

Navajo Nation Human Research Review Board Meeting Agenda

Meeting Date: 2024-01-16 Meeting Time: 9:00 AM
Location: Zoom

MEMBERS:

David Begay, Ph.D. - Scientific Education
Delvin Yazzie, MPH - Epidemiology
Kalvin White, Ph.D. - Scientific Education
Nanibaa' Garrison, Ph.D. - Genetics, Bio-Ethics
Rebecca Izzo-Manymules, Ph.D. - Chairperson -
Education
Sonya Shin, MD - Medicine
Ursula Knoki-Wilson, MSN, MPH - Nursing

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OLD BUSINESS:

I. Meeting Call to Order:

II. Roll Call:

- Invocation:

- Introduction:

III. Review and Approval of January 16, 2024
Meeting Agenda:

IV. Review and Acceptance of Quarterly Reports:

NEW BUSINESS:

V. Acceptance and Approval of New
Presentations:

VI. Acceptance and Approval of Returning
Presentations:

VII. Noon Hours Discussion: New NNHRRB
Appointments - 3 NAIHS, 3- NN OPVP

VIII. Acceptance and Approval of Serious Adverse
Events (SAEs):

IX. Review and Approval of Manuscripts: 1)
Exploring the Role of Indigenous Determinants of
Health in the Resilience of Native Nations during
COVID-19. NNR-21.397 Dr. Manley Begay,
Ed.M., 2) Care-seeking actions following
Helicobacter pylori testing among a high-risk
Indigenous Population.- NNR-16.263 Dr. Robin
Harris, Ph.D., 3) Impact of Pneumococcal

Conjugate Vaccines on Otitis Media among AI/AN children in the Southwest U.S. - NNR-97.108, NNR-19.343, Dr. Laura Hammitt, MD., 4)
Bridging the Gap: Development and Validation of a Scale to Measure Internship-Related Student Outcomes for Native American Students at Tribal Colleges and Universities -NNR-19.337, Dr. Crystal Loudhawk-Hedgepeth

X. Announcement / Adjournment:

QUARTERLY REPORTS

1. NNR-04.145 PI: Johnnye Lewis
Dine Network for Environmental Health Project (DINEH)
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering April 21 - July 20, 2023 period

2. NNR-09.241 PI: Barbara Overman
Giving Voice to Health Values from within the Navajo Culture
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering August 1-October 31, 2023 period

3. NNR-11.342 PI: Joan O'Connell
Comparative Effectiveness of Healthcare Delivery Systems for American Indian and Alaska Native using Enhanced Data Infrastructure
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering: 1) May 16, 2023 - August 15, 2023, 2) August 16, 2023 - November 15, 2023 periods

4. NNR-15.199 PI: Carmen George
REACH for Healthy Navajo Communities.
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering September 17, 2023 - December 17, 2023 period

5. NNR-18.309 PI: Christine Buzinde
Cultural Mapping for the Western Area Tribal Parks includingg the Former Bennett Freeze Area
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering October 1, 2023 - December 31, 2023

6. NNR-19.331 PI: Cathron Donaldson
Understanding Navajo Parents' Beliefs about Cradling and Early Mobility Practices
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Reports covering 1) May 19, 2023 - August 19, 2023, 2) August 19, 2023 - November 19, 2023 periods

7. NNR-20.373 PI: Vincent Werito
Cultural Characteristics of Successful Aging from a Dine Perspective: The Significance of Dine Elder knowledge in Achieving Long-Life Happiness as community well-being

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering August 12, 2023 - November 12, 2023 period

8. NNR-21.398 PI: Karletta Chief

Assessing Navajo COVID-19 Risks and Increasing Indigenous Resilience

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 17, 2023 - December 17, 2023 period

9. NNR-21.409 PI: Carmen George

Expanding and Evaluating a community-based intervention to increase healthy beverage consumption by Navajo Preschool Children

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance Quarterly Report covering July 20, 2023 - October 20, 2023 period

NEW PRESENTATION(S)

1. NNR-24.493 PI: Rachelle Begay

Effect of Din'e Health and Wellbeing on H.pylori and COVID-19 Infection among Navaj Adults

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 01/09/2024

RETURNING PRESENTATION(S)

1. NNR-21.426 PI: Sonya Shin

Global learning to Advance Health Equity: A Learning network

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of the Final Report covering November 16, 2021 - November 16, 2023 study period with enclosed published manuscript, and to request to Close-out Study. Protocol Data Transfer of Data on Thumbdrive.

