



# NATIONAL CONGRESS OF AMERICAN INDIANS

June 5, 2020

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## NCAI HEADQUARTERS

1516 P Street, N.W.  
Washington, DC 20005  
202.466.7767  
202.466.7797 fax  
www.ncai.org

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

Re: Planned COVID-19 Research

Sent by email to: [francis.collins@nih.gov](mailto:francis.collins@nih.gov);  
[lawrence.tabak@nih.gov](mailto:lawrence.tabak@nih.gov); [tara.schwetz@nih.gov](mailto:tara.schwetz@nih.gov);  
[NIHTribalConsultation@od.nih.gov](mailto:NIHTribalConsultation@od.nih.gov); [AOUTribal@nih.gov](mailto:AOUTribal@nih.gov)

Dear Director Collins:

We are writing to provide our formal input as a part of the **NIH Tribal Consultation on COVID-19 Research** initiated in a letter to tribal leaders on May 21, 2020. This letter focuses on our response to NIH's plan to support the conduct of two new research initiatives: 1) Rapid Acceleration of Diagnostics in Underserved Populations (RADx-UP); and 2) All of Us Research Program COVID-19 Serologic Study. We strongly believe that our comments should be meaningfully considered as a part of the tribal consultation process due to the government to government relationship with and the federal trust responsibility to tribal nations.

The National Congress of American Indians (NCAI) is the oldest, largest, and most representative national organization serving the broad interests of American Indian and Alaska Native (AI/AN) tribal nations and advocates to uphold and strengthen tribal sovereignty. Research that is conducted on tribal lands or with tribal citizens falls under the purview of tribal governance. In accordance with the Federal Policy for the Protection of Human Subjects, also known as the Common Rule, tribal research laws must be followed in human subjects research [45 CFR 46.101(f), Subpart A]. Any research that is conducted, from the initial consent process, collection and storage of data and specimens, analysis, reporting, publication, and any plans for data management and sharing, must follow tribal research laws and policies. Every tribal nation, as a sovereign nation, has the inherent right to determine how research is governed when it involves their citizens and lands even if they do not have specific research laws in place.

## **Concerns about Research with Vulnerable Populations during a Pandemic**

The COVID-19 pandemic has been devastating for AI/AN communities, and all data indicators reveal that cases continue to increase. As of June 4, 2020, the Indian Health Service (IHS) reports that the number of COVID-19 cases has increased to 12,422, and trends on new cases per day also continue to increase. The number of COVID-19 cases are increasing in all IHS Areas, some more than others, and the Navajo Nation has had the highest per capita rate of COVID-19 cases in the country. The latest CDC data on the number of COVID-19 deaths in AI/ANs is 463, with many more possible deaths from related conditions which could have been associated with COVID-19. The pandemic has been devastating for our communities, especially since we are losing many of our cherished elders. Most disappointing has been the slow response of the federal government to get supplies, testing, medications, and resources to our communities. Delays in federal funding and support have had devastating consequences in Indian Country. Every one of the lives lost is a loss for our people, our communities, and our culture.

Given the above context, we have concerns that during this devastating pandemic, when tribal nations are looking for solutions and desperate for more testing and supplies, NIH is asking tribal nations to participate in research on COVID-19. NIH officials have said that this research can “help get more testing” to our communities. However, “getting more testing” potentially means participating in research on new COVID-19 tests which may or may not be effective and/or using current tests, some of which are not optimally effective. In the context of a pandemic, we wonder if offering access to testing is somewhat coercive for communities desperate for more testing and supplies. Will our communities perceive there are benefits that are not really guaranteed, participate mainly to get access to tests to help their communities, and not understand the potential harms of the research? Will researchers understand the vulnerability of the communities and take extra precautions to minimize harm?

Given the history of harmful research in AI/AN communities in the past, our concerns about any new research are justified, and even more so in a pandemic. While we understand that conducting this type of research quickly is needed during a pandemic, all the regular considerations about how researchers appropriately partner with tribal nations still apply – there should be no assumption that there can be shortcuts in the process. The status of tribal nations as sovereign nations must be honored, and no research should be conducted without their approval. All researchers must follow tribal laws, codes, policies, and IRB or other tribal review processes. Tribal nations often do not recognize exempt research projects and require full review for all research. Research should be conducted in partnership with tribal nations, and resources must be shared fairly. The benefits of the research must outweigh the risks from the perspective of the tribal nation and its citizens. No results or publication can occur without the permission of the tribal nation. Research efforts should help build capacity and support the local workforce. The research project should allow time for meaningful partnership and collaboration. Pandemic or not, there are no shortcuts to meaningful tribal consultation.

