US Department of Health and Human Services (HHS) Tribal Consultation Call on January 5, 2016, (one day before the extended deadline of comment submission on the NPRM), Choctaw Nation would again make reference to the language contained within the 2009 Memorandum issued by President Barack Obama stating that, “executive departments and agencies (agencies) are charged with engaging in regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications, and are responsible for strengthening the government-to-government relationship between the United States and Indian tribes.” It is our view that this conference call did not fulfill these obligations. Moreover, one call does not have the capacity to fully address the ethical issues at the heart of what Tribal Nations face and we have tried to bring to light in our response to the call for public comment on the NPRM to revise the Common Rule.

Yakoke (Thank you),

Gary Batton, Chief
Choctaw Nation of Oklahoma