

TRIBAL CONSULTATION REPORT AND RESPONSE

**Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone
(IMPROVE)**

Centers of Excellence in Maternal Health Research

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

June 30, 2022

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Executive Summary

On June 15, 2022, the National Institutes of Health (NIH) initiated a formal request for a virtual rapid-response Tribal Consultation and Urban Confer on the NIH IMPROVE Initiative Maternal Health Research Centers of Excellence. Diana W. Bianchi, M.D., Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), presented information to Tribal leaders at the Consultation held on June 30, 2022. Overarching themes included the following: (1) ensuring that the goals and objectives of the Centers of Excellence are inclusive of the needs of Tribal communities; (2) including research priorities to specifically address the needs of expectant mothers and their families in Tribal communities; (3) facilitating and encouraging research partnerships with Tribal communities on maternal health topics; (4) identifying special considerations for Tribes that should be in place as funding opportunities are developed; and (5) establishing the data hub for the Centers of Excellence to incorporate recognize, and sustain Tribal sovereignty and take appropriate steps for Tribal data collection, storage, and release.

This report summarizes the input NIH received through Tribal Consultation and provides the agency's responses. It includes an executive summary, background, purpose of the Consultation, session details, and Tribal input with NIH responses.

Background

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

- NIH invests nearly \$50.54 billion¹ annually in medical research for the American people.
- NIH invested more than \$406 million in maternal health research in 2020, including \$223.5 million specifically for maternal morbidity and mortality research. This included research on diagnosing, treating, and preventing pregnancy complications as well as epidemiological studies of pregnancy-associated mortality.
- More than 80% of NIH's funding is awarded through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and research institutions in every state.
- About 10% of the NIH's budget supports projects conducted by nearly 6,000 scientists in its own laboratories, most of which are on the NIH campus in Bethesda, Maryland.
- Located in Bethesda, Maryland, NIH is part of the U.S. Department of Health and Human Services and is composed of the Office of the Director and 27 Institutes and Centers.

NICHD, NIH's Office of Research on Women's Health, and NIH's Office of the Director are leading these efforts to expand the existing agency-wide program known as Implementing a Maternal health and PRenancy Outcomes Vision for Everyone (IMPROVE),

¹ This amount includes discretionary budget authority of \$50.54 billion, Program Evaluation financing totaling \$1.27 billion, and slightly over \$140 million for mandatory special type 1 Diabetes research. The total request also includes \$6.50 billion for an Administration initiative to create a new Advanced Research Project Agency for Health (ARPA-H). Visit the links on the Budget Request for more information on the NIH request.

which focuses on reducing preventable causes of maternal deaths and improving health for women before, during, and after delivery. NIH has the opportunity to launch Maternal Health Research Centers of Excellence because Congress recently passed a FY 2022 appropriations bill that includes \$30 million for the IMPROVE initiative and the Centers.

NIH is focused on supporting research and projects that can increase our overall understanding of maternal morbidity and mortality. NIH's maternal health research has important implications for American Indians and Alaska Natives (AI/AN). NIH is committed to collaborating with Tribal Nations to address community priorities and needs and build upon existing strengths.

Purpose for the Tribal Consultation

The causes of maternal morbidity and mortality are multifaceted and vary widely by state and across populations, including among AI/ANs. NIH launched the IMPROVE initiative in 2020 to help address this public health crisis. To date, it has supported research through supplements to existing awards on how to mitigate preventable maternal mortality (MM), decrease severe maternal morbidity (SMM), and promote health equity. With this opportunity to expand the initiative, NIH seeks to build on and bolster community strengths to address maternal health.

As NIH plans to expand the IMPROVE initiative and establish Maternal Health Research Centers of Excellence, it is critical that the agency receives Tribal input on how best to address the needs of AI/AN peoples. For instance, NIH wants to hear from Tribal leaders on how to encourage applications from AI/AN researchers interested in proposing a Native-focused center, including input on responsible data management and sharing practices and strategies. Such information will inform the development of the Maternal Health Research Centers of Excellence funding opportunities, enabling NIH to support research that may save lives and improve well-being.

NIH is working to establish Maternal Health Research Centers of Excellence in geographically diverse regions and in partnership with communities that could benefit the most. These Centers will investigate biological, behavioral, sociocultural, and structural risk factors and mechanisms of the leading causes of severe maternal morbidity and maternal mortality. Components of the Maternal Health Research Centers of Excellence may include:

- Maternal Health Research Centers focusing on one or more research areas addressing MM/SMM
- Data hub that would provide technical assistance around data collection and analysis and provide data sharing and coordination across centers and hubs to the extent possible
- Implementation science hub that could serve as an expert resource for the Centers and other researchers and provide implementation science research training opportunities for a diverse cadre of researchers

Community partnerships are central to the development and success of the Centers. NIH recognizes that there may be unique concerns for AI/AN communities regarding broad data

sharing, including circumstances in which broad data sharing may not be appropriate. Some discussion questions to consider:

- How can the goals and objectives of the Centers of Excellence be inclusive of the needs of Tribal communities?
- Are there research priorities or types/areas of research, e.g., culturally-based practices, that should be included to specifically address the needs of expectant mothers and their families in Tribal communities?
- How can we better encourage and facilitate research partnerships involving Tribal communities on maternal health topics?
- What special considerations for Tribes should be in place as we develop funding opportunities?
- How should the data hub for the Centers of Excellence be established to incorporate and sustain Tribal sovereignty for data collected, stored, and shared?