The NIH has a duty to consult in a meaningful manner with tribal nations on any new initiatives that may have impact on their communities in a government-to-government relationship. We have concerns about the “rapid” virtual tribal consultation process since attendance by tribal

nations was not high, and the deadline for comments was short. We appreciate the extension of the deadline for comments, but we are concerned that there has not been enough time for tribal nations to learn about these initiatives and provide comments. While NCAI is happy to help disseminate any information about tribal consultations, NIH must communicate directly with tribal nations to ensure their full participation. We recommend additional tribal consultation before the Funding Opportunity Announcement (FOA) is released, before awards are made, and during the entire research process. The virtual tribal consultation session last week cannot be the only consultation activity given the stakes for tribal nations during a pandemic, and carefully assessing benefits and harms of research activities is especially important during this time.

### **Comments on the RADx-UP Initiative**

In your Dear Tribal Leader Letter dated May 21, 2020, the RADx initiative is described as putting “funding towards early innovative technologies to speed development of rapid and widely accessible COVID-19 testing,” and the RADx-UP initiative would “support a consortium of interlinked community-engagement projects to enhance testing among underserved and/or vulnerable populations.” Other descriptions of the RADx initiative in the framing paper describe it being about “speeding innovation, development and commercialization, and implementation of COVID-19 testing.” And while the framing paper mentions RADx-UP as being about enhancing testing for underrepresented communities, it also states that it “aims to develop an infrastructure to assess and expand evidence-based testing interventions and capacity for those populations that are disproportionately affected...” by COVID-19.

The supplemental appropriations language listed in the NIH tribal consultation PowerPoint presentation describes the purpose of RADx to “develop, validate, improve, and implement testing and associated technologies; to accelerate research, development, and implementation of point of care and other rapid testing; and partnerships with ... entities to research, develop, and implement the activities outlined in the provision.” From these descriptions, it seems that the RADx and RADx-UP initiatives are serving the following potential purposes, and we list our concerns below:

- RADx is about research to primarily test new and existing diagnostic tests and testing strategies; research on new tests vs. current tests present differing concerns;
- RADx-UP is about implementing strategies to enable and enhance testing in vulnerable populations; but we are concerned that this may include research with new tests;
- The NIH tribal consultation materials give conflicting information about whether RADx-UP includes research on testing new diagnostic tests, which is very different from just testing implementation of existing tests;
- The materials do not acknowledge that some existing tests have quality issues i.e. false negative rates that are significant and can lead to further inadvertent spread of COVID-19;

- The PowerPoint also says this network will be involved in vaccine trials in the future, but this critical fact was not included in any other written documents available at the time of consultation. Vaccine trials have different risks and harms that must be considered before participation;
- The role of tribal nations is not clear in the process for establishing a coordinating center, funding a collaborative network of clinical research centers/consortia, and then funding subsequent R01 grants;
- While the FOA is likely to be published on June 8, 2020, there is little time to consider tribal input from this tribal consultation. We recommend delaying the FOA until all tribal comments can be considered;
- The timeline for starting the awards is August 2020, with little time for “community-based partnership;”
- There is no mention of intellectual property rights available to tribal nations for participating in testing new diagnostic tests or vaccines. Tribal nations may have their own requirements regarding data ownership and intellectual property rights for research that must be honored for their participation;
- The Notice of intent to Publish an FOA mentions that NIH will solicit emergency competitive revision applications to existing NIH awards that are already in place and already have established community-engaged relationships;
- Options appear to be available for new individual research awards only focused on smaller populations or social, ethical, or behavioral implications of testing in underserved populations. Are these the only opportunities for tribal nations to receive a primary award under this FOA?; and
- A number of eligible organizations are listed including various types of tribal nations and organizations, but the likelihood of these applicants being an existing large consortia, multi-site trial, center or other current network that has existing NIH funding or would be competitive is low given the low numbers of NIH awards to tribal nations. It would not be fair to list potential applicants that have little chance of being funded.

