

Navajo Nation Human Research Review Board

Meeting Agenda

Meeting Date: 2022-11-15 Meeting Time: 9:00 AM
Location: Zoom

MEMBERS:

Beverly Becenti-Pigman - Community
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

OLD BUSINESS:

- I. Meeting Call to Order:
- II. Roll Call:
 - Invocation:
 - Introduction:
- III. Review and Approval of Agenda;
- IV. Review and Approval of June 21, 2022 Meeting Agenda:
- NEW BUSINESS:
 - V. Review and Acceptance of Quarterly Reports:
 - VI. New Presentations:
 - VII. Returning Presentations:
 - VIII. Serious Adverse Events (SAEs):
 - IX. Review and Acceptance of Manuscripts: 1) A Community-based health risk assessment following the Gold King Mine Spill: Results from the Gold King Mine Spill Dine Exposure Project (NNR-16.234). Karletta Chief, 2) Returning to School During Dikos Ntsaaigii-19 (COVID-19): Mental Health, Academic Self-efficacy, and Resilience among Dine Youth and their Families (NNR-21.419). Joshuaa Allison-Burbank, 3) Returning to School During Dikos Ntsaaigii-19 (COVID-19): Mental Health, Academic Self-efficacy, and Resilience among Dine Youth and

their Families (NNR-21.419). Denise Charron-Prochownik

X. Noon Hour Discussion: EXECUTIVE SESSION:

1) Navajo Nation Genetic Research Policy, 2) Research Code Amendments, NNHRRB Application (9-2-22), NNHRRB Procedural Guidelines (9-2-22)

XI. Announcements / Adjournment:

QUARTERLY REPORTS

1. NNR-97.018 PI: Laura Hammitt

A double Blinded, Controlled Study of the Efficacy, Immunogenicity, Safety and Tolerability, and Effectiveness of a Pneumococcal Conjugate Vaccine Containing 7 Serotypes (6B, 14, 19F, 23F, 18C, 4, and 9V) Compared to a Control Meningococcal C Vaccine in Navajo and Apache Indian Infants

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

2. NNR-02.094 PI: Mary Hoskin

Action for Health in Diabetes Look AHEAD

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2022 - September 30, 2022 period

3. NNR-04.151 PI: Laura Hammitt

A Phase 3 Study of MEDI -524 (Numax), an Enhanced Potency Humanized Respiratory Syncytial Virus (RSV) Monoclonal Antibody, for the Prevention of RSV Disease Among Navajo and White Mountain Apache Infants in the Southwestern United States

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

4. NNR-05.174 PI: Allison Barlow

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

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

5. NNR-06.195 PI: James Deaton

National Indian Education Study 2007

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 16, 2022 - October 14, 2022 period

6. NNR-07.216 PI: Laura Hammitt

Rapid-response investigation of pediatric cases of invasive Haemophilus influenzae in Navajo American Children

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

7. NNR-09.253 PI: Laura Hammitt

Impact of 13-valent pneumococcal conjugate vaccine (PVC13) on pneumococcal disease and colonization among Native American communities

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

8. NNR-11.325 PI: Laura Hammitt

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

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

9. 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: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

10. NNR-15.212 PI: Mark Solomon

2015 Safety Belt Use Estimates for the Indian Nations.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2022 - September 30, 2022 period

11. NNR-16.254 PI: Nicole Neault

Evaluation of NativeVision Year Round Program

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

12. NNR-17.293 PI: Jonathan Davis

Evaluating Geodesign as a Planning Framework for Navajo Nation Chapters

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) April 16, 202 - July 16, 2022; 2) July 16, 2022 - October 16, 2022 periods

13. NNR-17.277 PI: Denise Charron-Prochownik

Stopping Gestational Diabetes in Daughters and Mothers - Phase 2

Reason on Agenda: Quarterly Review

Description: Request review and Acceptance of Quarterly Report covering August 1, 2022 - October 31, 2022 period

14. NNR-18.330 PI: Laurie Hudson

Thinking Zinc

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 22, 2022 - October 1, 2022 period

15. NNR-19.350 PI: Laura Hammitt

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

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

16. NNR-19.354 PI: Allison Barlow

Cancer Care Project: Addressing Disparities in Cancer Education, Care and Outcomes in Native American Communities

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

17. NNR-19.355 PI: Sally Davis

Healthy Places-Healthy People

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering August 20, 2022 - November 19, 2022 period

18. NNR-19.357 PI: Laura Hammitt

A Phase 3 Randomized, Double, Placebo-controlled Study to evaluate the Safety and Efficacy of MEDI 8897, a Monoclonal Antibody with an Extended Half-Life Against respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants (MELODY)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

19. NNR-19.364 PI: Jennifer Richards

Replication of Respecting the Circle of Life (RCL) - Teen Pregnancy Prevention Program with Navajo Youth and Families

