

# Navajo Nation Human Research Review Board

## Meeting Agenda

Meeting Date: 2024-07-23 Meeting Time: 9:00 AM  
Location: Virtual (Rescheduled date from July 16, 2024)

### MEMBERS:

Paul Charlton, MD - Medicine   
Christopher Jentoft, - Medicine   
Delvin Yazzie, MPH - Epidemiology   
Nanibaa' Garrison, Ph.D. - Genetics, Bioethics   
Paula Mora, MD - Medicine/ Public Health   
Sonya Shin, MD - Medicine

### OLD BUSINESS:

I. Meeting Call to Order:

II. Call for Roll Call:

- Invocation:

- Introduction:

III. Review and Approval of July 23, 2024 Meeting Agenda:

IV. Review and Acceptance of April 16, 2024 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. Acceptance and Approval of Serious Adverse Events (SAEs):

IX. Review and Acceptance of Manuscripts: 1)  
Water is K'e': Pilot Result of a community-based Intervention to increase healthy beverage consumption by Navajo preschool children

-NNR-24.500 Carmen George; 2) Beverage consumption patterns among Navajo Children aged two to six years. NNR-21.409, Carmen George, 3) testing the effectiveness of Family Spirit Strengths (FSS)- a culturally informed intervention designed to prevent mental health and substance misuse for Indigenous families through home visiting. NNR-23.463 L. Nelson., 4) Lower respiratory tract infections following respiratory syncytial virus monoclonal antibody nirsevimab immunization versus placebo: Analysis from a Phase 3 randomized clinical trial (MELODY) NN-19.357 Dr. Laura Hammitt

X. Noon Hour Discussion:

XI. Announcements / Adjournment:

## QUARTERLY REPORTS

1.      NNR-11.323      PI: Johnnye Lewis  
Navajo Birth Cohort Study (NBCS)  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering February 23, 2024 - May 22, 2024.

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2.      NNR-23.489      PI: Debra MacKenzie  
Evaluating cumulative environmental exposure using geospatial modeling and personal exposure assessment  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering March 20, 2023 - June 20, 2024.

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3.      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 March 17, 2024 - June 17, 2024.

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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, 2024 - June 15, 2024.

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5.      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 April 2024 - June 2024 period

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6.      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 Report covering February 21, 2024 - May 21, 2024.

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7.      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 19, 2024 - June 19, 2024.

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8.      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 April 1, 2024 - June 30, 2024 period

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

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

Reason on Agenda: Quarterly Review

Description: Request Reveiw and Acceptance of Quarterly Report covering March 25, 2024 - Jun 24, 2024 period

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10. NNR-21.398 PI: Karletta Chief

Assessing Navajo COVID-19 Risks and I ncreasing Indigenous Resillience

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering March 17, 2024 - June 17, 2024 period

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11. NNR-23.467 PI: David Garcia

Advancing Liver Cancer Prevention for Arizona American Indian Communities

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report Covering April 1, 2024 to June 30, 2024 period

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12. NNR-23.470 PI: Lauren Eberly

Improving the Quality of Heart Failure Care for Patients Receiving Care Through the Indian Health Service at the Gallup Service Unit

Reason on Agenda: Quarterly Review

Description: Request Acceptance and Approval of Quarterly Report covering April 18, 2024 - July 18 2024 period

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13. NNR-11.321 PI: Christine Samuel-Nakamura

Uranium in the plant-animal-human food chain near abandoned mining sites and structures in an American Indian community in Northwestern New Mexico

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February 21, 2024 - May 21, 2024.

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14. NNR-19.360 PI: Debra MacKenzie

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

Reason on Agenda: Quarterly Review

Description: Request Reveiw and Acceptance of Quarterly Report covering March 18, 2024 - June 17, 2024.

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15. NNR-19.333 PI: Kevin Lombard

Engaging Navajo Elementary Schools in Randomized Controlled Trial of Y'eego! Healthy Eating & Gardening

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February 21, 2024 - May 20, 2024.

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16. 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 Report covering January 16, 2024 - April 16, 2024.

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17. NNR-19.337 PI: Crystal LoudHawk-Hedgepeth

Kresge Inquiry Project

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April 1, 2024 - June 30, 2024.

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18. 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 Report covering February 19, 2024 - May 19, 2024

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19. NNR-16.247 PI: Bruce Bender

Creating an asthma collaboration to reduce childhood asthma disparities on the Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April - June 2024.

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20. NNR-23.471 PI: Delphina Dayish

Navajo Grandparents Raising Their Grandchildren: Their Challenges and Needs

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June 1, 2024 - September 1, 2024.

