

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

Meeting Date: 2024-05-21 Meeting Time: 9:00 AM  
Location: Virtual

**MEMBERS:**

- Dr. Paul Charlton, MD - Medicine
- Dr. Christopher Jentoft, MD - Medicine
- Dr. David Begay, Ph.D. - Scientific Education
- Mr. Delvin Yazzie, MPH - Epidemiology
- Dr. Kalvin White, Ph.D. - Scientific Education
- Dr. Nanibaa' Garrison, Ph.D. - Genetics, Bioethics
- Dr. Paula Mora, MD - Medicine/ Public Health
- Dr. Rebecca Izzo-Manymules, Ph.D. - Chairperson - Education
- Dr. Sonya Shin, MD - Medicine

**OLD BUSINESS:**

- I. Meeting Call to Order:
- II. Call for Roll Call:
  - Invocation:
  - Introduction:
- III. Review and Approval of May 21, 2024 Agenda:
- IV. Review and Approval of March 19, 2024 Meeting Minutes:

**NEW BUSINESS:**

- V. Review and Acceptance of Quarterly Reports:
- VI. Acceptance and Approval of New Presentations:
- VII. Acceptance and Approval of Serious Adverse Events ( SAEs ):
- VIII. Review and Acceptance of Manuscripts: 1) Development of a Culturally enhanced caregiver-facilitated language nutrition intervention "+Language is Medicine" to address developmental delay in Dine (Navajo) toddlers - Joshuaa D. Allison-Burbank NNR-22.457)
- IX. Noon Hour Discussion:

X. 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 January 1 - March 31, 2024 period

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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 January 1, 2024- March 31, 2024 period

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3. NNR-02.110 PI: Vallabh Shah

Diabetes Prevention Program Outcomes Study (DPPOS)

Reason on Agenda: Quarterly Review

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

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4. NNR-05.175 PI: Kimberly Mohs

Navajo Area Indian Health Services - Cardiovascular Risk Reduction Demonstration Project

Reason on Agenda: Quarterly Review

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

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5. 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 January 1 - March 31, 2024 period

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6. 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 January 1 - March 31, 2024 period

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7. 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 January 15, 2024- April 14, 2024

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8. 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 January 1 - March 31, 2024 period

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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: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report Covering January 1 - March 31, 2024 period

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10. 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 January 1 - March 31, 2024 period

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11. 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 1) January 1 - March 31, 2024, 2) October 1, 2023 - December 31, 2023 period

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12. 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 January 1 - March 31, 2024 period

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13. 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 January 1 - March 31, 2024 period

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14. 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 January 1 - March 31, 2024 period

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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: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report Part 1 and Part 2 Covering January 1 - March 31, 2024 period

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16. 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 January 1 - March 31, 2024 period

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17. 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 January 1 - March 31, 2024 period

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18. 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 January 1 - March 31, 2024 period

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19. 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 January 1 - March 31, 2024 period

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20. 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 January 1 - March 31, 2024 period

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21. NNR-19.354 PI: Allison Barlow

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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 January 1 - March 31, 2024 period

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22. NNR-19.355 PI: Sally Davis

Healthy Places-Healthy People

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quaterly Report Covering February 21, 2023 - May 20, 2024 period

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23. 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 January 1 - March 31, 2024 period

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24. 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 January 1 - March 31, 2024 period

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25. 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 January 1, - March 31, 2024 period

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26. 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 January 1 - March 31, 2024 period

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27. 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 January 1 - March 31, 2024 period

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28. 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 January 1 - March 31, 2024 period

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29. 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 January 1 - March 31, 2024 period

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30. NNR-21.419 PI: Joshua 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 January 1 - March 31, 2024 period

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31. 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 January 1 - March 31, 2024 period

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32. 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 January 1 - March 31, 2024 period

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33. NNR-21.430 PI: Elise Christopher

High School & Beyond Longitudinal Study of 2022 (HS&B:22)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 21, 2024 - April 24, 2024 period

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34. 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 January 1- March 31, 2024 period
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35. NNR-22.445 PI: Joshuaa Allison-Burbank  
Piloting + Connection is Medicine  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Review Covering January 1 - March 31, 2024 period
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36. 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 January 1 - March 31, 2024 period
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37. NNR-21.425 PI: Wayne Morgan  
Healthy Hooghans Pilot Project  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report Covering January 1, 2024- March 31,2024 period
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38. NNR-22.449 PI: Ashley Thacker  
Dine' Household Water Survey  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report Covering January 1 - March 31, 2024 period
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39. NNR-22.457 PI: Joshuaa 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 January 1 - March 31, 2024 period
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40. NNR-22.451 PI: Christine Ami  
Dilji nidaiilah (today, we butcher): Dine Lessons from Sheep on Life, death, and re-membering  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering August 2023- December 2024 period
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41. NNR-23.463 PI: Leonela Nelson  
Family Spirits Strengths  
Reason on Agenda: Quarterly Review