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

20. 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: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

21. NNR-20.381 PI: Laura Hammitt

A Phase 1/2/3 Placebo-Controlled, Randomized, Observer-Blind, Dose-Find Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARs-COV 2 RNA Vaccine Candidates Against COVID-19 in Healthy Adults (Short Title: Pfizer COVID-19 Vaccine Study)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

22. NNR-20.376 PI: Laura Hammitt

Convalescent Plasma to Limit Coronavirus Associated Complications: A Randomized Double-Blind, Controlled, phase 2 study Comparing the Efficacy and Safety of Human Coronavirus Immune Plasma (HCIP) vs. Control (SARS-CoV-2 non-immune) Plasma Among outpatients with Symptomatic COVID 19 (Treatment Study)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

23. 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: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

24. NNR-16.238 PI: Laura Hammitt

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

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

25. NNR-17.282 PI: Laura Hammitt

A Study to Evaluate the Efficacy of Maternal Immunization with RSV F vaccine in Preventing RSV Lower Respiratory Tract Infection in Young Infants (RSV-M-302)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

26. NNR-18.307 PI: Laura Hammitt

Safety and Immunogenicity of V114 in Adults at Risk for Pneumococcal Disease (Adult PCV15 Study)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

-
27. 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: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.
-
28. NNR-21.431 PI: Allison Barlow
Evaluation of Navajo Safe Water Access Projects
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.
-
29. NNR-21.401 PI: Jennifer Richards
Evaluation of Azhee Bidziil (Strong Fathers) Program: Improving Outcomes Among Rural Fathers and their Families.
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.
-
30. NNR-21.405T PI: Emily Haroz
Pilot Evaluation of Psychological First Aid for Frontline Workers in American Indian/Alaska Native Communities
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.
-
31. NNR-21.414 PI: Laura Hammitt
Phase 3 Master Protocol to Evaluate additional Dose(s) of BNT162B2 in Healthy Individuals previously Vaccinated with BNT162B2
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period
-
32. NNR-22.445 PI: Joshuaa Allison-Burbank
Piloting + Connection is Medicine
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.
-
33. NNR-05.165 PI: Laura Hammitt
Long Term Impact of the Pneumococcal Conjugate Vaccine on Pneumococcal Nasopharyngeal Colonization and Immune Correlates for Disease Protection
Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

34. NNR-15.232 PI: Laura Hammitt

Etiology of pneumonia and burden of pneumococcal pneumonia in hospitalized American Indian adults

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

35. NNR-17.284 PI: Delvin Yazzie

Navajo Nation Healthy Dine' Act: An Implementation Study

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 2022 - November 2022 period

36. NNR-19.332 PI: Gyan Nyaupane

Understanding the changing relationships of Indigenous peoples with their natural environments: A cross-cultural Study

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) February 2022 - April 2022, 2) May 2022 - July 2022 period

NEW PRESENTATION(S)

1. NNR-22.453 PI: Katherine Speirs

Baby College 101: Courses for Alchini Yazhi Program Evaluation

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submission - TABLE at 10-18-2022 Meeting. PI to Change Protocol Title and Re-submit.; Date Received - 10/05/2022

2. NNR-22.454 PI: Elana Begay

How do Tribal Judges Understand Indigenous Peacemaking as Crime Control Tools, and their Varying Notions of Accountability

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submission - Resubmission; Date Received - 10/05/2022

3. NNR-22.456 PI: Dornell Pete

Navajo ABID Study II: Helicobacter pylori risk and treatment experiences in Navajo Adults

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submission - TABLED at 10-18-22 Meeting, PI to obtain NAIHS HIPPA Waiver agreement, and Sponsor or University IRB Approval Letter.; Date Received - 10/10/2022

4. NNR-22.457 PI: Joshua Allison-Burbank

Language is Medicine: A Language Nutrition Intervention to Prevent Development Delay in Dine Children

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 11/04/2022

RETURNING PRESENTATION(S)

1. NNR-18.312 PI: Laura Brown

Lactation and Technology for Community Health (LATCH)

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final Report covering August 21, 2018 - August 16, 2022 period. enclosed is Published manuscript and Raw data - . TABLED at September 27, 2022, and at October 18, 2022 Meetings.

Please use item packet from 10-18-22 Meeting.

2. NNR-02.110 PI: Vallabh Shah

Diabetes Prevention Program Outcomes Study (DPPOS)

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 19, 2021 - August 19, 2022 period

3. NNR-03.121 PI: Sherry Brown

2003 Navajo Youth Behavior Survey (YRBS)

Reason on Agenda: (Other)

Description: Request Acceptance and Approval to Close Study for Non-Research activities and Navajo Youth Behavior Survey Project is In Navajo Department of Health - Health Program Scope of Work, resulting Project is NDOH Administrative Project.

