

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

Meeting Date: 2024-08-20 Meeting Time: 9:00 AM  
Location: Virtual

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 August 20, 2024  
Meeting Agenda:

IV. Review and Acceptance of May 21, 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)  
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

2)Baseline Sociodemographic Characteristics and Mental Health Status of Primary Caregivers and Children Attending Schools on the Navajo Nation During COVID-19-NNR-21.419 Joshua D. Allison-Burbank,3)Indigenous Community-Based Participatory Research Approach and Safe Return to In-Person Learning for Dine Youths and Families- NNR-21.419 Joshua D. Allison-Burbank

X. Noon Hour Discussion:

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 April 1, 2024 - June 30, 2024 period

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2. NNR-21.419 PI: Joshuaa Allison-Burbank

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

Reason on Agenda: Quarterly Review

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

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

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4. 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 April 15,2024 - July 14,2024 period

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

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

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

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8. NNR-14.192 PI: Hendrik deHeer

Physical activity and cancer among Native American cancer survivors: A pilot study.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) December 20, 2023 - March 19, 2024, 2) March 20, 2024 - June 19, 2024 periods

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

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

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

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

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13. 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: Quarterly Review

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

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

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

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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 April 1, 2024-June 1, 2024 period

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

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

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19. NNR-23.492 PI: Kristin Mitchell

NATIVE-RISE (Risk Identification for Suicide and Enhanced Care)  
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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20. NNR-23.463 PI: Leonela Nelson

Family Spirits Strengths  
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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21. NNR-23.476 PI: Kristin Mitchell

Formative work with medical providers and personnel in preparation for the NATIVE-RISE clinical trial  
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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22. NNR-22.457 PI: Joshua Allison-Burbank

Language is Medicine: A Language Nutrition Intervention to Prevent Development Delay in Dine Children  
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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23. NNR-22.445 PI: Joshua Allison-Burbank

Piloting + Connection is Medicine  
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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24. 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 April 1, 2024 - June 30, 2024 period

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25. NNR-21.431 PI: Ashley Thacker

Evaluation of Navajo Safe Water Access Projects  
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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26. 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 April 1, 2024 - June 30, 2024 period

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

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

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

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

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

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32. 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 March 31- June 30, 2024 period

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

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34. 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 Approval of Quarterly Report covering April 1, 2024- June 30, 2024 period

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35. 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 January 01,2024 - March 31,2024

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36. 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 April16, 2024 - July 16, 2024 period

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### NEW PRESENTATION(S)

1. 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 Title

Description: Request Review and Approval of Revised New Study. Tabled at June 18, Meeting for incomplete application.

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2. 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 Title

Description: Request Review and Approval of Revised new study.

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3. NNR-24.512 PI: Sumayya Beekun

Staphylococcus aureus in Indigenous Communities in the Southwest United States: Estimating Invasive Disease Burden, Measuring Carriage Prevalence, and Exploring Knowledge and Attitudes Related to Disease Prevention

Reason on Agenda: NEW

Description: Remarks: Request Acceptance and Approval of New Study; Date Received - 07/31/2024

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4. NNR-24.513 PI: Jennifer Richards

The Hastiin Bidziil (Strong Man) intervention: A study to measure effectiveness of a secondary prevention program aimed at reducing substance use among Native men ages 18-26

Reason on Agenda: NEW

Description: Remarks: Request Acceptance and Approval of New Study.; Date Received - 07/31/2024

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5. NNR-24.514 PI: Jonathan Davis

The Colorado River Basin Water Resilient Agriculture- San Juan County New Mexico



Reason on Agenda: NEW

Description: Remarks: Request Acceptance and Approval of New Study.; Date Received - 07/31/2024

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6. NNR-24.515 PI: Stephanie Zone

Quality of Life Impact of Dermatologic Conditions of Patients in Montezuma Creek

Reason on Agenda: NEW

Description: Remarks: Request Acceptance and Approval of New Study.; Date Received - 07/31/2024

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7. NNR-24.516 PI: Kamille Williams

A Teacher Action Study: Analyzing the Importance of Family and Cultural Values to Guide Student- Directed Success

Reason on Agenda: NEW

Description: Remarks: Request Acceptance and Approval of New Study; Date Received - 07/31/2024

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8. NNR-24.517 PI: Keeley Joe

Toxic Tailings: The Lasting Impacts of Uranium Mining on Navajo

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 08/08/2024

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### RETURNING PRESENTATION(S)

1. NNR-21.405 PI: Emily Haroz

Pilot Evaluation of Psychological First Aid for Frontline Workers in American Indian/Alaska Native Communities

Reason on Agenda: Final Report

Description: Request Approval on Final Report and Request to close out study covering April 20, 2021 - April 20, 2025 period

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2. NNR-22.448 PI: Catherine Sutcliffe

Pneumococcal carriage among Native Americans in the Southwest (the PNEU-CARE Study)

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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Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment of 1. Participant Letter and 2. Johns Hopkins IRB approval letter.