Consultation Session Details

NIH initiated a formal Tribal Consultation on June 15, 2022, with a [Dear Tribal Leader Letter and Framing Letter](#) for a virtual rapid-response Tribal Consultation and Urban Confer on the NIH IMPROVE Initiative Maternal Health Research Centers of Excellence, to be held on Thursday, June 30, 2022. Prior to the Tribal Consultation, Diana W. Bianchi, M.D., Director, NICHD, presented about the NIH Tribal Consultation on the Maternal Health Research Centers of Excellence at the NIH Tribal Advisory Committee (TAC) Monthly Conference Call on Wednesday, June 22, 2022.

During the June 30th Consultation, Dr. Bianchi presented on the IMPROVE initiative with a focus on the Maternal Health Research Centers of Excellence. NIH sought guidance on (1) how the goals and objectives of the Centers of Excellence can be inclusive of the needs of Tribal communities; (2) research priorities to be included to specifically address the needs of expectant mothers and their families in Tribal communities; (3) how to facilitate and encourage research partnerships with Tribal communities on maternal health topics; (4) what special considerations for Tribes should be in place as funding opportunities are developed; and (5) how to establish the data hub for the Centers of Excellence to recognize Tribal sovereignty and take appropriate steps for data collection, storage, and release.

NIH Response to Tribal Consultation

NIH has comprehensively examined and analyzed feedback obtained through the Tribal Consultation process, including feedback from the live Consultation as well as written comments submitted after the meeting. NIH appreciates and acknowledges the points raised and supports the recommendations from Tribal leaders and the NIH TAC.

I. Research Needs Identified by Tribal Leaders

Tribal leaders identified several issues, including the impact of social determinants of health on Tribal populations' nutrition, mental health, and substance use. For example, nutrition issues – particularly the lack of access to nutritious food and food deserts – contribute to obesity and diabetes in Tribal communities. These issues make it difficult for pregnant individuals to have proper nutrition during pregnancy to maintain maternal health. In addition, mental health conditions, including high rates of depression and suicide, are compounded by isolation either due to COVID-19 or isolation due to intimate partner violence (IPV). Related to IPV, there is a need for shelters and childcare. Tribal leaders are also concerned about the impact of gun violence in Tribal communities.

NIH Response: The Maternal Health Research Centers of Excellence funding opportunity will encourage an integrated approach encompassing structural, social, and biobehavioral research strategies to address the multiple contributing factors that lead to adverse maternal health outcomes and health disparities, including nutrition, mental health, and substance use. Diabetes and obesity will be included as co-morbid conditions in the Funding Opportunity Announcement (FOA), and applicants could propose to address these conditions in their research proposals. Chronic stress will be included in the FOA, signaling those applications examining and/or addressing these issues are welcome. IPV and suicide will be included as research examples for applicants, with a focus on improving maternal health overall. The Maternal Health Research Centers of Excellence will be uniquely poised to collaborate on studies and projects with other networks and initiatives, such as the NIH Helping to End Addiction Long-term (HEAL) Initiative.

II. Behavioral and Culturally Competent Interventions

Tribal leaders stressed the importance of behavioral and culturally competent interventions when including Tribal Nations in research. Specifically, the Maternal Health Research Centers of Excellence should encourage researchers to examine historical trauma, the availability of current culturally based maternal health programs, the application of culturally competent interventions that may include the use of Tribal languages, and non-traditional models of care outside of the hospital and clinic model. NIH should also consider effects of the large landmass covered by some Tribes, obstetrical deserts, and long-term support of pregnant individuals (especially high-risk pregnancies) inclusive of doulas and other mid-level providers. Moreover, researchers should provide post-research plans, identifying next steps for effective planning and outcomes of research, including community-level sharing of data and results. Also, AI/AN researchers should be an integral part of the research team, and preferably a member of the Tribe with whom they are conducting research.