Tribal nations are likely to agree that more testing is needed since they are dealing with limited supplies. However, the most appropriate way to get more tests to tribal nations would be to fund efforts to obtain and deliver quality tests to them now, rather than wait for research results that might not be available for 1-2 or more years. However, we realize the purpose of this letter is to respond to the NIH plans for the RADx-UP initiative. We have concerns about the RADx and RADx-UP initiatives, and detail our questions and additional concerns below on the application and award process, the oversight of these initiatives, and Implementation of the research on developing new diagnostic tests:

- Application and award process:

- What is NIH doing to ensure that tribal nations receive accurate and plain language information about this initiative? As noted above, several details are not clear.
- It appears that existing NIH awardees will have the best chance for funding; what will NIH do to ensure that applications include respectful partnership with tribal nations?
- If tribal nations apply to conduct this research, do they have a realistic chance to be funded?
- Will applicants that claim they are partnering with tribes in their application be required to have a tribal resolution of support for this project specifically, and not just a general letter or old partnership letter for an existing or prior project?
- Will NIH require applicants to share funding with tribal nations that are participating in their research?
- Will NIH require that applicants and awardees follow all applicable tribal research laws, policies, and review processes before research begins?
- Will there be training and workforce development components to benefit the tribal nation and its citizens in these applications?
- Will NIH ensure that tribal nations and AI/AN researchers are a part of the review process that determines scores for funding decisions?
- Will tribal nations or AI/AN researchers be involved in the decision process for awardees?
- Will NIH require that all reviewers read the new NIH document *American Indian and Alaska Native Research in the Health Sciences: Critical Considerations for the Review of Research Applications* and hold any other training for reviewers about reviewing applications involving vulnerable and underserved populations?
- If tribal nations are involved in testing new diagnostic tests, how will NIH ensure that they can share in the intellectual property rights and/or any profit sharing arrangements if the test is successfully commercialized because of their participation?
- Will NIH ensure that all applicants have agreements about data sharing and intellectual property rights that honor the wishes of tribal nation partners in their applications?

- What is NIH doing to ensure diverse representation in applicants and awardees?
- Will NIH fund a set aside for research in the RADx-UP initiative on AI/AN diagnostic test implementation that would better enable tribal nations to participate in this research with partners of their choice? Will NIH fund a coordinating center for the AI/AN research components of this initiative?
- Oversight of the RADx and RADx-UP initiatives:
  - Will NIH have more consultation sessions on implementation of this initiative? How will NIH provide regular updates to the NIH Tribal Advisory Committee on the project?
  - Has NIH discussed this initiative with the Department of Health and Human Services' Secretary's Tribal Advisory Committee?
  - How is the IHS involved in this initiative? Will all sites be required to seek IHS National or Area IRB approvals?
  - What mechanisms will NIH establish to ensure that all researchers and centers/clinical networks conduct respectful partnerships with tribal nations before they begin the research and throughout the initiative?
  - What involvement will tribal nations and/or AI/AN researchers have with the coordinating center for this project to advise on the oversight of the initiative?
  - Will tribal partners be a part of oversight committees?
- Implementation of the research on developing new diagnostic tests:
  - Will NIH require that members of any Data Safety Monitoring Boards include experts familiar with respectful research partnerships with tribal nations?
  - Will NIH require that the coordinating center and all funded sites include tribal partners in any implementation, oversight, planning, and evaluation activities?
  - Will NIH require researchers to provide accurate information about whether they are testing a new or existing diagnostic test and their protocols to any participating tribal nations?
  - Will sites be encouraged to hire project staff in the participating tribal communities?
  - How will NIH ensure that this initiative is conducted in a community-based participatory manner with such short timelines?

- Will participating tribal nations have input in all phases of the research process, including recruitment, consent, implementation, analysis, and communication of results?
- Will participating centers be required to obtain approval from participating tribal nations on any public communications about the tribal nation or the results of the study?
- What will NIH do to ensure that the new diagnostic tests developed in this initiative are affordable for the Indian health system, AI/AN individuals, and tribal nations? No test is better than a new test that is unaffordable and thus unavailable.

The questions posted in the list above are similar to comments that NIH has received from tribal nations in prior consultations, and we hope that NIH has already considered and implemented these in the development of the FOA.

We also have concerns that there is little time available from when comments are due for the tribal consultation and the expected date of release for the FOA. We strongly recommend that NIH not release the FOA until it has considered all tribal input and responded to the above questions with concrete actions as this initiative is developed.

