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INFORMATIONAL/CONSULTATION WITH TRIBAL NATIONS

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1 PROCEEDINGS

2 [MEETING CALLED TO ORDER AT 3:00 PM]

3 **WELCOME AND INTRODUCTIONS**

4 DR. WILSON: Welcome, everyone, to the NIH informational/consultation session on tribal
5 interests in research involving human participants. [Brief introduction spoken in native language] My
6 name is Dr. David Wilson. I am the Director of the NIH Tribal Health Research Office, or THRO. I will
7 be serving as a moderator for this meeting along with Dr. Malia Villegas, a Council Member and a
8 member of the Native village of Afognak, who is also the Co-Chair of the NIH Tribal Consultation
9 Advisory Committee, commonly known as TCAC. So, thank you all for joining us today whether in-
10 person or remotely. We are holding this session in response to a request made during a meeting of the
11 HHS Secretary's Tribal Advisory Committee with input from the TCAC. We welcome this opportunity
12 for tribal leaders, officers, and tribal members to share perspectives or raise questions with the NIH about
13 our role in assuring the protection of research participants and to share perspectives on partnering with
14 tribes and integrating tradition and culture in research involving tribal population. I will begin this session
15 with three very short presentations: one briefly overviewing the NIH's role in advancing research and in
16 assuring the protection of individuals and populations participating in NIH-funded research, and we will
17 then address any questions and seek perspectives from participating tribal members. In the second part,
18 Dr. Villegas will serve as a moderator and the participating tribal leaders and members will be asked to
19 provide their perspectives on our role and ways that we can better partner with tribes in the design and the
20 conduct of research and the integration of tradition and culture. This is a very important session. We will
21 consider what is shared today very carefully and also present the outcomes to the TCAC and gather their
22 perspectives on these very important issues. Before we begin, I'd like to go over a few important
23 logistical points. First of all, to minimize background sound, we have muted all lines, and we would also
24 appreciate if you would use the mute button on your phone as well. And when we get to the consultation
25 section of the agenda, we'll ask for comments and questions, and if you'd like to make a comment or ask
26 a question, we'll ask you to click on the hand icon that you'll see on the right-hand side of the toolbar. In

1 keeping with standard consultation protocol, we appreciate allowing tribal leaders and officers to ask
2 questions first and then open the floor to tribal members. As we call on your name, your line will be
3 unmuted and everyone will be able to hear your question or comment, and if you would prefer to send
4 your question in writing you can certainly do so by using the question box in the tool bar on the right of
5 your screen, and we'll be monitoring the box throughout the meeting. If we aren't able to take all
6 questions or all of the comments before we adjourn at 5:00 p.m., we ask that you send your comments or
7 any additional comments to us via the TCAC mailbox which is NIH TribalCommittee@od.nih.gov, and
8 we've included the address at the bottom of the agenda so that you can find it in the handouts. We are also
9 recording this conversation today and we will create a transcript that will be posted on the TCAC website.

10 **PART ONE**

11 **NIH'S ROLE IN THE STEWARDSHIP OF NIH-FUNDED RESEARCH INVOLVING** 12 **INDIVIDUALS AND POPULATIONS**

13 ***ADVANCING RESEARCH TO ADDRESS PUBLIC HEALTH NEEDS***

14 DR. WILSON: Alright. So, let's turn to part one, which I'll begin by providing an overview of
15 the NIH's mission, and then Dr. Carrie Wolinetz, the Associate Director for Science Policy, will provide a
16 brief overview of the NIH's role in assuring protection of individuals and populations participating in
17 NIH-funded research. Dr. Sara Hull, who is the Chair of the IRB of the NIH's National Human Genome
18 Research Institute and the Director of NHGRI's Bioethics Core, will briefly describe the important role of
19 the Institutional Review Boards in protecting research participants. Alright. So, the NIH's mission is to
20 seek fundamental knowledge about the nature and behavior of living systems and the application of that
21 knowledge to enhance health, lengthen life, and reduce illness and disability. NIH research funds...I'm
22 sorry...NIH funds research to not only understand the processes of disease and dysfunction, but also the
23 basic research to understand the normal function of healthy living systems. Both types of research are
24 essential to the mission. The NIH is composed of 27 different Institutes and Centers; each is focused on a
25 particular living system, disease, population, or area of research. The NIH annual budget is about

1 \$32 billion a year, about 83 percent of which funds research conducted at institutions and organizations
2 across the country. About 10 percent of this...of the budget goes to supporting research conducted here at
3 the NIH in the Intramural Research Program, and each year the NIH awards more than 57,000 research
4 and training grants, supporting approximately 300,000 researchers at more than 2,500 universities and
5 organizations in every state, including tribal colleges and universities and tribal governments. More
6 specifically, in regards to Native American populations, the NIH focuses studies that focused on
7 American Indian health and of the American Indian/Alaska Natives. The Tribal Health Research Office
8 within the Office of the Director and the National Institute on Minority Health and Health Disparities
9 have primary roles and responsibilities in coordinating research on American Indian/Alaska Native health
10 within the NIH. Importantly, in 2015, the NIH spent \$160 million on research involving the health of
11 American Indian and Alaska Native communities, and within this research the NIH funds a variety of
12 health topics aimed at both improving health and reducing health disparities in American Indian/Alaska
13 Native communities, and these include cardiovascular disease, environmental health, drug and alcohol
14 misuse, and diabetes, as well as several programs that explore how best to empower individuals and
15 communities with the information they need to improve their health and prevent disease and injury. The
16 NIH also funds training programs that encourage American Indian and Alaska Native students to enter
17 into biomedical research careers and that support American Indian and Alaska Native investigators who
18 are already leading their own biomedical research programs. When setting priorities, the NIH takes into
19 consideration a few key factors—the first one being scientific peer review. The NIH funds the best and
20 most rigorous research as judged by our world-renowned two-stage peer review system. Scientific
21 opportunity is also a key factor. The NIH funds research that capitalizes on advancements in a particular
22 field where new technology permits new approaches to pressing questions and where unexpected
23 discoveries provide new opportunities for deeper investigation. Also, it's important to assess the public
24 health needs. The NIH funds research for both emerging public health needs, for example Zika and Ebola,
25 as well as existing issues such as rising burdens of chronic disease management. We are also committed
26 to studying rare diseases where there is a potential to learn a great deal that can be applied to other

1 conditions, but where private industry is less likely to invest. It's also important that the NIH strives to
2 maintain a portfolio balance and to maintain a diverse balance as well, in which a full range of diseases,
3 conditions, and healthy living systems are represented. The priority settings also involve meeting with
4 stakeholder communities, including but not limited to researchers, professional societies, patient
5 organizations and voluntary health associations, advisory boards and councils, Congress and the White
6 House, and NIH staff. We also take our responsibility here under the HHS Tribal Consultation Policy
7 very seriously, so that before actions that will significantly affect tribes, we undertake consultation to
8 obtain meaningful and timely input to ensure that tribal interests are considered in the development of
9 NIH policies. With that, the NIH is also pleased to hold consultations when requested to do so by Tribal
10 nations, as we are doing today. The Tribal Research Health Office, where I'm located, was established in
11 2015 in recognition of this importance of ensuring meaningful input from and collaborating with Tribal
12 nations on NIH programs and policies. This office is located, administratively, in the Division of Program
13 Coordination, Planning, and Strategic Initiatives within the Office of the Director. The TRHO office is a
14 focal point for the NIH and efforts to coordinate and support the NIH's Tribal Consultation Advisory
15 Committee and also coordinating all of the different activities within the NIH to address tribal needs and
16 concerns. So with that, now I would like to hand over the conversation and microphone to Dr. Sara Hull,
17 who is the Chair of the IRB with the National Human Genome Research Institute...

18 FEMALE: Carrie Wolinetz.

19 DR. WILSON: Oh, I'm sorry, Carrie Wolinetz. Sorry about that... Assuring the Protection of
20 Individuals and Populations Participating in NIH Research. Dr. Carrie Wolinetz, Associate Director for
21 Science Policy here at the NIH.