2. NNR-19.358T PI: Sonya Shin

Inter-generational Impact of Navajo Fruit and Vegetable Prescription (FVRx) Program

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final Report covering September 17, 2019 - September 17, 2023 Study Period

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination Plan for Study.

3. NNR-17.287 PI: Hannah Sehn

Understanding the Structural Barriers and Opportunities to Improve Cancer Treatment on Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 19, 2023 - December 19, 2023 period

Reason on Agenda: Annual Report

Description: Request Review and Acceptance of Annual Report covering December 19, 2022 - December 19, 2023 period

4. NNR-15.231 PI: Sara Selig

Engaging Patients and Stakeholders to Improve Cancer Outcomes in Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 15, 2023 - December 15, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering December 15, 2022 - December 15, 2023 period

Reason on Agenda: Amendment

Description: Request Acceptance and Approval to Remove Dr. Sara Selig as PI, and to add Ms. Olivia Muskett as Co-PI.

5. NNR-10.287 PI: Joel Gittelsohn

Multilevel Obesity Prevention Trial for American Indian Community (OPREVENT)

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering December 31, 2022 - December 31, 2023 period. TABLED at December 19, 2023 Meeting.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Annual Report covering December 31, 2023- December 31, 2024 period. TABLED at December 19, 2023 Meeting.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2023 period. TABLED at December 19, 2023 Meeting.

6. NNR-23.485 PI: Harrison Cayatineto

microRNA Based Inhibition against the Nucleocapsid Protein Synthesis in Bovine Viral Diarrhea Virus: A Surrogate Model for Hepatitis C. Virus

Reason on Agenda: Addendum

Description: Request Acceptance and Approval of Western Navajo Agency Council approved Resolution to support the Research

Reason on Agenda: New Title

Description: Request Review and Approval of New Study - TABLED at 11-21-23 Meeting

7. NNR-22.458 PI: James McKenzie

Dine Language and Culture Revitalization-Focused Schools

Reason on Agenda: Amendment

Description: Request Acceptance and Approval for University of Arizona IRB Approval Letter, Adult Consent Form, Parental Permission for Minor, Assent to Participate 8-12 years old Assent to Participate 13-17 years old. TABLED at 12-19-23 Meeting.

8. NNR-16.234 PI: Karletta Chief

To Litso, the water is Yellow: Investigating short term exposure and risk perception of Navajo communities to the Gold King Mine toxic spill

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October - December 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering January 2023 - January 2024 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering January 19, 2024 - January 19, 2025 period

9. NNR-16.263 PI: Robin Harris

Helicobacter Pylori Infection and Stomach Cancer

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 1, 2023 - November 30, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering November 19, 2022 - November 30, 2023 period

10. NNR-23.463 PI: Leonela Nelson

Family Spirits Strengths

Reason on Agenda: (Other)

Description: Request Acceptance and Approval of BSPH IRB Review Notification of Using Unstamped version of Consent Form.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval to Update Demographic Form around problematic alcohol and drug use to reflect any sort of drug or alcohol use.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval to Revise Adult Consent (Shiprock only), Parental Permission (Shiprock only), Assent (Shiprock and Chinle only).

Reason on Agenda: Amendment

Description: Request Acceptance and Approval to add two new sites (Chinle, AZ, Pokagon, MI)

Reason on Agenda: Amendment

Description: Request Acceptance and Approval Amendment of Protocol to add new site Chinle Chapter, Pokagon Band of Potawatomi Indian and Co-PI: 1)Track and Clean Protocol v6 revision, 2) Revised Adult Informed Consent, 3) Revised Parental Permission Form, 4) Co-PI Certifications, CV for Kristin Mitchell, MA, 5) Supporting Resolution from Chinle Chapter, and Letter of Support from Pokagon Band of Potawatomi Indians.