### **Comments on the All of Us Research Program Serology Testing**

We appreciate the efforts of the All of Us Research Program over the past 2 years to consult with tribal nations and to start implementing actions in response to tribal concerns. We feel that progress is being made and look forward to continued discussions and positive outcomes. The All of Us Research Program seems somewhat similar to the RADx-UP in that it is an effort focused on trying to conduct more research with underserved communities that are usually not represented in research and clinical trials. As we have stated before, an initiative structured in this manner cannot replace the real, and sometimes slow, process of developing partnerships with tribal nations to ensure a respectful, beneficial, and safe research experience for their communities. We hope that all the experience and comments from the NIH tribal consultation on the All of Us Research Program will have already been factored into the FOA and plans for these initiatives.

However, we also have concerns about the proposal to test all participants in the All of Us Research Program for antibodies to COVID-19:

- We still have concerns about the All of Us Research Program's lack of compliance with the Common Rule requirements for broad consent. This study is a good example of this concern – another new study is being proposed for the All of Us participants that was not mentioned in the original consent form, and we have noted previously that it is very difficult to opt out of the All of Us Research Program and any future studies with which a participant may disagree. We do not agree that the All of Us Research Program is exempt from IRB review since many tribal nations require review of all research studies, and the

information generated is potentially identifiable to the individual and the tribal community. Furthermore, genetic information is potentially identifiable to the individual per geneticists and represents a high risk research activity for tribal individuals and communities. We still do not concur with NIH that the All of Us Research Program is in compliance with broad consent requirements;

- Any research study must be considered based on the potential benefits and potential harms. While testing all participants will give information on the prevalence of COVID-19 antibodies in that group, there are several potential harms:
  - The PowerPoint slides from the consultation state that the aggregate results will be reviewed first, and then if possible, the individuals will be given results, likely much later. There is little benefit to an individual to receive results of serologic tests weeks or months after testing, since even if they were negative at the time of sample collection, they could be infected with COVID-19 days, weeks, or months later. Getting a negative result from weeks or months ago and thinking you are not infected now could be harmful. What is NIH going to do to ensure that proper education about the results is conducted with participants?
  - There is no information available about what aggregate reports will be made public. Does NIH plan to release the results by race/ethnicity? Public release of AI/AN results would be potentially harmful to tribal nations and AI/ANs since the current map of AI/AN participants is not representative of the actual geographic distribution of AI/AN individuals or tribes. If, for example, the participants were primarily from urban settings in areas with a higher prevalence of COVID-19, and a high prevalence of antibodies was reported for AI/ANs in the All of Us participant group when the actual prevalence in rural areas might be lower, there would be potential harm and stigmatization;
  - As with the All of Us Research Program, tribal affiliation should not be used without the expressed permission of that tribal nation in any research studies, public data, or dissemination of results;
  - We agree that there is minimum overall benefit due to the small number of AI/AN participants;
  - AI/AN data are not supposed to be made available to researchers until the tribal consultation is completed. Early release of this information on the COVID-19 antibody studies is not a benefit;
  - The benefit stated by NIH of the information benefiting a population experiencing disproportionate impact is not a benefit since the sample is not representative of the AI/AN population; and

- We recognize that public health surveillance is important, but we also know that current antibody tests have significant false positive rates. Tribal communities are still dealing with the fact that the federal government sent them diagnostic tests that are inaccurate and have a lot of false negatives. Trust in testing is an issue at this time, and tribal nations may not trust the results of the serologic testing by the All of Us Research Program.
- Participants must be given the option to easily opt in or opt out of serologic testing, and tribal affiliation should not be used in any reporting or research until the tribal consultation is completed; and
- Overall, we recommend that if AI/ANs participate in the serologic testing, results should not be disaggregated by AI/AN race, researchers should not have access to this data, tribal affiliation status should not be used, and significant education and counseling should be conducted with participants on proper use and understanding of the limitations of the results. Overall, the potential harms are much greater than any perceived benefits so we do not see how this information is helpful other than to be a part of aggregate results.

## Summary

We appreciate the effort of NIH to consult with tribal nations on these two new research projects. We encourage NIH to implement our recommendations and answer our questions with actions that will help ensure that the research can be beneficial to tribal nations and harms can be minimized. Clarification on how tribal nations can participate is needed in the FOA. We also recommend ongoing tribal consultation.

If you have any questions, please contact our Policy Research Center at [research@ncai.org](mailto:research@ncai.org).

Sincerely,



Kevin Allis  
Chief Executive Officer  
National Congress of American Indians