Description: Request Review and Acceptance of Quarterly Report Covering January 1 - March 31, 2024 period

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42. 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 1, 2024- March 31, 2024 period

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43. NNR-23.468 PI: Juliet Lee

Healthy Native Nations: Identifying Effective Alcohol Policies for American Indian Tribes

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 20, 2024 - April 19, 2024 period

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44. NNR-23.478 PI: Fatemeh Afghah

SCC-PG: Just in Time Intervention for Members with Chronic Heart Diseases in Arizona Tribes

Reason on Agenda: Quarterly Review

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

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45. 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 January 1 - March 31, 2024 period

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46. 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 January 1 - March 31, 2024 period

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#### NEW PRESENTATION(S)

1. NNR-24.495 PI: Priscilla Sanderson

Hozhoogoo Naashaa doo (I Will Live in a Good Way): Breast Cancer Prevention

Reason on Agenda: New Title

Description: Request Review and Approval of Revised New Study - 1) NAU IRB Approval Letter, 2) NNHRRB Revised Question #15, 3) Informed Consent Form. 4) Narrative Inquiry Questionnaire to match #15 question, 5) Navajo Historic Preservation Permit, 6) NAU Office of Native American Initiative Approval, 7) Copy of Mayo Clinic Letter of Support. (Tabled at March 19, 2024 Meeting, and Tabled at February 20, 2024 meeting Date. Use items from March 19, 2023 Agenda)

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2. NNR-24.496 PI: Rebecca Bird

Dib'e Wolgh'eii nima at'e: The Din'e Sheep Camp as a socioecological system

Reason on Agenda: New Title

Description: Request Review and Approval of New Study - TABLED in April 16, 2024 and March 19, 2024. Use document items from March 19, meeting packet

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3. NNR-24.502 PI: Kristen Seward

Having Opportunities Promotes Excellence: Developing scholar Identities Among Underserved Youth with High Potential

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 05/02/2024

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4. NNR-24.503 PI: Crystal Carr

The Quiet Crisis of Housing Injustice in Din'e Bikeyah: A Case Study on the Navajo Nation Homesite Lease Process

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 05/09/2024

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5. NNR-24.504 PI: Shawn Jordan

Culturally-Situated Immersive Virtual Learning and Engineering Design to Build STEM Capacity in Din'e Communities

Reason on Agenda: NEW

Description: Remarks: Request Review and Acceptance of New Study; Date Received - 05/09/2024

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6. 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; Date Received - 05/09/2024

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7. NNR-24.506 PI: Emily Haroz

Piloting a Model of a Systems-level Approach to Adolescent Integrated Care (Project MOSAIC) for Indigenous Youth

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 05/15/2024

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### RETURNING PRESENTATION(S)

1. 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: Final Report

Description: Request Acceptance and Approval of Final and to Close Study covering September 18, 2022 - September 18, 2023 period - TABLED April 16, 2024 and March 19, Meeting, Use documents from March 19th meeting packet.

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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: Continuation Request

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

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 16, 2023 - February 15, 2024 period

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Reason on Agenda: Progress Report

Description: Request Review and Acknowledge of Project Overview and Community Summaries report.

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February 16, 2024 - May 15, 2024 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering May 16, 2023 - May 15, 2024 period

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Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments: 1) Update Date pg. 1, 2) wording edits pg. 2, 3) Inclusion and Exclusion criteria. Population and Patient Accural. pg. 4, 4) Data Protection pg. 5, 5) Data Ownership pg. 6, 6) Timeline pg. 6, 7) Table 1, Sectin 3 on Chronic-Disease other.

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3.     NNR-15.212    PI : Mark Solomon

2015 Safety Belt Use Estimates for the Indian Nations.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering July 2024 - July 2025 period with support documents for new contract.

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4.     NNR-17.277    PI : Denise Charron-Prochownik

Stopping Gestational Diabetes in Daughters and Mothers - Phase 2

Reason on Agenda: Conference Presentation

Description: Request Review and Acceptance of Poster titled: Reproductive Health (RH) ad Gestational Diabetes (GDM) Knowledge Mediates the Intervention Effect on the Intention to Communicate in DYADS of American Indian and Alaska Native (NI/AN) Female Adolescent and Young Adults (FAYAs) at Risk for GDM and Their Adult female Caregivers at

American Diabetes Association Annual Scientific Meeting on June 21-24, 2024 in Orlando FL.

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 31, 2024 - April 30, 2024 period

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5. NNR-17.281 PI: Nanibaa' Garrison

Perspectives on Genetic Research in the Navajo Nation

Reason on Agenda: Conference Presentation

Description: Request Review and Acceptance of Conference Presentation Abstract titled: "Virtual Deliberations about Genetic Research & Policy Considerations on the Navajo Nation" on June 10, 2024 in New York City, NY at Ethical, Legal, and Social Implications Congress (ELSICon) Conference.

