

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

Meeting Date: 2023-04-18 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:

- Introductions:

III. Review and Acceptance of Agenda:

IV. Review and Approval October 18, 2022  
Meeting Minutes

**NEW BUSINESS:**

V. Review and Approval of Quarterly Reports:

VI. New Presentations:

VII. Returning Presentations:

VIII. Noon Hour Discussion: 1) Acceptance and  
Approval of Navajo Nation Genetics Research  
Policy Statement - Action Item: EJ John, Rene  
Begay

IX. Serious Adverse Events (SAEs):

X. Review and Acceptance of Manuscripts. 1)  
Applying Contextual Engineering to Engineering  
Needs for Bodaway Gap Chapter in the Areas of  
Water and Energy - 22.539 Dr. Ann-Perry  
Witmer, 2) Productive Use Institutional  
Continuity, Support Networks and Trust Building:

The Challenges of Deploying Technological  
Solutions in Rural and Remote Communities -  
NNR-22.439 Dr. Ann-Perry Witmer.

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 November 23, 2022 - February 22, 2023 period

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2. 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 January 1, 2023 - March 31, 2023 period

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3. 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 December 15, 2022 - March 15, 2023 period

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4. 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 December 15, 2022 - March 15, 2023 period

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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 January 1, 2023 - March 31, 2023 period

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6. NNR-19.360 PI: Debra MacKenzie  
Navajo Birth Cohort Study/environmental Influences on Child Health Outcomes Plus (NBCS/ECHO+)  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering December 18, 2022 - March 17, 2023 period

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7. NNR-19.363 PI: Charlene Poola  
Tribal Equine Assisted Psychotherapy: Building Youth Resilency through Horses  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering November 1, 2022 - January 31, 2023 period

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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: (Other)

Description: Request Review and Acceptance of 1) MedWatch Safety Report (202200607385) 1-26-23: 15 day follow-up #1, 2) Data Safety Monitoring Committee - Recommendation Memos.

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9. NNR-22.437 PI: Donnie Begay

The Lifeworld of Navajo Millennials: Seeking Balance and Harmony in their world and others

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering December 2022 - March 2023 period

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10. NNR-22.456 PI: Dornell Pete

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

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1, 2023 - March 21, 2023 period

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11. NNR-22.461 PI: Jeffery Hovermill

Project co-STEM

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1, 2023 - March 18, 2023 period

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12. NNR-19.337 PI: Crystal LoudHawk-Hedgepeth

Kresge Inquiry Project

Reason on Agenda: Quarterly Review

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

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#### NEW PRESENTATION(S)

1. NNR-22.460 PI: Ashish Amresh

Project Lets Talk Code

Reason on Agenda: New Title

Description: Request Review and Approval of New Submission

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2. NNR-23.469 PI: Otis Clarke

Evaluating the Impact of COVID-19 on Navajo Nation Indigenous High School Student Population

Reason on Agenda: NEW

Description: Remarks: Request Review and Acceptance of New Submission; Date Received - 04/06/2023

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3. 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: NEW

Description: Remarks: Request Review and Acceptance of New Submission; Date Received - 04/06/2023

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4. NNR-23.471: PI: Delphina Dayish

Navajo Grandparents Raising Their Grandchildren: Their Challenges and Needs

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submission; Date Received - 04/07/2023

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5. NNR-23.472 PI: Nancy Rumbaugh Whitesell

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

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submission; Date Received - 04/07/2023

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6. NNR-23.473 PI: Stephanie Klein

Characterization of Utahs live Interactive Teledermatology Outreach for Navajo Patients

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submission; Date Received - 04/11/2023

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### RETURNING PRESENTATION(S)

1. NNR-14.185 PI: Sheldwin Yazzie

Assessing Indoor Radon Exposure on the Navajo Nation.

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Powerpoint Conference Presentation at the University of Washington Department of Environmental and Occupational Health Science Seminar on April 27, 2023. Presentation Titled: Radon and Lung Cancer: Data Collection and Intervention in the Southwest.

