

Navajo Nation Human Research Review Board Meeting Agenda

Meeting Date: 2023-01-17 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

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OLD BUSINESS:

- I. Meeting Call to Order:
- II. Roll Call:
 - Invocation:
 - Introduction:
- III. Review and Approval of Agenda:
- IV. Review and Approval of August 16, 2022 Meeting Minutes:

NEW BUSINESS:

- V. Review and Acceptance of Quarterly Reports:
- VI. New Presentations:
- VII. Returning Presentations:
- VIII. Serious Adverse Events:
- IX. Noon Hour Discussions:
- X. Review and Acceptance of Manuscripts: 1) Antibiotic Resistance Rates for Helicobacter pylori in rural Arizona: a molecular-based study - (NNR - 16.263) Dr. Fernando P. Monroy, PhD.; 2) Using environmental health dialogue in a Din'e-centered approach for individualized results reporting in an environmental exposure study following the Gold King Mine Spill (NNR-16.234) Dr. Karletta Chief, PhD; 3) Nirsevimab for the prevention of RSV

Disease: follow-up through second RSV season -
NNR-19.357) Dr. Laura Hammitt, MD

XI. Announcements / Adjournment:

QUARTERLY REPORTS

1. NNR-11.348 PI: Simental Francisco
Navajo Behavioral Risk Factor Surveillance Survey
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Reports covering July 1, 2022 - September 30, 2022, October 1, 2022 - December 30, 2022 periods

2. 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 Reports covering 1) May 16, 2022 - August 15, 2022, 2) August 16, 2022 - November 15, 2022 periods

3. NNR-14.179 PI: Shawn Jordan
Engineering Design Across Navajo Culture, Community and Society
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering August 21, 2022 - November 20, 2022 period

4. 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 2022 - December 2022 period

5. NNR-19.359 PI: Angelina Castagno
Strengthening Teaching in Native Serving Schools Through Long-Term, Culturally Responsive Professional Development
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly report covering September 12, 2022 - December 12, 2022 period

6. NNR-19.363 PI: Charlene Poola
Tribal Equine Assisted Psychotherapy: Building Youth Resiliency through Horses
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Reports covering 1) May 1, 2022 - July 31, 2022, 2) August 1, 2022 - October 31, 2022 periods

7. NNR-20.380 PI: Regina Eddie

Examining School Wellness in American Indian Communities

Reason on Agenda: Quarterly Review

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

8. 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 Acceptance and Approval of 1) Clinical Trial Safty Update Report covering April 22, 2022 - October 21, 2022 period, 2) Data Safety Monitoring Committee-Recommendation Memo (25Oct2022)

9. NNR-21.414 PI: Laura Hammitt

Phase 3 Master Protocol to Evaluate additional Dose(s) of BNT162B2 in Healthy Individuals previoulsy Vaccinated with BNT162B2

Reason on Agenda: Quarterly Review

Description: Request Acceptance and Approval of 1) Clinical Trial Safty Update Report covering April 22, 2022 - October 21, 2022 period, 2) Data Safety Monitoring Committee-Recommendation Memo (25Oct2022) (13Dec2022)

10. NNR-21.417 PI: Matthew Barnett

Uranium Development in the Four Corners Region of the United States: Highlighting Environmental and Economic Concerns

Reason on Agenda: Quarterly Review

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

11. NNR-22.451 PI: Christine Ami

Diiji nidaiilah (today, we butcher): Dine Lessons from Sheep on Life, death, and re-memembering

Reason on Agenda: Quarterly Review

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

NEW PRESENTATION(S)

1. NNR-23.462 PI: Jos'e Luis Chavez

A Case Study Exploring the Experiences of Navajo Technical University Native American Students Enrolled in the Advance Manufacturing Network Initiative Educational Pathway

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 01/03/2023

2. NNR-23.463 PI: Leonela Nelson

Family Spirits Strengths

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 01/05/2023

3. NNR-22.460 PI: Ashish Amresh

Project Lets Talk Code

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 12/07/2022

RETURNING PRESENTATION(S)

1. NNR-21.423 PI: Akash Gupta

Evaluating the Impact of the Gallup COVID-19 Respiratory Shelter

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 27, 2022 - October 27, 2023 period- Deferred to 1-17-23 Meeting, Use packet form 12-17-22 Agenda Packet.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering August 1, 2022 - October 27, 2022 period - Deferred to 1-17-23 Meeting, Use packet form 12-17-22 Agenda Packet.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual and Final Report covering October 27, 2021 - October 27, 2022 period Deferred to 1-17-23 Meeting, Use packet form 12-17-22 Agenda Packet.

