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July 29, 2019

Francis S. Collins, M.D., Ph.D., Director
National Institutes of Health
Building 1, Room 118A
1 Center Drive
Bethesda, Maryland 20814

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NCAI HEADQUARTERS
1516 P Street, N.W.
Washington, DC 20005
202.466.7767

Re: "Tribal Consultation on NIH Intellectual Property Rights in Biomedical Research"

Dear Director Collins:

On behalf of the National Congress of American Indians (NCAI) and its Policy Research Center, this letter responds to your request for information on Intellectual Property, Inventions, and Patent Rights in Biomedical Research dated April 17, 2019. As the oldest, largest and most representative organization serving the broad interests of American Indian and Alaska Native governments, NCAI established its Policy Research Center in 2003 to focus on research and data support to inform policy development efforts of tribal nations. Thank you for consulting on this important issue and for conducting a tribal consultation session at the recent NCAI Mid Year Conference.

Comments on Tribal Consultation on Intellectual Property Rights

We appreciate the opportunity to comment on this important issue. We have reviewed the materials provided and our comments and recommendations are included below.

Comment #1 – Clarify the reasons NIH is seeking tribal consultation on Intellectual Property Rights in Biomedical Research

Questions remain as to the reasons NIH is seeking consultation. Is there a decision before the agency on this topic? What are the potential outcomes from this consultation? Will this consultation lead to policy modification? What policies and processes can be impacted by NIH to better protect tribal rights? Does this tribal consultation apply to all research, or is it limited to patents and inventions only from biomedical research funded under NIH? Answering these questions can enhance understanding and build trust among tribal governments and advocates.

Comment #2 – NIH should clearly articulate the rights of tribal governments to NIH funding recipients, including the rights of tribal nations to own and patent intellectual property and inventions from research

Anything resulting from research, including but not limited to new discoveries, holds the potential for profit and benefit to tribal governments. Tribal nations have an inherent interest in intellectual property, inventions, and patents resulting from NIH-funded research. Researchers must understand that when they conduct research with tribal nations, the tribal nation likely will want sole or shared ownership of the data, any inventions, and rights related to any patent that might result. The NIH should provide education to its researchers at all stages of NIH funding (announcement, award, reporting, and close out) that they must follow tribal research laws and partner with tribal nations on research. They should encourage researchers to consider entering into research collaboration agreements with tribal nations early in the research process, so all parties understand their expectations and obligations.

The NIH must ensure that tribal rights, including intellectual property rights, are safeguarded throughout the funding application and award process. As governments, tribal nations are entitled to the same intellectual property protections—including sovereign immunity—afforded to state governments and their universities. NCAI Resolution MKE-17-056, as amended, explains that tribal intellectual property is critical to self-governance and opposes any attempt to restrict tribal self-development by discriminating between sovereigns within this field. Ensuring that funding applicants understand the rights of tribal sovereigns aids partnerships and collaboration within biomedical research and NIH is best positioned for this role. This may include, but is not limited to, increasing language on the rights of tribal governments in NIH funding opportunity announcements (FOAs), application materials, and funding award letters, progress report instructions, and close out instructions to make certain recipients of federal funds know what is required or recommended for researchers in regards to tribal partners. Further, NIH funding materials should include information about the recent Common Rule update that federally-funded researchers must follow tribal laws.

Comment #3 – NIH should develop protection and enforcement mechanisms for tribal rights to intellectual property in research

The NIH should develop methods of enforcement if a tribal nation's intellectual property rights are violated or misused. Examples of this can include, but are not limited to excluding a tribal nation from a patent filing. Throughout the funding application and award process, reiterating tribal rights can better prevent abuse and protect tribal rights. For example, NIH can notify tribal nations of any applications that involve research conducted with their tribal nation and the application's progress. Additional protections may include alerting tribal nations of the option to assess the right for a patent when an application is filed for an invention that resulted from research conducted in their community or with their citizens.

Comment #4 – NIH should educate its staff on the rights of tribal governments in research and intellectual property law

The NIH should immediately educate all staff on the rights of tribal governments in research generally and specifically related to intellectual property rights. If the NIH as a whole better understands the rights of tribal governments, then staff is more prepared to help researchers understand those rights,

handle issues and violations of those rights, and put into place additional safeguards throughout the research and patent process so that tribal rights are not violated. If researchers are planning or conducting research that might result in an invention that could be patented, NIH must educate staff so that they can identify potential issues if the researcher is working with tribal nations. NIH staff should be encouraged or required to notify tribal nations of any potential issues that they uncover if researchers are filing for patents without tribal consent or participation if the researcher conducted their research with the tribal nation.

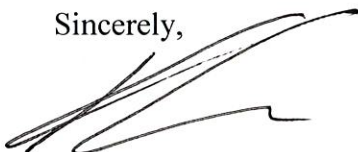
Comment #5 – NIH should post the comments it receives for this tribal consultation and notify tribal nations of the decisions and actions that result

Tribal nations have experience with tribal consultation with several agencies in the Department of Health and Human Services (HHS) as a part of the government to government relationship and expect that federal agencies will notify them of how their input and comments have influenced a decision before the agency. HHS' Tribal Consultation Policy, which is the policy that applies to NIH, states that "the Division shall report on the outcomes of the consultation within 90 calendar days of final consultation." NCAI recommends that NIH send a follow up letter to tribal nations after the consultation period ends and notify tribal nations of the actions taken in response to their comments.

Conclusion – This letter provides recommendations on what NIH can do to help protect the rights of tribal governments in relation to intellectual property rights regarding inventions and patents that might result from research conducted with tribal nations and with tribal citizens. We encourage you to review the recommendations submitted by all tribal nations in response to your letter and implement actions to address those recommendations as soon as possible. If you have any questions or comments, do not hesitate to contact us at research@ncai.org.

Thank you for your commitment to the tribal consultation process,

Sincerely,



Kevin J. Allis
Chief Executive Officer
National Congress of American Indians