22 ***ASSURING THE PROTECTION OF INDIVIDUALS AND POPULATIONS PARTICIPATING IN***
23 ***NIH-FUNDED RESEARCH***

24 DR. WOLINETZ: Thank you, Dave, and I'm honored to be part of this Tribal Consultation
25 session today. I'm here to provide an overview of NIH's role in assuring the protection of research
26 participants, plus to listen to tribal member perspectives on what other steps we should consider to ensure

1 that tribal interests are reflected, the policies governing the design, the conduct, and the dissemination of
2 NIH-funded research involving tribal populations. So, one important point I'd like to clarify right up front
3 is the role played by the NIH in this area, relative to other organizations within the Department of Health
4 and Human Services. In particular, the Office for Human Research Protections, or OHRP; Food and Drug
5 Administration, or the FDA; and the Office for Civil Rights; each play a different and important role in
6 the protection of research participants. And this is because, unlike the NIH, they have the regulatory
7 authority over the research we fund and they are responsible for enforcing those regulations in the event
8 of any sort of non-compliance. A helpful way, maybe, to think about this in terms of the difference in our
9 rules is that OHRP, FDA, and OCR write and enforce regulations such as the Common Rule, FDA
10 regulations, and the HIPAA Privacy Rule. The NIH has a voice early on in the process of development of
11 those rules, along with other federal agencies throughout the federal government, but the regulatory
12 agencies are the authorities on what the regulations say and what they mean and interpreting those
13 regulations. As a publicly funded research agency that relies on taxpayer dollars as well as the
14 participation of human research volunteers, we feel very strongly that we need to be careful stewards of
15 the research that the NIH funds. And in part, how we carry out that stewardship role is by requiring
16 anyone who receives our funds to comply with federal regulatory protections of research participants as
17 well as any applicable state, local, and wherever relevant, tribal laws. Most of the research we fund is
18 carried out through grants, so the way we make sure that our grantees adhere to the regulations is by
19 making compliance a term and condition of award. When grant applications undergo peer review, the
20 study section reviewers check to make sure that the proposed research meets regulatory requirements. If
21 any questions are raised during that process, those issues will be resolved by the Office of Extramural
22 Research at the NIH before any funds are released, and we also require a confirmation that an Institutional
23 Review Board, or IRB, has reviewed and approved the project before funds are released, and Dr. Hull will
24 be talking a little bit more about the IRB process. We also develop and issue policies of our own to
25 address ethical issues that are not covered by the regulations or when the need for additional safeguards
26 arises. Some examples of those sorts of additional guidance or policies include the inclusion of women,

1 minorities, and children in research; monitoring of clinical trials for safety and data integrity; genomic
2 data sharing; or the conduct of sensitive types of research, for example, involving drug and alcohol
3 treatment. Certificates of Confidentiality are another way in which the NIH protects research participants.
4 Currently, the NIH makes Certificates available to research investigators who are collecting sensitive
5 research information. An investigator who holds a Certificate cannot be compelled by legal authorities to
6 release information about study participants. Whenever the NIH develops a policy, it is our practice to
7 seek public comments before issuing a final approach and to do outreach to our stakeholder communities.
8 In particular, for policy proposals that may have significant effects on Tribal nations, the NIH will also
9 seek input from tribal leaders and representatives through consultation. We are also, I should point out,
10 continually reviewing our existing policies and guidance to be sure that they are still current and
11 sufficient—they're not set in stone. These are dynamic, living policies that we are continually looking to
12 improve. We hope, to that end, that today's session will help us identify policies that might be improved
13 or to inform the development of new guidance to assist research investigators who collaborate with tribal
14 populations to contribute the knowledge about how to improve health, lengthen life, and reduce illness
15 and disability. So, in anticipation of questions that might arise today about revisions to the Common Rule,
16 which was published in January of this year, we want to point out that the Office of Human Research
17 Protections, OHRP, will be happy to try to address such questions, and that the email address to
18 which...to address those questions is OHRP@HHS.gov. With that, I'd like to turn it over to Sara Hull,
19 and I look forward to listening to you.

20 ***ASSURING THE IRB REVIEW AND APPROVAL PROCESS, INCLUDING RESEARCH***
21 ***WITH TRIBAL POPULATIONS***

22 DR. HULL: Thank you. I'm also very honored to have been invited to be included in this
23 conversation and to have this opportunity to provide you with a brief overview of the IRB review and
24 approval process for NIH research, including research with tribal populations. To begin with, all research
25 that involves human participants that the NIH is involved in supporting in some way—whether it's
26 through funding or through collaboration, or conducting the research themselves—this research must be

1 reviewed by an Institutional Review Board, or an IRB. And I'll just mention that sometimes there are
2 different terms used to describe this role—Research Ethics Committee, Research Review Committee—
3 but IRB is the term that's used in our federal regulation, so I'm just going to use that term for purposes of
4 our conversation today. So, IRBs are committees that are responsible for providing independent review of
5 human research proposals to protect the rights and welfare of participants—of volunteers in that
6 research—and this happens both before the research begins and also as the research proceeds. The key
7 point to understand is that if HHS or, specifically for our conversation, if NIH funding is involved, the
8 IRBs that are reviewing the research must be registered with the Office of Human Research Protections,
9 or OHRP, and the institutions that are doing the research must have what's called a Federalwide
10 Assurance, or an FWA. This is basically an agreement that those institutions will follow the Common
11 Rule, which are the Federal regulations for the protection of human research participants. And this means
12 that they have to have VPL policies and procedures in place that do things like spell out who the members
13 of the IRB will be, how they're going to go about reviewing all of the documentation related to the
14 protocols and consent forms and other aspects of the research, what the training requirements will be for
15 investigators, etc. The Common Rule is grounded in three principles that were articulated in 1978 in a
16 report called the *Belmont Report*, and these are the ideas of respect of persons or respect for their
17 autonomy—this gives rise to the idea of informed consent, that we have to get permission from people to
18 do research that involves them before we can proceed, and that's a very individual-focused concept; the
19 principle of beneficence and the related principle of non-maleficence, or the idea of benefitting and not
20 harming individuals, and that pushes us to try to balance the risks and benefits of research and do what we
21 can to minimize those risks; and then the principle of justice, which refers to things like fairly distributing
22 the benefits and burdens of research and also paying attention to the fair selection of the subjects...the
23 participants of research. The history of research that's been conducted with tribal populations suggests
24 that, although these are...these principles are a good starting point to protect individual research
25 participants, there are additional values that also need to be addressed to ensure the respectful and ethical
26 conduct of research with tribal communities; for example, respect for community values and culture and

resources, as well as traditional knowledge; respect for tribal sovereignty and self-determination; and research that promotes resiliency. Increasingly, these kinds of values are being incorporated into the IRB review of tribal research in a variety of ways, for example, through the involvement of tribal councils and governments and Tribal IRBs in the research planning and approval process. There are actually many different IRBs in the United States. I checked just last week with OHRP and they confirmed that there are 3,485 IRBs registered in the United States with OHRP. Twelve of those IRBs are located here at the NIH to review our intramural research, which is where a very small amount of research with tribal populations is conducted. So, most NIH research, including research with tribes, is reviewed by IRBs that are located at universities and other institutions that receive extramural NIH grant funding. According to the Indian Health Service IRB website, there are currently 26 registered IRBs that they're aware of that are specifically Tribal IRBs or tribally focused IRBs. Tribal IRBs are typically established by tribal resolution, ordinance, or research codes, and many Tribal IRBs also seek an FWA—a Federalwide Assurance—from OHRP. So, this means that Tribal IRBs include, but also go beyond, those Belmont principles that I mentioned. They may often have additional policies related to things like the need for tribal government approval and publication review. So, if NIH-funded tribal research is being conducted, say at a university or the Intramural Research Program here, and are being reviewed by one of those IRBs, they generally also need to get approval from a tribal government or a Tribal IRB. Sometimes this is referred to as dual review, so an investigator may have to go through multiple IRBs before conducting the research with tribal populations. If the research is being conducted in an Indian Health Service facility or with IHS staff, then it would need to be reviewed by either the IHS national IRB, one of the IHS area IRBs, or an appropriate Tribal IRB that has its own FWA—independent FWA—and that also goes along with extra requirements with things like written approval of the tribal government and publication review. Just to reiterate what Dr. Wolinetz said in her overview, the NIH requires anyone who receives NIH research funding to comply with Federal and regulatory protections for research participants, as well as all of the applicable state, local, and where relevant, tribal laws. This means that investigators who want to conduct research with tribal populations will need to be familiar with any of the specific review

1 requirements of the different tribes that may be involved. So, thank you very much for your time and I
2 really do look forward to hearing everyone's questions and perspectives on these projects.

3 **PERSPECTIVES AND RECOMMENDATIONS FROM PARTICIPATING TRIBAL MEMBERS**

4 **ABOUT NIH'S STEWARDSHIP ROLES**

5 DR. WILSON: Thank you very much Dr. Wolinetz and Dr. Hull, in that order. Sorry for the
6 confusion. And now it's time that we'd like to hear from the folks who are online. We want to hear the
7 perspectives and recommendations from participating tribal members about the NIH's stewardship roles
8 in research. So with that, we will take a question. You can raise your hand online so that we can select
9 you from the list of attendees. [no audio] Apologies for the delay. We are working through some technical
10 difficulties here, but we now...I think we have everything online. Let's see here. So, one of the questions
11 that has come in is: "Please address the following issues of concern to the Cherokee Nation...the
12 IRB...the single national IRB for multisite studies, genomic research, Precision Medicine Initiative (the
13 lack of outreach to Indian communities), tissue repositories, data ownership and intellectual property
14 rights, how the NIH ensures that Institutes support community-engaged research." So, thank you for that
15 question.

