Comments of the Revision of the
Federal Policy for the Protection of Human Subjects (the “Common Rule”)
Docket ID:  HHS-OPHS-2015-0008

The Sault Tribe of Chippewa Indians has concerns with the proposed revision of the federal Policy for the Protection of Human Subjects.

The proposed rulemaking is light on human protections and heavy on reducing burden on researchers. The “Common Rule” is meant to be a “floor” for the minimal amount of protections that keep safe the individuals who volunteer to be in some way involved in research. These individuals are willingly putting themselves at risk in exchange for a benefit to the common good. Many of the Native Americans that volunteer are vulnerable members of our tribal communities. If the “Common Rule” is the “floor” of protection it must focus to protect our most vulnerable research volunteers. In addition, there also needs to be community protections for our historically traumatized communities.

To enhance the protection of these individuals and communities we suggest a few additions to this revision of the “Common Rule”:

Once an individual has consented to be a participant in research and data has been collected there should be a mechanism to under any circumstance allow for that individual to remove their information from the data-set. This should be considered a “floor level” protection and in addition is a necessary component to re-building trust in tribal communities where that trust is currently unstable.

Once an individual has consented to be a participant in research and data has been collected there should be no risk to other members within the same community. It is possible that the data associated with research or secondary data could be used to identify the individual’s tribe or community. The tribe should be given rights to prevent the use of data that identifies tribal affiliation on behalf of individuals within the tribe that were not allowed opportunity to give consent. This must be included as a basic “floor level” of protection to protect our vulnerable populations that are not given the opportunity for self-representation.

The rule change regarding the web-based “decision tool” is also a concern. As with any ability to avoid using an external body such as an IRB to determine if research is exempt or not there will be an incentive to circumvent oversight. The use of digital technology could be used to enhance individual’s ability to track future use of their data, to get updates on how their data is being used to better society, or to give additional consent for that data to be used by their own tribal community. It is unclear how the web-based decision tool enhances human protections.
In addition, the technology exists to ask incrementally for continual consent. If the data is going to be used in any other way than originally intended that data should in all cases be subject to additional consent. This will void the need for obtaining broad consent for future uses of data that are not actually knowable at the time of collection.

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