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## NEW PRESENTATION(S)

1. NNR-24.505 PI: Rebecca Girardet

Measuring Child Maltreatment Incidence and Community Protective Factors in New Mexico

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study - TABLED at June 18, 2024 Meeting - submit Northern, Eastern Council Agency Resolution.; Date Received - 05/09/2024

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2. NNR-24.507 PI: Joaquin Lopez-Huertas

Indigenous Knowledges in Settle-State Planning

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of new study - TABLED at June 18, 2024 Meeting - Identify Participates, need Cultural Group Advisory approval; Date Received - 06/04/2024

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3. NNR-24.508 PI: Paul Bernstein

Non-Invasive Screening of Vitamin a Deficiency in Pregnant Women and Children in the Navajo Nation  
Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study - TABLED at June 18, 2024 Meeting: Resubmit complete Applicaton, to include Consent Forms, Part 5 Certification, Agency Council Resolution, Recruitment and Compsation, another PI.; Date Received - 06/05/2024

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4. NNR-24.510 PI: Ronda Jenson

Advancing Hzh in Autism Assessment (AHAA) for Din Families

Reason on Agenda: NEW

Description: Remarks: Request Review andApproval of new study.; Date Received - 07/08/2024

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5. NNR-24.511 PI: Oliver Tapaha

Hazh' Baa Nitshkeesgo Anlh: Considering Insider-Outsider Perspective on Navigating the Initial Phases of a Tribal IRB Process.

Reason on Agenda: NEW

Description: Remarks: Request Review andApproval of new study.; Date Received - 07/08/2024

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### RETURNING PRESENTATION(S)

1. NNR-17.282 PI: Laura Hammitt

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

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final Report covering August 15, 2017 - August 15, 2024 period and request to Close-Study.

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2. NNR-23.479 PI: Mark Tanner

Document-Based & Oral Histories of Dine Experiences in the Mormon Indian Student Placement Program 1947-2000

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 2024 - March 2024 period TABLED at June 18, 2024 Meeting - No available PI

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Cotinuation Request covering July 2024 - July 2025 period TABLED at June 18, 2024 Meeting - No available PI

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering July 2023 - July 2024 period TABLED at June 18, 2024 Meeting - No available PI

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3. 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: Annual Report

Description: Request Acceptance and Approval of Annual Reports covering July 20, 2023 - July 20, 2024

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Reason on Agenda: Quarterly Review

Description: Request Review and Accepted of Quarterly Reports; 1. October 20, 2023 - January 20, 2023, 2. January 20, 2024 - April 20, 2024, 3. April 20, 2023 - July 20, 2024

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering July 20, 2023 - July 20, 2024.

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4. NNR-23.474 PI: Alark Saxene

The Role of Southwest Forests in the Social-Ecological Resilience of the Navajo (Din'e) Nation: A Case-Study of the Chuska Mountains and Defiance Plateau

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Coneference Presentation titled: "Pathways to Sustainability." At PECS-III Conference in Montreal, Canada on August 12-15, 2024

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5. NNR-24.500 PI: Carmen George

Water is K'e': Multi-level intervention to promote healthy beverage among Navajo Families

Reason on Agenda: Amendment

Description: Request Accepted and Approved of 5 Amendments; 1. Updated Enrollment Sites (as reflected in updated Detailed Protocol), 2. Updated Consent Forms, Assent and Consent Flipchart, 3. Updated Master Data Collection Form, 4. New Data Collection form, 5. New Recruitment Flier.

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6. NNR-21.425 PI: Wayne Morgan

Healthy Hooghans Pilot Project

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April 2024 - June 2024.

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering May 15, 2024 - May 16, 2025.

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7. 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 2023 - August 2024 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 19, 2024 to August 19, 2025 period

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8. 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: Addendum

Description: Request Acceptance and Approval of Addendum 1. New Funding 2. Additional Participants 3. Design Modification

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9. 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: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 18, 2024 - August 18, 2025 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report Covering August 18, 2009 - August 18, 2024 period

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10. 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: Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 20, 2019 - August 20, 2024 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 20, 2024 - August 20, 2025



period

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11. NNR-19.354 PI: Allison Barlow

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

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 20, 2019 - August 20, 2024 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 20, 2024 - August 20, 2025 period

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12. 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: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 27, 2024 - August 27, 2025 period.

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report Covering August 27, 2020 - August 27, 2024 period.

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13. 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: Continuation Request

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

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering May 19, 1997 period

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14. NNR-23.477 PI: Mayela Gillan

Understanding Workplace Hazards while Remediatig Legacy Uranium Mine Waste in Cove Chapter

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment of UC Berkley graduate research assistant.

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15. NNR-17.284 PI: Delvin Yazzie

Navajo Nation Healthy Dine' Act: An Implementation Study

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 21, 2024 - August 21, 2025.

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 21, 2023 - August 20, 2024 period

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16. NNR-18.302 PI: Mark Bauer

Navajo NARCH Partnership: Evaluation of the Student Enhancement Program

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Reports covering April 17, 2023 - April 17, 2024

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17. NNR-17.289 PI: Eudora Redhouse

Youth Builders

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering July 1, 2024 - June 30, 2028.

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