16 DR. WOLINETZ: So, I will start by addressing the single IRB policy. For those of you who are
17 perhaps not familiar with this, the NIH has recently a policy that essentially mandates the use of a single
18 Institutional Review Board of record or multi-site studies involving human research participants, and this
19 was a policy that had been issued initially in draft form and received a number of comments, including
20 those from Tribal nations and leaders, and then the final policy was released and is effective in September
21 of 2017, for applications coming in. The aim of issuing that policy is—you've heard for many, many
22 years—that the involvement of multiple IRBs in reviewing a multi-site study that had a single protocol, in
23 fact, could cause significant delays in review of that protocol and potentially cause some issues when
24 there were disagreements between the IRB in sort of the details, and so this was seen as a huge bottleneck
25 in the initiation of studies—clinical research studies. The NIH final policy...I would note while it requires
26 the use of a single IRB of record for multi-site studies, it does have an allowance for exception and, for

1 example, the use of such a single IRB or a centralized IRB would not be permitted by local laws, and that
2 would include tribal laws, for example. And so, we do have an exceptions process that would allow multi-
3 IRB review of multi-site trials when appropriate, and hopefully that will alleviate, potentially, some of the
4 concerns that we've heard specifically from the Tribal nations.

5 DR. WILSON: Great. Thank you for that. Next, I'd like to actually hand over the next part of this
6 question in regards to the Precision Medicine Initiative to Daozhong Jin, who is the Outreach Coordinator
7 for the Precision Medicine Initiative.

8 DR. DEVANEY: Thank you very much. So, I'll take that. My name is Stephanie Devaney. I am
9 the Deputy Director of the All of Us Research program, which is one of the central components of the
10 Precision Medicine Initiative. So, I think...could someone repeat the question for me or read the full
11 question for me?

12 DR. WILSON: The question is in regards to genomic research, IRB, and a lack of outreach to
13 Indian communities.

14 DR. DEVANEY: Well, I can address...we actually have just begun, really, building the
15 infrastructure for the All of Us Research program, so we have been, over the last 8 or 9 months doing a
16 lot of building the solid infrastructure and also thinking about ways of engaging specific communities and
17 populations across the country. We will be beginning a more careful outreach with communities that are
18 related to American Indians and Alaska Natives, so I think you'll be hearing a lot more from us. I know
19 that Eric Dishman, our Director who took the reins in July of last year, has spoken with TCAC and will
20 be joining the meeting on March 9 as well, and we'll be able to provide a fuller update on where we are
21 with the planning of the program. We haven't enrolled any individuals yet, so we really are just in the
22 planning phase and intend to do a pretty thorough consultation with all of the folks who need to have
23 input on these issues.

24 DR. WILSON: Great. Thank you. And the third part of that question, we will actually respond to
25 that at a later date. We want to move on to as many questions as possible. Alright. So, the next question

1 is: “If the tribe has an IRB and someone wants to conduct research on that reservation, is approval needed
2 from both the IHS IRB and the Tribal IRB?”

3 DR. HULL: This is Sara Hull. I’ll do my best to answer that question. My understanding is that it
4 depends both on tribal policies as well as the Indian Health Service policy and whether it’s in an Indian
5 Health Service facility or staff are involved in that research, so I think the [inaudible] might vary from
6 place to place, depending on those factors.

7 DR. WILSON: Thank you, Dr. Hull. Many are worried...next question is: “Many are worried
8 about the Common Rule changes that will allow genetic analysis without the subjects’ knowledge, and
9 what are our thoughts on that?”

10 DR. WOLINETZ: This is Carrie Wolinetz speaking. I think, if I can extrapolate from that, that is
11 perhaps a provision related to consent for biospecimens, regardless of whether or not they’re identifiable.
12 So, just to take a step back again in case people are unfamiliar with the issue, under the previous version
13 of the Common Rule of the long-standing version of a Common Rule, use of a biospecimen for research
14 was allowable without consent as long as there was no...as long as it was de-identified, essentially. And
15 one of the proposals that came through the various stages of the most recent revision of the Common
16 Rule, which was released mid-January, was a proposal that would mandate consent for biospecimens
17 regardless of whether or not the biospecimen was identifiable, and this would also allow the use of what’s
18 known as broad consent in which you didn’t necessarily have to specify how that biospecimen was going
19 to be used for, sort of, secondary research purposes. You could specify it, given prohibited specific
20 consent, but it would have allowed broad consent. And so, as the Common Rule proposal was put out for
21 public comment, and again I want to reiterate that this is a regulation of the Office of Human Research
22 Protections, so the NIH is not the writer or controller of this particular rule—that’s OHRP—but they...the
23 comments that came back about that particular provision were sort of overwhelmingly concerned about
24 the impact that requiring consent for de-identified biospecimens would have in a number of different
25 ways. There were many thousands of comments to the Common Rule, so, you know, I’ll just leave it at
26 that in terms of the concerns. Ultimately, in the Final Rule, that provision was dropped, so we essentially

1 stayed at the status quo of not requiring consent for de-identified biospecimens. These are, for example,
2 biospecimens that might be collected in the process of a medical procedure and then could be used
3 without consent for research. The NIH has a long, sort of, standing position...I mean, it can read this as a
4 matter of public record. The Director of the NIH, Francis Collins, along with the Deputy Director at the
5 time, Kathy Hudson, published a commentary in the *New England Journal of Medicine* at the end of 2015
6 supporting the use of consent for biospecimens, regardless of whether or not they were identifiable and
7 citing the fact that this was an ethical issue...that there was a great deal of evidence that people wanted to
8 be able to specifically consent for the use of their biospecimens. You know, the rule-making process is a
9 pretty regulated, sort of, process in and of itself, and so agencies who create rules are guided strongly by
10 public comments, which I said in this...as I mentioned in this particular space, were sort of
11 overwhelmingly negative against that particular provision, which is likely the reason that it was...it did
12 not end up in the Common Rule. So, that is sort of the current status quo that has been maintained and we
13 are very interested in continuing to hear perspectives on how people think about that as, sort of, we go
14 forward in the future collectively and think about what policies and levers we might have under our
15 control in that space.

16 DR. WILSON: Great. Thank you for that and we'll move on to the next question. It's going to be
17 directed back to you, Dr. Wolinetz. "Can you clarify how the single IRB exemptions will be
18 implemented, and does the tribe have to have an official law passed indicating that they have a body
19 assigned to review research, or will other policies suffice? Also, if an exemption has been granted once,
20 will paperwork or verification of the tribal law need to be provided for future studies?"

21 DR. WOLINETZ: So, this is Carrie Wolinetz again. I hope you're not sick of my voice yet. The
22 investigator will be sort of responsible both for identifying a single IRB of record or making the case for
23 an exemption, and we'll have sort of an internal committee that will really be led by our Office of
24 Extramural Research to work with our Institutes to determine those exemption processes. It does not have
25 to be just tribal law—we tried to make the exemption fairly broad to include policies, rules, guidelines,
26 etc., so it does not have to be necessarily an official law, and we are hoping to implement this in a way

1 that once an exemption has been made, that essentially serves as case law for future exemptions so that
2 you don't have to continually go through the exemption process.

3 DR. WILSON: Great. Thank you very much. And we have a call regarding...I mean...I'm sorry.
4 We have a question regarding overlapping jurisdiction. So, if the person who presented the question can
5 clarify that, we can address that, Raj Shah has been unmuted.

6 DR. SHAH: Yeah. So, the question was to figure it out because when you look at Native
7 Americans and, you know, 10 years ago when they were out of the reservations but now they are living in
8 and around big cities and our local [indiscernible] doesn't require us to have the approval. However, when
9 we go to our [indiscernible] they tell us that if something goes wrong and those ties can get back to you,
10 what...or legal things taken [indiscernible]. So, how does that affect the local IRB, which is your
11 institutional IRB, where you are going by but you are not required to have [indiscernible] IRB?

12 DR. WILSON: So, can you clarify...is your question in regards to the jurisdiction in terms of the
13 urban Indians residing in cities as opposed to reservations?

14 DR. SHAH: Sure. Exactly.

15 DR. WILSON: Can you present that or say that one more time so that we can get the answer for
16 that?

17 DR. SHAH: So, I'll use a simple example. We are trying to recruit people who come to the
18 hospital here, which is part of the University in Albuquerque, and those Native Americans live in and
19 around Albuquerque, but they may be from Navajo Nation or some other [indiscernible]. So, one of my
20 meetings with [indiscernible] for the IRB...they said I should get the [indiscernible] for IRB also in case
21 those people who go back to the community...they may actually bring legal things against the institution
22 where you didn't have the IRB.