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

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Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment of 1. Research Plan - Track Changes. 2. Informed Consent of Supplemental Interview. 3. Recruitment Script for Supplemental Interview

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

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Reason on Agenda: Continuation Request

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

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 18, 2023 - September 18, 2024.

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5. 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: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering September 6, 2024 - September 6, 2025.

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Reason on Agenda: Quarterly Review

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

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 6, 2023 - September 6, 2024.

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6. 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 April 1 - June 30,2024 period.

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Reason on Agenda: Continuation Request

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

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Reason on Agenda: Annual Report

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

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7. NNR-22.449 PI: Ashley Thacker

Dine' Household Water Survey

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 13,2024 period

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Reason on Agenda: Amendment

Description: Request Acceptance and Approval to Revise Dissemination Plan.

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8. 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 #3 covering January 21,2024 - April 20,2024, Project Year 2023-2024.

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering July 21,2024 - July 20,2025 period

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) July 21,2023 - October 20,2023, 2) October 21,2023 - January 20, 2024, 3) January 21, 2024 - April 20, 2024 periods

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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: Addendum

Description: Request Acceptance and Approval of Addendum to add Graduate Research Assistants Ashley Johns and Rachel Lynn Whitman to Protocol. Attached is their Human Subject Research Certificates (CITI)

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10. NNR-18.302 PI: Mark Bauer

Navajo NARCH Partnership: Evaluation of the Student Enhancement Program

Reason on Agenda: Modification

Description: Request Acceptance and Approval of Modified Evaluation Instrument of Summer Research Enhancement Program (SREP) Pre-Test (Modified)

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Reason on Agenda: Quarterly Review

Description: Request Acceptance and Approval of Quarterly Report covering April 17, 2024 - July 17, 2024 period

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11. NNR-09.241 PI: Barbara Overman

Giving Voice to Health Values from within the Navajo Culture

Reason on Agenda: Annual Report

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

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 1,2024 - July 31,2024 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 1, 2024 - July 31, 2025 period

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12. 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 May 21, 2024 - July 29, 2024.

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 21, 2023 - July 29, 2024 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request Covering August 21, 2024 - August 20, 2025 period

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13. NNR-11.348 PI: Simental Francisco

Navajo Behavioral Risk Factor Surveillance Survey

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 1,2024- August 30, 2024 period

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2024, 2) April 1 - June 31, 2024 periods.

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14. NNR-17.277 PI: Denise Charron-Prochownik

Stopping Gestational Diabetes in Daughters and Mothers - Phase 2

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Reports covering July 19, 2023- July 18, 2024 period

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15. 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 17, 2024-July 16, 2024

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering July 16, 2024- July 26, 2024.

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16. NNR-21.398 PI: Karletta Chief

Assessing Navajo COVID-19 Risks and Increasing Indigenous Resilience

Reason on Agenda: Amendment

Description: Amendment to update survey for Four Corners Indigenous Farm Assessment.

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Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination Approval of FEWS (Food, Energy, & Water) Perceptions Focus Groups and COVID-19 Mitigation Focus Group & Interviews.

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17. NNR-23.477 PI: Mayela Gillan

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

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 15, 2023- August 15, 2024.

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18. NNR-23.487 PI: Dornell Pete

Navajo ABID Study III: Effects of Helicobacter pylori on the human gut microbiota in the Navajo ABID Study

Reason on Agenda: Add/Change Co-Investigators

Description: Request Acceptance and Approval to Add Co-PI Dr. Joslynn Lee and students Averlee Lander and Tse'yi'nii Begay III to study. Attached CV, Part V Certification and Human Subjects Research Certificates.

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19. NNR-21.427 PI: Lorenda Belone

Family Listening Program a Culturally-Centered Dissemination & Implementation Project

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April 16,2024- July 16,2024.

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Reason on Agenda: Modification

Description: Request Acceptance and Approval of Protocol Modification

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20. NNR-16.254 PI: Nicole Neault

Evaluation of NativeVision Year Round Program

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final Report covering September 2016 - September 2024 period, and request to Close Study.

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*Last Page and End of Agenda*