

**Navajo Nation Human Research Review Board
Meeting Agenda**

Meeting Date: 2023-09-19 Meeting Time: 9:00 AM
Location: by 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 September 19, 2023 Meeting Agenda:
- IV. Review and Approval of March 21, 2023 Meeting Minutes:

NEW BUSINESS:

- V. Review and Acceptance of Quarterly Reports:
- VI. Acceptance and Approval of New Presentations:
- VII. Acceptance and Approval of Returning Presentations:
- VIII. Noon Hour Discussion: 1) Acceptance and Approval of Abstracts for 2023 Research Conference - ACTION ITEM.; 2) 2023 Bi-Annual Navajo Research Conference Update
- IX. Serious Adverse Events (SAEs):
- X. Review and Acceptance of Manuscripts: 1) Community-Based intervention to promote awareness and implementation accuracy of food and beverage tax policies in stores on Navajo

Nation NNR-17.284;
2) Barriers and Facilitators to COVID-19 Return
to School NNR-21.419;
3) Impact of the COVID-19 pandemic on invasive
pneumococcal disease and Indigenous
communities in the Southwest NNR-19.343; 4)
Incidence of COVID-19 associated Hospitalization
and risk factors for severe disease among
Indigenous persons in the southwestern United
States and Alaska NNR-19.350

XI. Announcements / Adjournment:

QUARTERLY REPORTS

1. NNR-02.106 PI: Dana Dabelea
SEARCH for Diabetes in Youth Study
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering February 21, 2023 - May 21, 2023 period with attached published manuscript.

2. NNR-10.287 PI: Joel Gittelsohn
Multilevel Obesity Prevention Trial for American Indian Community (OPREVENT)
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly report covering 1) January 1, 2023 - March 30, 2023, 2) April 1, 2023 - June 30, 2023 periods

3. NNR-05.175 PI: Kimberly Mohs
Navajo Area Indian Health Services - Cardiovascular Risk Reduction Demonstration Project
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering January 1, 2023 - June 1, 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 March 15, 2023 - June 15, 2023 period

5. NNR-17.266 PI: Jani Ingram
Mutton Consumption Survey
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Reports covering 1)February 22, 2023 - May 22, 2023, 2)May 22, 2023 - August 21, 2023 periods

6. 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 March 15, 2023 - June15, 2023 period

7. NNR-17.288 PI: Dana Dabelea
Tribal Turning Point (TTP)
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering April 2023 - June 2023 period

8. NNR-21.430 PI: Elise Christopher
High School & Beyond Longitudinal Study of 2022 (HS&B:22)
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering May 21, 2023 - August 20, 2023 period

9. NNR-22.439 PI: Ann-Perry Witmer
Contextualization of Rural Infrastructure Systems for Improved Sustainability
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering April 1, 2023 - June 30, 2023 period

10. NNR-22.447 PI: Amanda Fretts
Development and Evaluation of a Culturally-informed Food Insecurity Screening Protocol with American Indian Adults from Northern Navajo Medical Center
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering May 26, 2023 - August 24, 2023 period

NEW PRESENTATION(S)

1. NNR-23.480 PI: NaNaya Cook
Teachers Experiences in Motivating and Helping Navajo Students Academically and Developing or Improving Self-Efficacy: A Qualitative Descriptive Study
Reason on Agenda: NEW
Description: Remarks: Request Review and Approval of New Study; Date Received - 08/29/2023

2. NNR-23.473 PI: Stephanie Klein
Characterization of Utahs live Interactive Teledermatology Outreach for Navajo Patients
Reason on Agenda: New Title
Description: Request Review and Approval of New Submission - TABLED August 15, 2023 Meeting - Need Lead PI to answer questions. Use Documents from April 18th Meeting Packet. Also, Tabled at April 18, 2023 Meeting, Use Agenda item from 4-18-23 agenda packet

RETURNING PRESENTATION(S)

1. NNR-23.478 PI: Fatemeh Afghah
SCC-PG: Just in Time Intervention for Members with Chronic Heart Diseases in Arizona Tribes
Reason on Agenda: New Title
Description: Request Acceptance and Approval of Revised new Study. Conditional Approval at July 18, 2023 meeting - to revise and resubmit the Aim I Statement on the device usage. Attached revise IRB letter, NAIHS Acknowledgement

Letter, Revised Consent Forms.