23 DR. HULL: Part of what we're trying to do behind the scenes is figure out what kind of expertise
24 we have available to answer the questions. We're getting lots of really good and tough questions, and I
25 think for now, what I want to say is that...a great question and an important one, one that's challenging us
26 to answer...we're actually getting others on the phone popping in and saying that they have ideas and

1 support. We want to collate all of these and make this available as an ongoing resource and note that this
2 is the beginning of an ongoing conversation that we're committed to having. We're not sure we have
3 anybody who can give you a really pointed answer at this exact moment, but we're taking careful note of
4 it.

5 DR. SHAH: Sure. Because it's mainly...[indiscernible] genetics here in Navajo persons living in
6 Albuquerque, but the Navajo IRB requires for me to get...you know...I cannot do any genetics on Navajo
7 persons, right? So, which IRB should I follow? Should I go back to the Navajo Nation or should I still go
8 back and use the institutional IRB that I'm importing?

9 DR. WILSON: Thank you, Raj, for that, and we actually have a person on the line who has
10 offered to provide some insight into your question. And so now we're going to call on Abigail Echo-
11 Hawk. You're now unmuted Abigail. [no response] Thank you. [no response] Abigail, you might be on
12 mute on your end for the computer. [no response] Raj, we will try to connect you and provide you the
13 information after the session. Thank you for that really important question. And so, the next question is:
14 "Will your program connect native researchers with tribes if a tribe prefers to utilize the 'indigenous
15 research methods' or just want a native researcher?"

16 DR. ETZ: So, this is Kathy Etz, and I'm the former Senior Advisor for Tribal Affairs at the NIH
17 and now a program official at the National Institute on Drug Abuse, and most of the research that the NIH
18 conducts is investigator-initiated research. So, we are happy to work with native investigators or with
19 investigators who use indigenous research methods. We...if you contact us post this call, we can give you
20 the name of a program official at an Institute in the substantive area of research in which you're interested
21 and they might be able to help you and discuss with you your idea and tell you who is doing research in
22 that area. So, that's the way that we tend to try to help connect people up.

23 DR. WILSON: So, the next question would be: "Why would a Tribal IRB seek an FWA if they
24 are not IHS?"

25 DR. HULL: Sara Hull again. That's a great question. Tribes have the choice to set up whatever
26 review mechanism works best for them within the context of their own community, so the decision about

1 whether or not to seek an FWA would depend on the tribes' interest in either receiving NIH funding to
2 conduct research if members of the tribes themselves are researchers who want to be able to conduct
3 research there or if they're interested in collaborating with NIH-funded researchers and want their IRB to
4 be able to serve as the IRB of record for the research that involves that Federal funding. And that...comes
5 a requirement to follow at least a baseline of the minimum set of standards...the requirements of the
6 Common Rule, but that is a minimum and additional tribal rules and regulations can be layered on top of
7 that, so I think...there are actually really nice toolkits that are being developed, and I'll point to one of the
8 references that Dr. Collins had included in notes to his Dear tribal leader letter...the CRCAIH Toolkit—
9 C-R-C-A-I-H—provides tribes with a decision tool to work through whether or not that's the kind of IRB
10 review process they want to set up.

11 DR. WILSON: Thank you. And the next question is: "What are the recommendations for
12 individuals who want to provide educational—for example, computational methods and analysis
13 training—experiences to American Indian/Alaska Native students? The training doesn't include handling
14 or the collection of biospecimen research, but the audiences are students from various tribal
15 communities."

16 DR. HULL: The answer to that kind of question generally involves figuring out if the people
17 engaged in that activity are engaged in human subjects research. Will they have access to identifiable,
18 private information about individuals? There are a series of guidance documents that the Office for
19 Human Research Protections offers to help work through that question on a case-by-case basis. It's a little
20 bit difficult to know how to answer that question in the abstract, but it really comes down to the issue of
21 [indiscernible] in research and whether human subjects or human participants, as they're defined in
22 Federal regulations, are involved in some way in that activity.

23 DR. WILSON: Thank you for that. And maybe a little easier question: "What are the benefits of
24 obtaining an FWA for a health facility with a Title V compact?"

1 DR. WOLINETZ: Well, you would be able to be in receipt of NIH funding—it would certainly
2 be one potential benefit—and enter into reliance agreements, potentially, with collaborating institutions or
3 organizations as well.

4 DR. WILSON: Great. Thank you.

5 DR. ETZ: This is Kathy Etz again. We have a question asking about the NIH research budget and
6 pointing out that in the 2010 U.S. Census AI/ANs comprised roughly 1.7 percent of the U.S. population,
7 but our dollars spent on research don't reflect 1.7 percent of the NIH budget. And I would just say that we
8 don't fund research according to population density. As Dr. Wilson pointed out in the beginning of the
9 presentation, there are multiple factors that go into funding decisions and much of the research that the
10 NIH conducts is basic science and has relevance for all human organisms, and so we don't make
11 decisions according to race or ethnicity in apportioning the budget, but rather, in advancing the public
12 health for the population. There's another question and it's a very specific question about research being
13 conducted in Montana, and I would suggest that it would be better for us to respond individually to that
14 question, so we will follow up with you. Please give us a moment to read some questions that just came
15 in.

16 DR. WILSON: So, this is a great question that came in, and it's rather lengthy, so hang in there
17 with me. "Applicable knowledge about how to remedy the extreme health needs of Native American
18 communities is in strikingly short supply. In response to a similarly emergent situation in that Nation, the
19 Canadian Institutes for Health Research include a stand-alone Institute for Aboriginal People's Health that
20 helps to ensure that a significant block of health research funding is allocated for distribution to
21 indigenous community health research through tailored RFAs, standing review panels with relevant
22 expertise, etc. What would be necessary for the creation of a parallel National Institute for Native Health
23 here at the National Institutes of Health?" And in response to that, this is a very big ask, and it would
24 require actions by Congress.

25 DR. ETZ: Um...so, while this question's being addressed, I'm going to answer a different
26 question. This question is: "NIH has been encouraging widespread sharing of data. Without appropriate

1 tribal governance of any future data sharing, tribal leadership and community members will be hesitant to
2 participate, particularly since what the NIH is proposing is to integrate culture and traditional knowledge
3 into funding announcements and research projects. Although the integration of culture and traditional
4 knowledge into funding announcements and research is a worthwhile goal, since it could make
5 interventions more applicable, traditional knowledge is sacred and thus sensitive. So, this integration
6 needs to be done very carefully. Are there plans to address this?" And I think the answer to that question
7 is that this consultation is part of our plan to address this. We very much understand that culture and
8 traditional knowledge are sacred, and we would take our lead from tribes on this, and the reason that those
9 two points are in this listening session and consultation is because they come from the community. The
10 NIH is not asking that tradition and culture be integrated as a top-down move but rather this has come to
11 us from the communities and we very much plan to take our lead from the communities there. There's a
12 second part of this question, which is that: "Any benefits from the integration of culture and traditional
13 knowledge in research should be shared with tribes to include any financial benefit from inventions or
14 medications or other discoveries that then lead to products which potentially would be sold. Has this been
15 addressed or is there a plan to have consultation on this?" I think that there are many different products
16 that could come out of research. We did have one specific conversation around this, which had to do with
17 traditional medicine, and the plan there was very much specifically to understand how to ensure that
18 tribes would gain any financial benefit from that. So certainly, we would be looking to support that,
19 and...but I think that those negotiations would probably take place between the investigators and the
20 tribes...the investigators' institutions, I should say, and the tribes.

21 DR. WILSON: Okay. Next question is: "Due to the potential high turnover in Tribal IRB
22 personnel, what steps have or has the NIH taken to assist tribes with sustaining IRBs?"

23 DR. HULL: One step that we're taking is working to expand some of our training programs that
24 are geared towards research ethics and capacity-building for IRBs and tailoring them specifically to tribes
25 and tribal needs. And so, we're trying to both identify people who are interested in moving into this kind
26 of work and to supporting IRB infrastructure and creating IRBs and to provide them with ongoing

1 training to help them with new issues that are coming up. One program that I'm personally very involved
2 in is in the Department of Bioethics in our Clinical Center. I know that there are other efforts that are
3 attached to different funding mechanisms and the different Institutes and Centers across the NIH, but for
4 my part I'm aware of this and we're trying to leverage resources that we have and expand them...be
5 relevant to supporting Tribal IRB personnel who I know are often wearing multiple hats and working in
6 different roles. And so, it's challenging to be able to maintain those kinds of positions over time. We have
7 another question. This one reads: "Urgent health research with Native American communities is
8 frequently hamstrung by numerous challenges, including the importance of developing a genuine
9 collaboration, the lack of community capacity for supporting research operations, and inherent limitations
10 for scientific rigor, for example, small sample sizes. As a consequence, proposals for Native community-
11 based health research are frequently at a disadvantage for funding in comparison to most non-Native
12 studies. How does the NIH ensure that these intrinsic challenges do not further dispossess tribal
13 communities of their fair share of desperately needed health research investment and attention?" I think
14 this is a very important question and I think that we've undertaken a multi-faceted strategy to try to ensure
15 that this does not happen. One of the approaches is to develop funding opportunity announcements that
16 are directed only at Tribal nations. Examples of those include the NARCH Program, the
17 Intervention...uh, the Research...the IRINAH initiative. I cannot remember what the acronym stands for,
18 but there are about 17 studies on...or maybe 21 at this point on interventions in American Indian
19 communities—interventions to improve Native American health. And then a third example is the suicide
20 pub research that the NIMH issued in the last year and I think will continue to feed funding...targeted
21 funding opportunity announcements. And then I think we also have some reviewer training programs, and
22 our hope is that we will help and ensure that American Indian/Alaska Native reviewers get experience
23 with reviewing and then also that...have other strategies that ensure that the review process considers this.