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) August 16, 2023 - November 21, 2023, 2) November 21, 2023 - February 20, 2024 period

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Reason on Agenda: Amendment

Description: Request Review and Acceptance of Amendments to

- 1.) add Dalaki Lovington, PhD to Study
  - 2.) Update in-person deliberation
  - 3.) Offer \$400 for participation and completion of post-deliberation survey
  - 4.) revised Consent Form for In-person deliberations.
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6. NNR-21.398 PI: Karletta Chief

Assessing Navajo COVID-19 Risks and Increasing Indigenous Resilience

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Project Status Report covering 2020 - 2023 period to Disseminate to Communities and Partners and Abstract titled: Investigating Linkages between arsenic exposure, diabetes and COVID-19 Infections and risks on the Navajo Nation, for 8th ISFEV Conference Tokyo, Japan on June 9, 2024

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7. NNR-18.302 PI: Mark Bauer

Navajo NARCH Partnership: Evaluation of the Student Enhancement Program

Reason on Agenda: Amendment

Description: Request Review and Acceptance of Amendment of SREP practicum Site Mentor Survey (Modified)

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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: Conference Presentation

Description: Request Review and Acceptance of Conference Presentation title: "Dine Parents Taking Action for Autism: A Community- Engaged Program Adaption & Pilot Trial". At Autism Consortium of Texas on May 10, 2024 via zoom.

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Reason on Agenda: Quarterly Review

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

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Reason on Agenda: Add/Change Co-Investigators

Description: Request Acceptance and Approval to add Dr. Davis Henderson and Dr. Candi Running Bear as Principal Investigators. Attachments: CVs, Human Research Certification.

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9. NNR-18.311b PI: Nancy Whitesell

Multisite Implementation Evaluation of Tribal Home Visiting (MUSE)

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract for Presentation titled: Multi-Site Implementation Evaluation of Tribal Home Visiting (MUSE) at Research and Evaluation Conference on Self-Sufficiency (RECS), in Washington, DC on May 29-31, 2024.

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10. NNR-23.472 PI: Nancy Rumbaugh Whitesell

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

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering April 18, 2023 - April 17, 2024 period.

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11. NNR-18.307 PI: Laura Hammitt

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

Reason on Agenda: Continuation Request

Description: Request Review and Acceptance of Continuation Covering June 19, 2024- June 19, 2024 period

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Reason on Agenda: Annual Report

Description: Request Review and Acceptance of Annual Report Covering June 19, 2024- June 19, 2024 period

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12. NNR-19.343 PI: Laura Hammitt

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

Reason on Agenda: Continuation Request

Description: Request Review and Acceptance of Continuation Covering June 18, 2024 - June 18, 2025 period

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Reason on Agenda: Annual Report

Description: Request Review and Acceptance of Annual Report Covering June 18, 2024 - June 18, 2025 period

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report Covering January 1 - March 31, 2024 period

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13. 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 January 1 - March 31, 2024 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report Covering June 22, 2023- June 22, 2024 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request Covering June 22, 2024- June 22, 2024 period

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14. 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: Conference Presentation

Description: Requesting Review and Acceptance of Conference Hosted by the Society for Prevention Research on May 28 - 31, 2024 at Washington, DC

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15. NNR-21.401 PI: Jennifer Richards

Evaluation of Azhee Bidziil (Strong Fathers) Program: Improving Outcomes Among Rural Fathers and their Families.

Reason on Agenda: Amendment

Description: Request Review and Acceptance of Amendment: Recruitment Handout (v5, 20 December 2023)

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Reason on Agenda: Continuation Request

Description: Request Review and Acceptance of Continuation Covering June 15, 2024- June 15, 2024 period

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Reason on Agenda: Conference Presentation

Description: Request Review and Approval of Conference Presentation Hosted by the Society for Prevention Research on May 28 - 31, 2024 at Washington, DC

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report Covering January 1 - March 31, 2024 period

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16. 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 January 1 - March 31, 2024 period

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Reason on Agenda: Annual Report

Description: Request Review and Acceptance of Annual Report covering June 20, 2024 - June 20, 2025 period

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Reason on Agenda: Continuation Request

Description: Request Review and Acceptance of Continuation covering June 20, 2024 - June 20, 2025 period

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17. NNR-23.463 PI: Leonela Nelson

Family Spirits Strengths

Reason on Agenda: Amendment

Description: Requesting Review and Acceptance of Amendment: 1) Addition of two indicator questions to the depression screener (CESDR-10), 2) Addition of question "Which IHS service unit are you closest to" in the interest Form.

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18. 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: Annual Report

Description: Request Review and Acceptance of Annual Report Covering June 20, 2023 - June 20, 2024 period

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Reason on Agenda: Continuation Request

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

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### SERIOUS ADVERSE EVENT

1. NNR-21.401 PI: Jennifer Richards

Evaluation of Azhee Bidziil (Strong Fathers) Program: Improving Outcomes Among Rural Fathers and their Families.

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Participant Deceased

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*Last Page and End of Agenda*