2. NNR-19.337 PI: Crystal LoudHawk-Hedgepeth

Kresge Inquiry Project

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering 1-April 1, 2023 - June 30, 2023, 2-January 1, 2023 - March 31, 2023 period, attached updated CITI certificate for Crystal Loudhawk-Hedgepeth and Julie Lucero. TABLED at 8-15-23 Meeting

Reason on Agenda: Approval for Dissemination

Description: Request Review and Acceptance of Updated Dissemination Plan for 2023. TABLED at 8-15-23 Meeting

3. NNR-20.374 PI: Laura Hammitt

Immunogenicity of H, Influenzae type b PRP-OMP vaccines in American Indian and Alaska Native Children (the HibVax Study)

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract titled: Immunogenicity of Haemophilus influenzae Type b (Hib) Vaccines in American Indian/Alaska Native (AI/AN) Infants: Combination Hexavalent Hib Vaccine Versus Monovalent Hib Vaccine at IDWeek Conference on October 11-15, 2023 in Boston, Massachusetts.

4. NNR-19.350 PI: Laura Hammitt

Surveillance for RSV and Other Respiratory Infections among Native American Children and Pregnant Women

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments: 1) update documents to reflect from old - "Center for American Indian Health to new - Center for Indigenous Health, 2) removal of blood collection language from participant-facing material. no longer collecting blood part of this study, 3) addition of recruitment material for two recently added study sites (Gallup, NM, Ft. Defiance, AZ): revised study material: Consenting Flip Chart, Recruitment post A, B, Participant Information Sheet, Participant Letter Reporting Results Adults v2, Child v2.

5. NNR-16.261 PI: Laura Hammitt

Evaluation of maternal immunization and interventions to increase uptake of vaccines among expectant American Indian women

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 18, 2023 - October 18, 2024 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 18, 2022 - October 18, 2023 period

6. NNR-23.463 PI : Leonela Nelson

Family Spirits Strengths

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments: 1) Revised Adult Informed e-Consent v3, 2) Parent Permission Form v4, Provider Referral Forms v4, Self Referral Form v3.

7. NNR-23.476 PI : Kristin Mitchell

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

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments: 1) Revised Research Plan v3, 2) Adult Oral Consent Script v3, 3) Qualitative Guide v4, 4) Opinion Survey v4, 5) Qualitative Guide for Community-based Service Providers v1, 6) Opinion Survey Infographic v1

8. NNR-05.174 PI : Allison Barlow

In-home Prevention of Substance Abuse Risk in Navajo Teen Families

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 17, 2023 - October 17, 2024 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 17, 2022 - October 17, 2023 period

9. NNR-21.424 PI : Chelsea Lutz

Characterizing SARS-CoV-2 Vaccine Effectiveness Evidence of Infection, and Immunity among American Indian and Alaska Native Persons in the United States

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 19, 2023 - October 19, 2024 period

Reason on Agenda: Annual Report

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

10. NNR-02.094 PI : Mary Hoskin

Action for Health in Diabetes Look AHEAD

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request 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, attached NIH Appendix.

Reason on Agenda: Addendum

Description: Request Acceptance and Approval of Addendum to Look AHEAD Protocol.