24 DR. WILSON: Excellent. I think that we've answered a majority of the questions that have been
25 presented to us, and in the recognition of time we are now at the 4:00 hour where we are going to hold
26 Part Two of our session, which is going to be moderated by Dr. Malia Villegas, who is a Council Member

1 of the native village of Afognak, and she's also the Co-Chair for the NIH's Tribal Consultation Advisory
2 Council, and she will be taking all of the perspectives and recommendations from the participating tribal
3 members on ways of integrating the tradition and culture into the design and the conduct of research
4 involving tribal populations. Malia, are you able to hear us? Are you on? [no response] We thank you all
5 for bearing with us through these technical difficulties and trying to learn and building a lot of the
6 wonderful conversations and questions that have been presented. There you are, Dr. Villegas.

7 **PART TWO**

8 **PERSPECTIVES AND RECOMMENDATIONS FROM PARTICIPATING TRIBAL MEMBERS** 9 **ON: WAYS OF INTEGRATING TRADITION AND CULTURE IN THE DESIGN AND** 10 **CONDUCT OF RESEARCH INVOLVING TRIBAL POPULATIONS, AND PARTNERING** 11 **WITH TRIBES IN THE DESIGN AND CONDUCT OF RESEARCH**

12 DR. VILLEGAS: [speaking native language] Can you hear me okay, Dr. Wilson?

13 DR. WILSON: Yes, we can.

14 DR. VILLEGAS: Okay. Wonderful. [speaking native language]...everyone. Good afternoon. My
15 name is Malia Villegas. As Dr. Wilson mentioned, I'm an enrolled member and a part of the Tribal
16 Council of the Native Village of Afognak out of Alaska and a Co-Chair of the NIH Tribal Consultation
17 Advisory Committee. So, I'm very happy to be with you today, just helping to steward and moderate this
18 very important discussion. I have just some very brief remarks to hopefully help frame some of what we
19 hear from you. There are two focus areas that the NIH is asking for feedback on, but certainly other
20 insights that you have to bring to bear will very much be appreciated. The participants list that I'm
21 looking at is just very exciting and I appreciate all of you being on. So in terms of that first theme area—
22 ways of integrating tradition and culture in the design and conduct of research involving tribal
23 populations—I just wanted to offer that this is not a one-off conversation by any means and just to
24 acknowledge that there are a number of organizations that are very involved with this and can be
25 resources in stewarding this ongoing conversation going forward around the integration...appropriate
26 integration and use of culture and tradition in the design of research. NCAI... the TCAC, which will be

1 meeting on March 9 and 10. The Urban Institute...Urban Indian Health Institute in Seattle does great
2 work there on perspectives on genomics research...there was a question earlier. CRCAIH...Collaborative
3 Research Center for American Indian Health...I know several of you are on and have shared resources.
4 Black Hills Center... Cherokee Nation...several of you are on and already active in this space. I do
5 want to point you to a document that NCAI prepared in commenting on the Common Rule that has
6 outlined several of the areas where we had seen, certainly, the integration of tradition and culture come up
7 when it comes to research policy, and that is available online, but it talks about some of the things related
8 to research and consent in the realm of biospecimens, which I know is a big conversation. Also, research
9 with people who are no longer alive and what happens with their biospecimens...are they still protected in
10 that space? The role of tribal regulatory bodies that we've heard a bit about, as well as the principles of
11 research ethics that Dr. Hull noted...beneficent justice, respect for persons. But there are some concerns
12 about how those principles of research ethics are being traded off in policy and thinking about how tribal
13 values might inform the development of those ethics, so we certainly would love to hear about that...the
14 balance on both looking at the risks involved but also the benefits that have to be delivered to American
15 Indian/Alaska Native people and Tribal nations, as well as the discussion about responsibilities for
16 individual researchers and research institutions in stewarding and being accountable for the outcomes of
17 this work, and then ultimately commitment to tribal consultation. These are some of the elements that
18 really framed that document and some of the ongoing conversations that many of these organizations are
19 stewarding. So, I just offer those as kind of a kicking off here. And then the second item here around
20 partnering with tribes and the design and conduct of research...just some quick comments about the fact
21 that there are different levers that can be pressed or examined to really improve the conduct of research in
22 an appropriate and culturally based way when we look at partnership. We can do that in the realm of
23 research policy. You've heard a bit about the Common Rule in genetics research, policies...single IRB
24 policy, for instance, but there are other levers in the realm of research process. There are levers when it
25 comes to workforce as well as training and engagement with program officers at the NIH that can be
26 involved with this partnership in a cultural-fit conversation...appropriateness, and then the role of tribal

1 governments to name just a few. So, hoping those can be some of the hooks, but we really want to open it
2 up and hear from you as key members and stakeholders and leaders in this space about some of your
3 perspectives and recommendations for participating in this in these two arenas. I'm looking at the
4 questions here. I don't see any new questions that have come in. [short pause] Are there any hands up that
5 you can see, Dr. Dave?

6 FEMALE [Unidentified]: Yeah, we don't see anything here.

7 DR. VILLEGAS: And the comment is: "Due to small numbers and often rural settings,
8 identifiability is often possible for tribal groups." Again, "Due to small numbers and often rural settings,
9 identifiability is often possible for tribal groups, so the common rule is concerning for biospecimens." I
10 think this is a question about some of the protections, certainly, when we're dealing with a small
11 population research as well as communities that, you know, broad description could be clearly identified.
12 I'm not sure if Dr. Wolinetz...maybe...

13 DR. WOLINETZ: This is Carrie Wolinetz. I hear you. I would suggest that that's a good
14 comment or question to refer to our colleagues at the Office of Human Research Protections, who are the
15 keeper of the Common Rule and creator of further guidance for specific situations.

16 DR. VILLEGAS: Cherokee Nation, raises a question and says: "Can you talk about community
17 engagement in study design?" I'm guessing, you might be referring to what this could look like, what the
18 expectations might be from announcements that will be coming out...what the framework of community
19 engagement and study design might be with regard to current populations of American Indian/Alaska
20 Natives.

21 DR. WILSON: Dr. Villegas, we will field that one over here, and we've heard clearly from the
22 communities about the importance of this, and most of the American Indian/Alaska Native research
23 supported by the NIH is conducted in this manner. Recent tribal-specific FOAs, or Funding Opportunity
24 Announcements, have indicated that this is extremely necessary for the research, and Dr. Etz mentioned
25 some of those FOAs previously, which are the...here now, which is the Intervention Research to Improve

1 Native American Health, the Native American Research Centers for Health, the NARCH program; and
2 also the suicide hubs.

3 DR. CALDWELL: So, we just want to remind folks that the chat part, I guess, is not really a
4 functional part, so if you want to ask questions, you need to go to the “question” box and ask the question
5 within that area so that we can see it. Thank you.

6 DR. VILLEGAS: Okay. ...it looks like he’s concerned about the lack of availability of clinical
7 trials in Indian country. Is there someone who could speak to the availability of clinical trials currently?

8 DR. ETZ: So, it would be very helpful if people could frame things as questions when sending
9 them in. I think that, again, much of NIH-funded research is investigator-initiated. So, if we get
10 applications for clinical trials in Indian country, they’re considered along with other applications they get
11 for clinical trials. In terms of NIH-conducted clinical trials, I don’t think I’m the best person to answer
12 that particular question.

13 DR. CASTILLE: So, NIMHD does fund some small behavioral trials, but they’re not drug
14 clinical trials, and so I think there needs to be a distinction made between behavioral trials and drug trials.

15 DR. CALDWELL: I think each NIH IC could speak to the fact that there are certain clinical trials
16 supported within their Institute, but the point really is that it is investigator-initiated. And in regards to
17 any clinical trials conducted by the NIH, those are actually the intramural side of the NIH, and again, that
18 would really be dependent on each IC and what they are conducting. So, it would vary across the board
19 and I’m not quite sure we have each IC intramural represented here, but again as Kathy had mentioned, it
20 really is investigator-initiated, so they...I guess they need to come in to have them conducted, if you will.
21 So, Dave, you want to go to the next question?