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Reason on Agenda: Quarterly Review

Description: Requesting Review and Acceptance of Quarterly Report covering November 1, 2022 - January 31, 2023 period

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2. NNR-16.263 PI: Robin Harris

Helicobacter Pylori Infection and Stomach Cancer

Reason on Agenda: Amendment

Description: Request Acceptance and Approval to discuss the Tabled Amendment from February 21, 2023 meeting. The use of isolated H.pylori bacteria for bacterial whole genome sequencing.

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3. NNR-17.281 PI: Nanibaa' Garrison

Perspectives on Genetic Research in the Navajo Nation

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Presentation at Primary Immune Deficiency Treatment Consortium Workshop in Cincinnati, OH on April 19, 2023.

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4. NNR-18.302 PI: Mark Bauer

Navajo NARCH Partnership: Evaluation of the Student Enhancement Program

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 17, 2023 - April 17, 2023 period

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Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Revised Alumni Survey and Revised Consent Forms and: Bachelor of Science in Public Health Alumni Survey for their career outcomes in academics and employment.

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Reason on Agenda: Annual Report

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

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Reason on Agenda: Continuation Request

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

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5. 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: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination Plan of Final Report

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6. NNR-21.419 PI: Joshuaa 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 obtain feedback about the Backpack testing program sent over the counter rapid test kits home with students

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7. NNR-22.457 PI: Joshuaa Allison-Burbank

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

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to extend the study's recruitment radius from 50 to 100 miles of the Shiprock Johns Hopkins for Indigenous Health field office.

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8. NNR-22.445 PI: Joshua Allison-Burbank

Piloting + Connection is Medicine

Reason on Agenda: Continuation Request

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

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Reason on Agenda: Annual Report

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

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9. 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: Conference Presentation

Description: Request Acceptance and Approval of Presentation titled: "Metabolomic Insights into Early Childhood Caries Among Navajo Infants" at American Academy of Pediatric Dentistry Conference on May 25-28, 2023 in Orlando, FL

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10. NNR-23.463 PI: Leonela Nelson

Family Spirits Strengths

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments: 1) Updated Research Plan so the effectiveness of FSS on reducing the number of poor mental health days will be assessed, and will allow to compare findings to the standard population. 2) update to indicate to approach participants from previous studies who may be eligible and indicated would be interested in participating future research studies.

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11. NNR-19.331 PI: Cathron Donaldson

Understanding Navajo Parents' Beliefs about Cradling and Early Mobility Practices

Reason on Agenda: Addition of Co-Investigator

Description: Request Acceptance and Approval to Add Co-Investigator Dr. Lisa Granger. CITI Human Research Certificate is attached. TABLED at March 28, 2023 Meeting, Use item from 3-28-23 Agenda.

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Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination Plan. TABLED at March 28, 2023 Meeting, Use item from 3-28-23 Agenda.

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering February 19, 2022 - February 19, 2023 period. TABLED at March 28, 2023 Meeting, Use item from 3-28-23 Agenda.

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Reason on Agenda: Annual Report

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

TABLED at March 28, 2023 Meeting, Use item from 3-28-23 Agenda.

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reviews covering: 1) February 19, 2022 - May 19, 2022; 2) May 19, 2022 - August 19, 2022; 3) August 19, 2022 - November 19, 2022; 4) November 19, 2022 - February 19, 2023 periods. TABLED at March 28, 2023 Meeting, Use item from 3-28-23 Agenda

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12. NNR-22.439 PI: Ann-Perry Witmer

Contextualization of Rural Infrastructure Systems for Improved Sustainability

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request Covering March 16, 2023 - March 15, 2024 period

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering: 1) January 1, 2023 - March 31, 2023, 2) July 1, 2022 - September 30, 2022, 3) October 1, 2022 - December 31, 2022, 4) April 1, 2022 - June 30, 2022.

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Reason on Agenda: Annual Report

Description: Request Review and Acceptance of Annual Report.

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### 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: RSV + bronchiolitis

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2. 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: Primary - Off Site SAE

Description:

Diagnosis: Unexpected Serious Adverse Reactions: 1) October 21, 2022-participant diagnosed with pneumonia. Participant not enrolled in CIH (Colombia)

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Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Participant experienced vomiting. Participant not enrolled in CIH (France)

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Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Participant experienced bronchiolitis. Participant not enrolled in CIH (France)

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Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Participant experienced grade two RSV bronchiolitis. Participant not enrolled in CIH (USA)

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