11. NNR-18.322 PI: Vincent Werito

Developing Community Partnerships Through Research to Define Community Well-Being from a Dine' Centered Perspective with Three (Dine') Navajo Communities in New Mexico

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Request for Continuation covering October 16, 2023 - October 16, 2024 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 16, 2022 - October 16, 2023 period

12. NNR-21.428 PI: Vincent Werito

Wide Engagement for Assessing Vaccine Equity in New Mexico (WEAVE NM)

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering November 16, 2023 - November 16, 2024 period

13. NNR-19.360 PI: Debra MacKenzie

Navajo Birth Cohort Study/environmental Influences on Child Health Outcomes Plus (NBCS/ECHO+)

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Revised Consent forms, and new Survey Forms

14. NNR-21.397 PI: Manley Begay, Jr.

Understanding Resilience and Mental Wellbeing: Southwest Indigenous Nations and the Impact of COVID-19

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering January 1, 2023 - December 31, 2023 period

15. NNR-22.452 PI: Suzanne Singer

Transportation Behaviors Related To Food & Energy In Rural Navajo And Hopi Communities

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 27, 2022 - December 19., 2023 period

16. NNR-23.478 PI: Fatemeh Afghah

SCC-PG: Just in Time Intervention for Members with Chronic Heart Diseases in Arizona Tribes

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of new funding entity of Strong Heart Study startng on January31, 2024.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Revised Consent Form

Reason on Agenda: Addendum

Description: Request Acceptance and Approval of Ph.D students Timothy Curry nad Stanley Njikho as student/graduate assistants.

17. NNR-14.192 PI: Hendrik deHeer

Physical activity and cancer among Native American cancer survivors: A pilot study.

Reason on Agenda: Continuation Request

Description: Request of Continuation Request covering December 20, 2023 - December 19, 2024 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering December 20, 2022 - December 19, 2023 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) December 20, 2022 - March 19, 2023, 2) March 20, 2023 - June 19, 2023, 3) June 20, 2023 - September 19, 2023 periods

18. NNR-16.238 PI: Laura Hammitt

Active Bacterial Surveillance for Staphylococcus aureus on the Navajo and White Mountain Apache Reservations.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering February 16, 2024 - February 16, 2025 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 16, 2023 - February 16, 2024 period

19. NNR-11.325 PI: Laura Hammitt

Study of a vaccine for reducing ear and lung infections in children

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 21, 2023 - February 21, 2024 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering February 21, 2024 - February 21, 2025 period

20. NNR-22.449 PI: Ashley Lee

Dine' Household Water Survey

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination Plan of Preliminary Findings

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Study Preliminary Findings

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Powerpoint Presentation of Preliminary Findings for Water Access Coordination Group input and feed back

21. NNR-21.401 PI: Jennifer Richards

Evaluation of Azhee Bidziil (Strong Fathers) Program: Improving Outcomes Among Rural Fathers and their Families.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Revision of Radio PSA v2

22. NNR-21.429 PI: Mary Cwik

Validation of the ASQ - AskSuicide Screening Questions (ASQ) Questionnaire, in the Navajo Area Indian Health Service (NAIHS) Health Care Setting

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval Continuation Request covering February 15, 2024 - February 16, 2-25 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 15, 2023 - February 15, 2024 period

23. NNR-11.332 PI: Kristen Speakman

Evaluation of an Edible School Garden Program; Evaluation of the Feast for the Future Community Visioning Program.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 21, 2023 - February 21, 2024 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering February 21, 2024 - February 21, 2025 period

24. NNR-21.431 PI: Ashley Thacker

Evaluation of Navajo Safe Water Access Projects

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering February 15, 2024 - February 15, 2025 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 15, 2023 - February 15, 2024 period

25. NNR-23.476 PI: Kristin Mitchell

Formative work with medical providers and personnel in preparation for the NATIVE-RISE clinical trial

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Conference Abstract titled: Co-designing the Implementation of a Machine Learning Model to prevent suicide in Care Pathways for Native American Adults

26. NNR-23.472 PI: Nancy Rumbaugh Whitesell

Multi-Site Study of State-Tribal Collaboration in Home Visiting (MUSE-STC)

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract titled Learning from a qualitative multi-site study of state-tribal Collaboration on January 29-31, 2024 at 2024 Maternal, Infant, and Early Childhood Home Visiting (MIECHV) all Grantee

meeting in Arlington, VA. TABLED at December 19, 2023 Meeting.

SERIOUS ADVERSE EVENT

1. NNR-02.110 PI: Vallabh Shah

Diabetes Prevention Program Outcomes Study (DPPOS)

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Diarrhea

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Bowel Obstruction

Last Page and End of Agenda