22 DR. WILSON: Thank you. That was Dr. Sheila Caldwell. Shall we go ahead and field the next
23 one? There’s a really nice question that talks about: “Does the NIH have a process for evaluating
24 proposals, including tribal-specific approaches that are submitted to grant programs, not exclusive to
25 Native populations? The usual scientific reviewers might not be familiar with tribal aspects.” So, this is
26 one of our ongoing initiatives here at the NIH to involve the Center for Scientific Review, and Dr. Karyl

1 Swartz...we've been working together to try to create a strategic plan to address this very specific
2 question, so it is under consideration here at the Agency, so thank you for that question.

3 DR. ETZ: All of these questions are absolutely fabulous, but we do want to remind people that
4 one of the goals of this session is for us to really hear from tribes and to ask what you would like the NIH
5 to know and for us to be considering as we are trying to better engage and develop our research program.
6 I just do want to remind people that we would love to hear comments and perspectives on how we can
7 best engage in this area.

8 DR. VILLEGAS: And I think, on that note, I see a comment here. She says: "There must be a
9 recognition of the importance of cultural rigor and holding it to the same importance as scientific rigor in
10 the review process. In particular, the need to fund both equally in proposals. Often reviewers don't
11 understand the importance of this. How can the NIH work to ensure that reviewers receive the needed
12 training to ensure they understand the importance of cultural rigor?"

13 DR. SWARTZ: This is Karyl Swartz at the Center for Scientific Review. One of the ways that
14 we're trying to address that is to increase the representation of tribal reviewers in our pool of reviewers.
15 I've been working very specifically on that and let me say...let me ask right now if there are any people
16 who would be interested in participating in scientific review of these kinds of applications? We are
17 searching for you and please write to me or ask other people to write to me. This is a slow process but
18 we're dedicated to it, and as Dr. Wilson said, we're working on various strategies in trying to solve this
19 problem as directly as we can.

20 DR. VILLEGAS: There are a couple of comments here that look like they're related to how to
21 diversify some of that pool. I'll read through a couple of them. "Are there mechanisms in place to have
22 research findings reviewed by tribal organizations prior to publication?" So, this is bringing in those tribal
23 orgs. "In the past, sometimes results are presented in a culturally inappropriate manner." In addition to
24 looking at reviewers of proposals, it looks like this is about publications and results. I'm not sure if
25 there's someone who can speak to that, just in terms of the role of tribal organizations, many of whom I
26 know we have on the phone today.

1 DR. ETZ: So, I think that...

2 DR. VILLEGAS: There's another one here...

3 DR. ETZ: So, the NIH would not specifically be in charge of reviewing tribal publications, but
4 we would expect that funded investigators would have some sort of mechanism in place with any tribe
5 that they're working with and that tribes would work with the investigators to ensure that any publication
6 or any other work disseminated from a project would go through whatever process they have in place for
7 that. But that's not...that's typically something that's done through a memorandum of understanding or a
8 memorandum of agreement between researchers and tribes.

9 DR. HEURTIN-ROBERTS: I'd like to comment on that. This goes back to the earlier question
10 about community engagement. What we're talking about are basic principles of community-based
11 participatory research, so that being involved in the design and study and publication from start to finish
12 is certainly a principle of that...that kind of research, and it is done in study...by individual study but
13 there's no particular policy or effort that I know of to make this happen. So, I think this can be written
14 into funding opportunities...the CBR be included in those kinds of principles...of...you know, could be
15 part of that. Oh, I'm sorry. My name is Suzanne Heurtin-Roberts. I'm with the National Cancer Institute.

16 DR. VILLEGAS: Thank you. I think I'm seeing a similar, perhaps, suggestion. "For tribal health
17 organizations NOT associated with a university, please address the requirement that investigators,
18 particularly PIs, hold a faculty position." And she asks about: "What would be the equivalent of a faculty
19 position?" It seems to me that that kind of clarification would be helpful. I know that there was a statistic
20 cited at the outset about the large percentage of research dollars that do go through universities or other
21 research organizations, and I think this sounds like a suggestion about...to clarify here on that front.
22 Similarly, I'm seeing another suggestion about the...he says: "It is striking to me how few university-
23 based Native health researchers are listed on the NIH TCAC roster." The Tribal Consultation Advisory
24 Council. "This seems like a missed opportunity. In what ways might health researchers who are
25 themselves enrolled tribal members bring their important perspectives to bear on the NIH tribal
26 consultation advisory process?" So, I can speak to the fact that the TCAC was designed to be inclusive of

1 tribal leadership appointed by their tribal council to be a representative body geographically. There are
2 rules for, certainly, university-based Native health researchers as technical advisors. We would like
3 [indiscernible] our technical advisors for their insight, but I certainly can bring this question to the TCAC
4 in the next 2 weeks when we meet. I think this is just another suggestion in terms of how to leverage the
5 expertise we already have out there in some ways. Other comments on the tribal organizations or health
6 researchers' participation?

7 DR. WILSON: Yes. This is Dr. Wilson. I would like to say that there is no requirement. The
8 individual applying for the grant just has to be qualified to receive the grant and also has to have the
9 infrastructure to support and complete the activities that are listed within the proposal.

10 DR. VILLEGAS: And here's a pretty straightforward question, but may be more difficult. :
11 "Does the NIH have American Indians who work specifically with American Indian tribes who conduct
12 research?" I can [indiscernible] several [laughs] but I think the answer for that is yes. Any other comment
13 to that? So, a question about mentorship and asking whether there are "plans to fund programs for new
14 researchers that are located on reservations." I know we did this question...we hear this question a bit at
15 TCAC just about the centralization of funding out of the NIH versus some of the other programs that are
16 really great [inaudible]...other efforts [indiscernible] that are outside of the region and a question about
17 funding programs and possible solutions to help grow the capacity of workforce and leadership who are
18 familiar with communities and tribal cultures here.

19 DR. ETZ: Malia, could you repeat whose question you just read?

20 DR. VILLEGAS: Sure.. And I don't want to put Sheila...Dr. Sheila on the spot, but I know you
21 have a huge footprint in this arena, and I'm not sure if you want to speak to some of the leadership and
22 work you've been doing.

23 DR. CALDWELL: Thank you, Dr. Villegas. Yes. So, this is Sheila Caldwell. We do have a
24 couple of programs that are NIH-wide, actually, that aren't necessarily specifically for mentoring, but that
25 is a component of the program. So for example, the NARCH program—the Native American Research
26 Centers for Health—which about 10 to 12 different NIH ICs participate in...where part of the

1 components are both faculty development and support as well as student enhancement programs that can
2 be supported. And we have, over the years actually, supported quite a few projects that are both for
3 mentoring of junior faculty and moving forward and up, out of the tribal communities, because NARCH
4 is unique in that the NARCH program and grants must be issued to tribal...federally recognized
5 tribes...tribal organizations. That is where the application actually comes from, rather than from a
6 research-intensive university. They have been able to provide that mentorship right to the tribal
7 members...tribal students and junior faculty who are involved.

8 DR. VILLEGAS: Great. some [indiscernible] ways of integrating tradition and culture might
9 involve utilizing tribal elders, obtaining oral history through stories, maybe make a new story that
10 explains research with visuals and just some ideas, she says. So, this kind of speaks to, perhaps, kind of
11 an inter-generational approach. I know there's research on aging specifically but this sounds like she's
12 encouraging bringing to bear culture bearers into the research base where appropriate, as well as trying to
13 develop some new narratives to help explain, perhaps, the value of research in some different ways here.
14 Thank you,. And a comment from...I haven't heard from in a long time but I'm glad and I know she's
15 doing good work... "As a member of the Athabascan Nation, even as a Native researcher I have found
16 tribes reluctant to engage in research because of fears that they have no say in how the information is
17 used. Many of us are trying to design research with tribal input, but then we are limited to competing for a
18 few Native-oriented grants or taking our chances in more general NIH grants...tough spot to be in." But
19 then she raises at least two issues. One is how to address fears about...I'm guessing here this is about how
20 information research data might be shared publicly...published, and then the concern that tribes may have
21 little role in saying how that information is shared and what goes out, and that certainly is a very real fear,
22 but also a question and a concern here about just competing in either a limited number of Native-oriented
23 grants, as she says, or trying to be competitive in the broader arena. That sounds like, perhaps, we need to
24 bridge some of this. So, it's not just an either/or approach. Can anyone there speak to, perhaps, some of
25 the programs? I'm thinking of the K award, for instance, or some approaches that investigators who do

1 want to compete in some of the other RFPs that are out there for FOAs might receive support in doing
2 that at the outset?

