January 5, 2016

To: U.S. Department of Health and Human Services  
   Office for Human Research Protections (OHRP)  
   Attn: Jerry Menikoff, M.D. J.D.  
   1101 Wotton Parkway  
   Suite 200  
   Rockville, MD 20852

From: Richard McCloud, Chairman, Turtle Mountain Band of Chippewa Indians


The Turtle Mountain Band of Chippewa Indians offers our critique of the proposed changes to the Common Rule, and appreciates the efforts to improve the system of regulations and practices in research, for the protection of human research subjects. While we only speak on behalf of our tribe, the comments we share are concerns that are likely to be shared by other United States American Indian/Alaska Native tribes.

The Turtle Mountain Band of Chippewa Indians are located in North Dakota, near the geographical center in North America, ten miles south of the Canadian border. The Turtle Mountain tribe is an autonomous government within the United States, one of the 566 federally recognized tribes with a government-to-government relationship with the United States [1]. We are located on a six mile by twelve-mile land base reservation, considered one of the most densely populated reservations per square mile. Our reservation was established by 1882 and 1884 Executive Orders of the United States government.

While we believe that some of the proposed changes will strengthen research participant protections, there are certain changes that will hinder the protection of human research subjects, in particular the protection of our tribe's members, and of our tribe as a whole. The focus of this letter is two of these items from the Notice of Proposed Rule Making as follows:

46.114(b) Regarding the Use of a Single IRB

We request that research conducted on American Indian reservations involving tribal members as human subjects, not be subject to the requirements of this provision. We advocate that the use of a single IRB is not appropriate for research conducted on American Indian land, especially given the sovereign status of the American Indian/Alaska Native tribes. The revisions to the Common Rule should include this exception. To ensure adequate protections for our tribal
members and resources; existing regulatory systems within the tribe, such as a tribal IRB (e.g. Turtle Mountain Band of Chippewa Indians Research Review Board), research review committee, or Tribal Council, need to be utilized, in addition to another IRB of Record.

We are not opposed to reducing regulatory burden; however as a sovereign nation, with our own laws and customs, we are certain that an external IRB will not be able to sufficiently ensure research protections for our tribe. Review and monitoring of research occurring on our land and with our people must include regular case-by-case consultation with our researchers, cultural experts, and leaders. Our review of research goes beyond the existing federal regulations to adhere to our own customs and regulations. Furthermore the Turtle Mountain Band of Chippewa Indians has its own government, culture, and language, as do the other tribal nations in the United States. Therefore community representation on an external IRB by a person of American Indian descent, who may be from one of the over 500 nations in the United States, will not be sufficient to ensure adequate research protections for our people.

46.116 (c) Regarding broad consent for secondary research use of biospecimen

Secondary research with biospecimen is a part of an egregious past with research for American Indian/Alaska Native tribes[2-4], with serious research violations exposed in just the last 15 years[5]. Our tribe is aware of this history as well as the history of research violations involving biospecimen that have impacted other communities, such as the African American community, in the United States[6]. We therefore do not support this proposed revision to the Common Rule. Allowing for broad consents for future secondary research use of biospecimen will not allow the tribe to know how the specimen is being used, and if it is being used in a manner that will lead to individual or larger community benefit or risk. It will also remove the possibility of individuals withdrawing their specimen from research.

Thank you again for your consideration of our recommendations. Should you have any questions, or require more information, please contact Anita Frederick, TMBCI Research Director and President of Tribal Nations Research Group at 701-477-5526 or via email at anitabfrederick@gmail.com.

Sincerely,

Richard McCloud,
Chairman, Turtle Mountain Band of Chippewa Indians
On behalf of Turtle Mountain Band of Chippewa Indians Tribal Government

References