2. NNR-19.332 PI: Gyan Nyaupane

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

Reason on Agenda: Continuation Request

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

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering August - October 2022 period

3. 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: Continuation Request

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

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 21, 2022 - February 21, 2023 period

4. 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: Annual Report

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

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October 2022 - December 2022 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering January 19, 2023 - January 9, 2024 period

5. NNR-21.398 PI: Karletta Chief

Assessing Navajo COVID-19 Risks and Increasing Indigenous Resilience

Reason on Agenda: Addition of Co-Investigator

Description: Request Acceptance and Approval of Addition of Co-PIs: Dr. Kevin Lombard, Brandon Francis, David Delmar. Certification and CV attached.

6. NNR-17.293 PI: Jonathan Davis

Evaluating Geodesign as a Planning Framework for Navajo Nation Chapters

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering January 16, 2022 - January 16, 2023 period, Attachment Photo of Coppermine Winning Best in Public Outreach 2022

7. NNR-18.302 PI: Mark Bauer

Navajo NARCH Partnership: Evaluation of the Student Enhancement Program

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract Titled: Developing meaningful partnerships to promote an Indigenous public health workforce on February 23, 2023, at Arizona Public Health Association Conference in Phoenix, AZ

8. 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, 2022 - December 31, 2022 period

Reason on Agenda: Conference Presentation
Description: Request Acceptance and Approval of Abstract titled: "Understanding Resilience and Mental Wellbeing During COVID-19: Example from Three Native Nations in the US Southwest" on April 12-15, 2023 in Tempe, AZ

9. 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 1) May 16, 2022 - August 16, 2022, 2) August 16, 2022 - November 16, 2022 periods

Reason on Agenda: Annual Report

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

Reason on Agenda: Continuation Request

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

10. NNR-22.450 PI: Candi Running Bear

Culturally Relevant Dialogic Reading to Increase Vocabulary in Navajo Preschoolers with Disabilities

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments: 1) Revised Consent Forms, 2) Revised Parent Permission Form.

11. 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: Amendment

Description: Request Acceptance and Approval of Amendments to revise Youth Outcome Assessment to add questions to assess the youth's prior knowledge of reproductive health and Navajo Culture, and to revise Adult Outcome Assessment not to be used in the analysis.

12. 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 the process to note the start and end date for each sequelae and new conditions, 2) update questions about RSV prevention products (RSV monoclonal antibodies) and maternal vaccination questions (RSV vaccine), as well as question follow-up visit or hospital was associated with positive RSV to evaluate effectiveness of the preventions

13. 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: Conference Presentation

Description: Request Acceptance and Approval of Abstracts titled: Safety and Efficacy of Nirsevimab for Prevention of Medically attended RSV Lower Respiratory Tract Infection in All Infants Enrolled in the Phase 3 MELODY Trial. for reSViNET 2023 Conference on February 22-24, 2023 in Lisbon, Portugal.

14. NNR-11.325 PI: Laura Hammitt

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

Reason on Agenda: Continuation Request

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

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 21, 2022 - February 21, 2023 period

15. 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, 2023 - February 16, 2024 period

Reason on Agenda: Annual Report

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

16. 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 of Continuation Request covering February 15, 2023 - February 15, 2024

period

Reason on Agenda: Annual Report

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

Reason on Agenda: Amendment

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

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. NIH requests Data Sharing with RADx-UP initiatives.

18. NNR-22.445 PI: Joshua Allison-Burbank

Piloting + Connection is Medicine

Reason on Agenda: Amendment

Description: Request Acceptance and Approval Amendments: 1) Study Completion Certificate, 2) Study Completion script.

19. NNR-21.431 PI: Ashley Lee

Evaluation of Navajo Safe Water Access Projects

Reason on Agenda: Continuation Request

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

Reason on Agenda: Annual Report

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

20. 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 October 1 - December 31, 2022 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering July 2021 - July 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: Influenza

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Urinary Tract Infection

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Bronchiolitis, RSV

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: AGE with dehydration and metabolic acidosis

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Influenza A, RSV Bronchiolitis, Hypoxemia

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: RSV Bronchiolitis

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: RSV Bronchiolitis

Last Page and End of Agenda