NIH Response: Research projects undertaken by Maternal Health Research Centers of Excellence must include an emphasis on developing new and improved approaches to address the biological, behavioral, environmental, sociocultural, and/or structural

factors that affect maternal health and well-being and promote health equity. NIH will require equitable partnerships with communities as well as culturally competent interventions, which could include use of Native languages, Tribal maternal health programs, or non-traditional models of care. Moreover, there is specific language throughout several initiatives within the IMPROVE program that discuss community-engaged research which incorporates the community at all levels of the research. The Centers of Excellence funding opportunity will focus on populations that experience maternal health disparities, including underserved rural populations (e.g., living in obstetrical deserts). The Centers of Excellence can also include research training for mid-level providers and doulas.

III. Community Engagement and Building Trust with Tribal Communities

Tribal leaders stressed the importance of building trust and listening to Tribal input to shape the partnerships with Tribal communities, the representation of Tribal health communities, training and building research capacity, and providing support for community partners to understand their own data priorities. Specifically, NIH should promote holistic and Indigenous approaches to maternal health, recognizing Indigenous methods and strategies, and include many stakeholders in addition to researchers. NIH must be transparent in communicating potential impacts to funding and support. Tribal leaders also recommended for Tribal Consultations to be conducted with each Tribe to understand the specific needs of each Tribe. They also recommended seeking advisement from Tribal Institutional Review Boards (IRBs) for their preferences and requirements to establish partnerships that allow for implementation of traditional and cultural practices blended with western medicine to address maternal health. Moreover, they stressed the importance of establishing data sharing agreements and working with community-focused groups, non-profit organizations, and Tribal Urban Centers to develop and initiate research opportunities.

NIH Response: Equitable community partnerships will be a primary focus of the Maternal Health Research Centers of Excellence and the proposed Data Innovation and Coordinating Hub/Resource Center. The Maternal Health Research Centers will require a cooperative and equitable partnership between the Research Center and community partner(s) in each stage of the research process (concept, implementation, evaluation, and dissemination). A community healthcare partner will need to be included on the research team. Incorporating the community in these ways will enable the needs and culturally appropriate practices for each Tribe involved in the research projects to be taken into account.

In accordance with input from the Consultation, the FOA will also emphasize training and building research capacity within local communities, including Tribal communities. Helping the community partners understand the data collected will be a task for the proposed Data Innovation and Coordinating Hub.

IV. Data, Funding, and Infrastructure

Participants in the Consultation and written contributions also highlighted considerations for data management, funding mechanisms, and infrastructure support. For example, Tribal leaders asserted the need for HHS agency-wide data agreements, a centralized data warehouse for Tribal Nations, direct NIH funding to Tribal Nations, providing funding through Indian Health Services Self-Governance Compacts, and collaboration with other HHS agencies to build infrastructure in Tribal Nations. Another suggestion was to add a Tribal liaison to the NIH Maternal Morbidity and Mortality Task Force.

NIH Response: NIH appreciates the views of Tribal leaders and will ensure that all research for the Maternal Health Research Centers of Excellence follow policies and protections that will prevent ethical violations against Tribal communities and the use of their data. Developing an HHS-wide data agreement is beyond the purview of NIH, and a central data warehouse for Tribal Nations is beyond the scope of this initiative. NIH will use funding mechanisms available to the agency by law and policy, while prioritizing ways to encourage collaboration with Tribal Nations. One of the goals of the Maternal Health Research Centers of Excellence is to help build research capacity in participating communities, and NIH may seek future opportunities to partner with other HHS agencies to develop infrastructure in accordance with the research-focused mission of the agency. Finally, the NIH Maternal Morbidity and Mortality Task Force consists of NIH staff and no external members; thus, appointing a Tribal liaison would not be possible. However, NIH and the leaders of the IMPROVE initiative are committed to collaborating with Tribes and seeking input on future funding or other partnership opportunities through other means, such as future Consultations and Confers.

Next Steps

Incorporating many of the recommendations from Tribal Consultation, NIH released three companion FOAs for the Maternal Health Research Centers of Excellence, which aim to generate innovative approaches to address maternal morbidity and mortality and promote maternal health equity.

- RFA-HD-23-035 invites applications to participate as a Research Center as part of the Maternal Health Research Centers of Excellence initiative: <https://bit.ly/3BZHT75>
- RFA-HD-23-036 seeks applications for the Data Innovation and Coordinating Hub/Resource Center for the Maternal Health Research Centers of Excellence initiative: <https://bit.ly/3QkeRU4>
- RFA-HD-23-037 seeks applications for the Implementation Science Hub/Resource Center for the Maternal Health Research Centers of Excellence initiative: <https://bit.ly/3Ah6xyz>

Closing

NIH appreciates the time and invaluable recommendations provided by Tribal leaders who participated in this important Tribal Consultation on expanding the IMPROVE initiative and establishing Maternal Health Research Centers of Excellence. We are grateful to Tribal Nations and leaders for their insights. NIH looks forward to our continued collaboration and engagement on IMPROVE.