4. 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, 2022 - July 20, 2022 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering July 21, 2021 - July 20, 2022 period

5. NNR-16.258 PI: Randall Swaim

Substance use among American Indian Youth attending schools on or near Reservation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2022 - September 30, 2022 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 1, 2021 - September 30, 2022 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 1, 2022 - September 30, 2023 period

6. NNR-18.319 PI: Bryan Jones Brayboy

Culturally Responsive Making: Developing High-Low Tech Maker Activities in Local and Mobile Spaces for Supporting American Indian Youth

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June 18, 2022 - September 18, 2022 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of the Annual Report covering September 18, 2021 - September 18, 2022 period

7. NNR-15.223 PI: Jennifer Richards

Formative Research to Inform the Development of an Intergenerational Strengths-Based Program for American Indian Girls as they Transition to Adulthood.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering December 15, 2021 - December 15, 2022 period

Reason on Agenda: Continuation Request

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

8. NNR-20.380 PI: Regina Eddie

Examining School Wellness in American Indian Communities

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract for Conference Presentation at 3rd International Indigenous Nursing Research Summit, at University of Texas at Austin, TX on November 4-5, 2022

9. NNR-20.389 PI: Olivia Lindly

Parents Taking Action to Improve Autism Services Access for Navajo Families in Northern Arizona: Intervention Adaptation and Pilot Trial

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering November 17, 2022 - November 17, 2023 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2022 - October 28, 2022 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering November 17, 2021 - November 17, 2022 period

10. NNR-21.425 PI: Wayne Morgan

Healthy Hooghans Pilot Project

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment of Revised Consent Forms: 1) University of Arizona IRB approval, 2) Consent and /or Parental Permission to Participate in Research, 3) Assent to Participate in Research Ages 13-17 years old; 4) Assent to Participate in Research Ages 8-12-year-old

11. NNR-21.427 PI: Lorenda Belone

Family Listening Program a Culturally-Centered Dissemination & Implementation Project

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering November 16, 2021 - October 31, 2022 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering November 16, 2022 - November 16, 2023 period.

12. NNR-22.442 PI: Jay Sutcliffe

A culturally-Relevant Micronutrient-Dense Plant Rich (mNDPR) dietary intervention for Native American

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to revise Consent Form

Reason on Agenda: Change in Investigators

Description: Request Acceptance and Approval of Change in Investigator from Jay T. Sutcliffe PI to Co-PI, and Nanette V. Lopez as Principal Investigator. NIH and NAU Notice of Award Notification included

13. NNR-19.349 PI: Tasha Seneca Keyes

Restorative Justice practices for improving school-based relationships

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering July 16, 2022 - July 17, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering July 17, 2021 - October 24, 2022 period

14. NNR-11.346 PI: Nicole Neault

Together on Diabetes Study: Evaluation of a pilot Diabetes Prevention and Management Program for American Indian Youth.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering December 21, 2022 - December 21, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering December 21, 2021 - December 21, 2022 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

15. NNR-16.264 PI: Allison Barlow

Preventing Early Childhood Obesity, Part I: Family Spirit Nurture, 3-9 Months, Part II: 18 Months

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Part I Annual Report covering December 20, 2021 - December 20, 2022 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report Part I, II covering July 1 - September 30, 2022 period.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Part I Continuation Request covering December 20, 2022 - December 20, 2023 period

16. 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: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of 2 Amendments: 1) Estimate the incidence of and risk factors for COVID-19 associated hospitalization including vaccination status among all persons in the parent study NNR-19.350, 2) Quantify and characterize long COVID-19 and assess risk factors for Long COVID among a subset of SARS-CoV-2 positive participants from parent study NNR-19.350.

17. NNR-21.419 PI: Joshua Allison-Burbank

Project Safe Schools: Re-opening schools serving Native children and adolescents SAFELY

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to add 3 items related to loss of loved ones/caregiver during the pandemic to both parents and youth surveys at Wave 3 timepoint.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

18. NNR-19.343 PI: Laura Hammitt

Active Surveillance for Invasive Bacterial Disease Among Native Americans in the Southwest (US)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to add Group A Streptococcus to the ABS program. To conduct surveillance, staff will contact participating labs to find out if GAS has been found in patient with sore throat or serious illness, GAS specimen will be collected and tested.

19. NNR-20.392 PI: Laura Hammitt

Protecting Native Families from COVID-19

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2022 period.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering December 21, 2022 - December 21, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering December 21, 2021 - December 21, 2022 period

SERIOUS ADVERSE EVENT

1. 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: Primary - Off Site SAE

Description:

Diagnosis: possible seizure activity

Last Page and End of Agenda