11. NNR-02.110 PI: Vallabh Shah

Diabetes Prevention Program Outcomes Study (DPPOS)

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 19, 2023 - August 19, 2024 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 19, 2022 - August 19, 2023 period, attached Progress Report

12. NNR-09.241 PI: Barbara Overman

Giving Voice to Health Values from within the Navajo Culture

Reason on Agenda: Continuation Request

Description: Requesting Acceptance and Approval of Continuation Request covering August 1, 2023 - July 31, 2024 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 1, 2023 - July 31, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering July 31, 2022 - August 1, 2023 period

13. NNR-11.323 PI: Johnnye Lewis

Navajo Birth Cohort Study (NBCS)

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 23, 2023 - August 22, 2024 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 23, 2022 - August 22, 2023 period

Reason on Agenda: Quarterly Review

Description: Request Review And Acceptance of Quarterly Report covering May 23, 2023 - August 22, 2023 period

14. NNR-19.360 PI: Debra MacKenzie

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

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering September 18, 2023 - September 17, 2024 period

Reason on Agenda: Consent Modification

Description: Request Acceptance and Approval of 2023-2024 Consent Form.

15. NNR-14.185 PI: Sheldwin Yazzie

Assessing Indoor Radon Exposure on the Navajo Nation.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) February 1, 2023 - April 30, 2023, 2) May 1, 2023 - July 31, 2023 periods

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering July 30, 2023 - July 30, 2024 period

16. NNR-18.330 PI: Laurie Hudson

Thinking Zinc

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April 22, 2023 - July 21, 2023 period

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments to Protocol: 1) New funding from N Higher Education Department, 2) Expansion of Geographical study area, 3) increase in the number of maximum from 100-200, 4) Increase amount of compensation, 5) Increase amount of blood collected from 1-2 tablespoons of blood, 6) De-identified urine sample to be sent to Columbia University for analysis, 7) addition of 24-hour food recall to help with nutrient intake assessment.

Reason on Agenda: Consent Modification

Description: Request Acceptance and Approval of Consent Modification to be part of a Research Study

17. NNR-16.257 PI: Kevin Lombard

Engaging Family and School in Navajo Gardening for Health

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June 30, 2023 - September 19, 2023 period

Reason on Agenda: Annual Report

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

18. NNR-19.348 PI: Teresa McCarty

Indigenous- Language Immersion and Native American Student Achievement

Reason on Agenda: Annual Report

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

Reason on Agenda: Continuation Request

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

Reason on Agenda: Consent Modification

Description: Request Acceptance and Approval of Consent Forms for 2023 - 2024 period. 1) Child (ages 7-12) Assent to Participant, 2) Adolescent (age 13-17) Assent, 3) Focal-Grade Teachers Consent, 4) Case Study Site Administrator-Liaisons Consent, 5) Parents, Grandparents & Community Member Consent, 6) General Participants Consent, 7) Oral Consent Form, 8) Consent Given In-Person or by Mail.

19. NNR-16.245 PI: Joel Gittelsohn

Engaging Tribal Policy Makers to Sustain Improvements to the Food and Physical Activity in American Indian Communities (OPREVENT2)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 01, 2023 - March 31, 2023 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering June 30, 2023 - June 30, 2024 period

Reason on Agenda: Annual Report

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

20. NNR-21.412 PI: Joel Gittelsohn

Formative Research to Improve WIC Participation in Three Diverse Native American Communities

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1, 2023 - March 31, 2023 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering June 15, 2023 - June 15, 2024 period

Reason on Agenda: Annual Report

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

21. NNR-17.281 PI: Nanibaa' Garrison

Perspectives on Genetic Research in the Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) February 21, 2023 - May 16, 2023, 2) May 17, 2023 - August 16, 2023 periods

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 17, 2022 - August 15, 2023 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 15, 2023 - August 15, 2024 period

22. NNR-18.302 PI: Mark Bauer

Navajo NARCH Partnership: Evaluation of the Student Enhancement Program

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of New and Revised evaluation instruments for Study: 1) Digital Storytelling Workshop- College Study Survey (New), 2) Digital Storytelling Workshop- College Student Consent Form (new), 3) Digital Storytelling Workshop -High School Student Survey (Modified)

23. NNR-21.426 PI: Sonya Shin

Global learning to Advance Health Equity: A Learning network

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 16, 2023 - August 16, 2023 period

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination Plan.

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: Atrial fibrillation with RVR

Last Page and End of Agenda