3 DR. ARROYO: This is Judy Arroyo from the National Institute on Alcohol Abuse and
4 Alcoholism. We have...I appreciate Malia's comments on that because we have found that increasingly
5 we do have people who are from Native and Alaskan backgrounds who are being competitive in the K
6 series. I think identifying program officials who are willing to work closely with them to help walk them
7 through the process and learn how to speak government-ese so that they can do that better is one issue.
8 Another mechanism that I have found that's been very effective recently in bridging that gap is something
9 that NIDA and NIAAA have been using very effectively...is a mechanism called an R34—basically
10 developing an intervention that could be treatment or prevention intervention—and I know that we've had
11 two that have been very recently funded in treatment, and they're Native American investigators who
12 successfully competed for that. We've got two more in the hopper right now. I think...getting people to
13 know that they're there and then getting people to work with the program officers very closely so that
14 they can get that information. Finally, there's one other thing that I sort of wanted to jump in on: a sense
15 of having tribal ability to control what's being done with the research results and how they're published
16 and whether or not they're being published in culturally appropriate ways. That's one of the areas where
17 the more tribes are able to step up and get their own IRBs and get their own ability to negotiate strongly
18 with the university-based researchers, that's the way to get their control because part of the IRB clearance
19 then...those things don't get published until the tribes clear it.

20 DR. VILLEGAS: Thank you, Dr. Arroyo. We appreciate it. It's great to see you. I've got two
21 here that I'll read that I think are related. "I am a member of the Fort Peck Tribes IRB and NARCH
22 recipient. I believe one of the biggest challenges around integrating culture is the time it will take to build
23 those relationships in Indian Country. Helicopter research still appears to be the norm with few
24 researchers who really want to engage and integrate in a deep or meaningful way with tribal life." So, one
25 of the challenges was raised in here about kind of the in and out helicopter quick set of approaches to
26 research relationships, "Does the NIH conduct outreach to AI [American Indian] communities to inform

1 those communities about research in general and how research may help those communities?” So,
2 perhaps a suggestion here and a request for some information about what does that education look like?
3 What does that engagement look like from an NIH level but also figuring out ways to improve support, so
4 have the researchers...to invest more deeply in the relationships that are really required to do this work
5 well.

6 DR. CALDWELL: So just speaking to the outreach component, the NIH has done some outreach
7 out to the communities, to work with the communities in communicating what exactly the NIH does—
8 what’s within our purview—and really trying to emphasize and distinguish that our role at the NIH is,
9 again, the life sciences—the basic sciences. It’s really the health research rather than health services and
10 hoping that the communities will be able to understand that better to participate more in that research
11 component and have more control, as Judy had said. I think it’s really important that these communities
12 be able to know what control that they have and what those steps are to maintain that control over the data
13 or the publication and be part of that research from the beginning and the development of that research.
14 We have done, again, outreach. I will say that it has probably dwindled recently. Our budget,
15 unfortunately, especially for travel, is not looking very good at the moment. So, it unfortunately has
16 diminished, but what many of the ICs have done or the NIH itself has been to develop webinars or
17 recorded videos to better explain what we do at the NIH in that participation and research and what that
18 looks like. But I think that’s a great comment in thinking about what the new Tribal Office will be able to
19 participate in and start to move forward with. Again, travel out to the sites may be limited...but maybe the
20 potential to develop some webinar series.

21 DR. VILLEGAS: And I know when I think about this question as well, I think about the map of
22 NARCHs that are out there and thinking about them as a really great set of communities of
23 researchers...tribally based programs that can be great ambassadors in this work with our Tribal Nations,
24 so thank you for that. Sorry...Dr. Dave?

25 DR. WILSON: Yeah. I just wanted to add to that, that there are funding announcements from the
26 National Institute on Minority Health and Health Disparities that actually address the community-based

1 participatory research and foster relationship-building within communities. We understand the importance
2 of that, and that may be something that we can push more investments towards or suggest in the future.
3 There's also an R34 mechanism that actually does a similar thing from other Institutes. Yes. Thank you.

4 DR. VILLEGAS: Alright. I'm just beginning to take back that perhaps, you know, a two-page
5 summary of some of these pieces would be something that the TCAC and THRO might be able to work
6 on collectively. So, I'm just making a list here. This is great. We have another comment here who says:
7 "Multiple NIH summary statements have included statements that the PI, although well published, and
8 despite substantial descriptions of research support and infrastructure, does not hold a faculty position and
9 should not be funded. NARCH is an exception to that requirement, but the funding is limited." So, I
10 think...revisiting the comment earlier about when tribal organizations are competing that the need to
11 clarify some of this and look at capacity in some broader ways is a suggestion here. It's very helpful.
12 Symma Finn from NIEHS...the NIEHS Director notes that the Director there "continues to make visits to
13 tribal communities and to convene tribal forums reflecting the Institute's commitment to understanding
14 tribal environmental health disparities." So that's great, Symma, in terms of commenting on the outreach
15 component...that the NIEHS is focused on environmental health and looking at the diversity of
16 environmental regions...that it's critical to go out and meet and engage in a place as part of the mission.
17 It's great to hear. Thank you for that, Symma. So, thus far I've been hearing...I've been making notes of
18 a couple of things in terms of perspectives on these two items and some others...that it would be helpful
19 to really look at the roles of tribal organizations, tribal health organizations...we have a few about urban
20 and clinical partners from Indian Country on the phone and thinking about how to leverage it. I think
21 there's an NIHB representative also on, so that would be great to just clarify and look at how to encourage
22 the participation of these organizations in the research domain. We heard comments about mentorship and
23 support for investigators, either to compete in more of the Native-focused opportunities or...as well as the
24 broader opportunities and some guidance about what that looks like, especially in light of some of the
25 comments about investigator-driven, kind of, clinical trials and that investigators drive some of the
26 portfolio. So, the need for those kinds of support...also, several comments about outreach and building

1 those relationships with Indian Country with tribal communities to help influence how culture is used in
2 an appropriate and meaningful way, as well as the need for culturally based training and ways of engaging
3 with touch-point issues that might come up over time, whether it be in research proposals or in the
4 implementation and use of research that way. Dave, are there others...other themes...goals that we should
5 be...

6 DR. WILSON: Absolutely. Thank you for that really nice summary. One of the things that we're
7 really interested in, also, is mentorship, and how do we increase the number of American Indian/Alaska
8 Natives to engage in the biomedical research fields and how do we support them not only to get their
9 degrees in that, but beyond to make them viable investigators at various institutes across the country. So,
10 that is definitely a priority of ours as well.

11 DR. VILLEGAS: Another comment about partnering with tribes. We've heard about the
12 rules...some of these organizations. Other suggestions or solutions...we talked about ways of integrating
13 tradition and culture in the design – a comment here and he says: Efforts to enhance tribal infrastructure
14 to both conduct or support health-related research will depend as much on specific funding as much as on
15 trained personnel.” Efforts to enhance tribal infrastructure to conduct or support health-related research
16 will depend as much on specific funding as on trained personnel. So, it looks like he's pointing out that
17 there needs to be a dual focus on investments in terms of tribal infrastructure as well as the training that
18 goes along with it. I think that's right.

19 DR. WILSON: I think we'll hand this one also to Dr. Caldwell to add to this.

20 DR. CALDWELL: So, I think a very good point, one that we recognized a few years, and hence
21 the reason we decided to add the capacity-building component as part of the NARCH, which was very
22 well-received by the different NIH ICs in supporting building capacity within the communities, and we
23 have certainly seen an increase in those projects coming in since we incorporated that into the funding
24 opportunity announcement. But I agree that it's something that we truly have to think about in regards to
25 the tribal communities—NARCH is only one. I think that many ICs at the NIH are interested and do
26 support certain forms of capacity-building within the communities, but it is definitely becoming an

1 increasing area of importance in understanding the way to really sustain the research within those
2 communities—it's through that infrastructure and capacity-building first. So, we really do appreciate that
3 and incorporate that into our thoughts in moving forward.

4 DR. WILSON: So, other initiatives that the NIH funds are the BUILD programs, which are the
5 Building...we'll look up the acronym, but they're linked to training initiatives and programs and they're
6 investigator-initiated efforts and we're...let me give you a name for the acronym for BUILD: Building
7 Infrastructure Leading to Diversity Initiative.

8 DR. VILLEGAS: And I think it's important to note that..., he says: "Unfortunately, the NARCH
9 program is hamstrung by a myriad of funding obstacles." And he also says he believes it's "vitally
10 important to target tribal infrastructure capacity-building efforts outside of the NARCH initiative." So, it
11 sounds like BUILD may provide a supplement and alternative as well to help grow some of the work that
12 NARCH has initiated but may not be able to carry much further, so...

13 DR. ARROYO: This is Judy Arroyo again. I'd like to remind you that a BUILD also has a
14 mentoring component. We're told not to call it NRMN, but it is a Web-based linking of people who say
15 that they desire mentorship with more senior people, and I can't tell you how important it is for somebody
16 who knows their way around the block to provide information to young Native American scholars about
17 how to go to grad school, what you do, things along those lines. So, there are ways of doing it and they
18 don't need to [inaudible due to sound interference].

19 DR. CASTILLE: Within the NRMN...this is Dorothy Castille from NIMHD, and with the
20 NRMN there's a face-to-face program called GUMSHOE. You might want to look that one up as well.

21 DR. WILSON: Thank you for the question. The NIH understands the importance of building
22 infrastructure outside of the NARCH, and we are currently working towards building that capacity.

23 DR. VILLEGAS: I know one of the things that we are always talking about around the TCAC is
24 just the diversity of perspectives, and that's one of the things that brings us here today...is how to take
25 into account the unique cultural and place-spaced insights, and I know several folks on the phone are
26 involved in trying to capture the range of perspectives on a number of topics like investments in genetics,

1 training, need of researchers and different approaches. And so, that's always a question, too, that I have in
2 this space and how to think about capturing that range but also being able to move forward with some
3 policy recommendations and approaches that are appropriate and that can guide, and that's what I've
4 heard in a few of the questions and comments. How do we continue to move this work forward in a good
5 way, honoring the diversity that's out there? So just...I'll throw that in there. I'm rethinking, too, about
6 what was raised in the first part of the discussion that I might just reiterate because I think it's appropriate
7 here. She said: "The NIH has been encouraging widespread sharing of data. Without appropriate tribal
8 governance of any future data sharing, tribal leadership and community members will be hesitant to
9 participate, particularly since what the NIH is proposing is to integrate traditional...culture and traditional
10 knowledge into funding announcements and research projects." This is definitely one of the tensions that
11 exist in this space, so I'm thinking about the role of tribal governance in this. I know several folks on the
12 phone are involved in developing research codes and policies at a tribal level to help inform the use and
13 practice and development of research, which I think is really important. And how do we honor that some
14 of this knowledge is just not appropriate for the research base—it is, as she said, "sacred and thus
15 sensitive"—while still trying to generate benefit for our people and our places from research? How do we
16 hold those two things in balance is certainly a big question in this space. We have about...

17 DR. WILSON: I don't see any more comments coming in.

18 DR. VILLEGAS: ...just about 6 more minutes before we move to wrap-up, so I'm just going to
19 say if there are any other comments or questions, now is the time. In the meantime, do we want to begin
20 to highlight some of the next steps or wrap-up, Dr. Dave?

21
22 *[QUESTION SENT VIA EMAIL]:*

23 *Hello Dr. Wilson:*

- 24 1. *There is very little participation by AI/AN in clinical trials. Some of us have tried to*
25 *address this issue through student training, reports back to tribes, conferences, etc.*

26 *Example: I use the women's study that reports primarily about white women's health due*

1 to lack of AI/AN women. The Diabetes Prevention study did include AI/AN so that results
2 could be generalized to us. Yea!

3 2. See my comment below about question from UNM earlier.

4 3. Publications: Navajo IRB requires review of publications and public presentations
5 (slides) in advance. Madam Chair (BBP) wants to know what is being said about Navajo
6 people and ensures that the findings are not just about negatives but always encourages
7 researchers to see the positive side of the tribal community being described.

8 Navajo Nation IRB has had a moratorium on genetic studies and would not approve any genetics
9 studies with their population.

10 If Navajo tribal members live off the reservation and on their own wish to join a study, it would
11 be up to them to participate without Tribal IRB approval. However, if they join as part of a group
12 or referred from the IHS, they might require both tribal and IHS approval.

13 My understanding is that anytime an IHS staff or facility is used, one needs IHS research
14 approval; or if a patient is referred to an off-reservation facility and gets recruited for research
15 by a university.

16
17 For clarification, I recommend consultation with the Navajo IRB Chair, Beverly Becenti Pigman.

18
19 Re: data ownership

20 Navajo spells out that they own the data and that upon completion of data analysis, data be
21 returned to the NN. Other tribes are following this lead.

22 The Canadian Institute does a nice job of this as well.

23
24 We have an organization called the Native Research Network, Inc., that has AIANNH and First
25 Nations members (students, researchers, elders, community members) and institutional
26 faculty/researchers.

We have been partnering with the IHS to conduct a national health research conference since 1998 and as our own nonprofit organization, we have partnered with Federal agencies, including NIH, CDC, EPA to put on conferences. Our last one was in June 2016 in Cherokee, NC. See <http://www.nativeresearchnetwork.org>

We showcase native researchers who are conducting research and some who are funded by these Federal agencies; we provide travel assistance to students, post docs, and junior faculty; we usually hold a half-day workshop on Tribal IRB issues as a pre-conference event; and we have held mentoring workshops.

WRAP UP AND NEXT STEPS

DR. WILSON: Absolutely. I've been feverishly writing, as you have, the tremendous amount of ideas that we have here are excellent. Some of the things that have really come to the top throughout are mentoring, capacity-building, culturally competent reviewers in study sections, community engagement and building relationships within communities. Those are write-ins...resources. Are there any others that you can think of, Malia?

DR. VILLEGAS: I think those are some of the big ones. I, again, think the role of tribal organizations and those that may not on their face appear as traditional quote-unquote “outreach organizations.” I think we’ve gotten a number of questions about those entities and the kind of support and I think you mentioned infrastructure, which I think is a really a piece that kind of ties into that about other organizations that may be doing some of this work. I do also...I know that urban...the question about urban populations came up in the Part One, but I do think that’s an important piece...to think about our different populations and how we support the integration of tradition and culture across different types of communities. So yeah, I think those are some of the big themes, certainly, that we’ve heard.

DR. WILSON: And some other topics that we may want to present to the TCAC group is concerning the biospecimens and the ownership and responsibility for those. And I also want to...and also data ownership, which is also a very important topic, and that may require its own conversation or its own space, and that we will look towards TCAC to provide those recommendations as well. I also wanted

1 to remind everybody who's still on the call that if you have any questions that you would like...to
2 answer...for us to answer, please feel free to send them to our email address, which is
3 NIHTribalCommittee@OD.NIH.GOV, and we will respond to those in short order. And we are also open
4 for any comments that any of our participants may have at this time as well.

5 DR. VILLEGAS: It looks like we have a couple that just came in from a caller. She says she's
6 thankful "for the insightful discussion today." She "would like to see the NIH invest in the development
7 of an Indigenous Research Framework (similar to the framework NSF funded for the American Indian
8 Higher Education Consortium). The IRF is a robust methodological framework rooted in indigenous
9 values, knowledge, and histories." And I know there was some discussion of this at our Tuskegee
10 symposium almost 2 years ago now, modeling after what Canada has done in terms of their First Nation's
11 model. So, I think this is a great idea and certainly one we'll take to TCAC in the next couple of weeks
12 here. She also says she's "interested in the NIH application review." I know there was someone here who
13 was looking to increase that pipeline, so that's great. Thank you, Iris, for that. And another caller says:
14 "Thank you for holding this conversation and discussion." I think that's great. I'll just reiterate that
15 TCAC is having our next in-person meeting on March 9 and 10—they're in D.C. Those meetings are
16 streamed live and it's certainly a place that we will be looking at some of these issues and trying to figure
17 out how we can add value to these conversations. If we can be a resource...myself and Co-Chairperson
18 Aaron Payment from the Sault Ste. Marie Tribe of Chippewa Indians are here as resources as well.

19 DR. WILSON: Fantastic. Dr. Villegas, not only does...not only will the transcripts from this
20 meeting be posted on the website, but also Dr. Hull has additional information.

21 DR. HULL: A lot of people have shared very helpful links and resources and really robust
22 answers to some of the questions that have come up throughout this conversation, and we're talking about
23 how to capture that and put that into a document that would be posted on the Tribal Health Research
24 Office website so that both folks on this call and others who maybe weren't present for this call could
25 have access to that information. So, thank you so much, everyone who has been providing us with those
26 resources in real time in response to this conversation.

1 DR. WILSON: Do we have any more comments coming in? I don't see any additional comments.

2 DR. VILLEGAS: No, just a lot of "thank-you's" to everybody around the table and on the phone.

3 DR. WILSON: Well, we definitely appreciate everybody's contribution and engagement in this
4 very robust discussion. Maybe through the Web camera you've seen all of us here on this side scrambling
5 to try to get answers for the questions, because they are absolutely terrific questions, and we look forward
6 to more engagements with not only the research community but also the tribal leaders and representatives
7 from across the country. And all of this information not only goes to developing policies and the research
8 agendas for the National Institutes of Health, but it also helps us develop the priorities and the strategic
9 plan moving forward for the Tribal Health Research Office. We are greatly appreciative for all the
10 information that everybody has contributed during this call. So I think, Dr. Malia, with that we can close
11 this session.

12 DR. VILLEGAS: Right. Thank you, everybody.

13 DR. WILSON: Thank you all for joining, and we look forward to your participation in any future
14 events. Thank you. Have a great weekend.

15 [MEETING ADJOURNED AT 4:51 PM]