Navajo Nation Human Research Review Board Meeting Agenda

Meeting Date: 2023-11-21 Meeting Time: 9:00 AM Location: ZOOM

MEMBERS:

David Begay, Ph.D S	Scientific Education
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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

OLD BUSINESS:

- I. Meeting Call to Order:
- II. Roll Call:
- Invocation:
- Introduction:

III. Review and Approval of November 21, 2023 Meeting Agenda:

IV. Review and Acceptance of Quarterly Reports:

NEW BUSI NESS: V. Acceptance and Approval of New Presentations:

VI. Acceptance and Approval of Returning Presentations:

VII. Serious Adverse Events (SAEs):

VIII. Review and Acceptance of Manuscripts: 1) Educators as Emotionall/Social Guardians, Advocates, and Leaders: Finding Resilience and wellbeing amidst the pandemic for Indigenous communities - Dr. Angelina Castagno NNR-19.359, 2) Prevalence and Predictors of Female Sexual Dysfunction Among Sexually Active Women in the Diabetes Prevention Program Outcomes Study - Dr. Shah, NNR-02.110, 3) Persistance of vaccine serotype carriage in the PCV-13 era and differences in the pneumococcal carriage by laboratory method and sample type among Indigenous children and adults in the Southwest United States - Dr. Laura Hammitt NNR-09.253, 4) Multi-strain carriage and intrahost diversity of Staphylococcus aureus among Indigenous adults in the United States. Dr. Laura Hammitt NNR-16.238, 5) Longitudinal Associations of Depression and Diabetes with Alzheimer's and Related Dementias riak among American Indian and Alaska Native Peoples - Dr. Joan O'Connell NNR-11.342. 6) Machine Learning to Prodict Dementia for American Indian and Alaska Native Peoples. Dr. Joan O'Connell NNR-11.342 7) Trends in Anti-Diabetic Medication Use, Severe Hyperglycemia, and Severa Hypoglycemia among American Indian and Alaska Native Peoples 2009-2013. Dr. Joan O'Connell NNR-11.342

IX. Noon Hour Discussion: IRB Exemption Request for Navajo Epidemiology - Delvin Yazzie

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 July 1, 2023 - September 30, 2023 period

2. 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 July 1, 2023 - September 30, 2023 period

3. 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 July 1, 2023 - September 30, 2023 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2023 - September 30, 2023 period

4. 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 July 1, 2023 - September 30, 2023 period

5. 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 July 1, 2023 - September 30, 2023 period

6. 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

NNR-17.282 PI: Laura Hammitt 7.

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: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2023 - September 30, 2023 period

8. NNR-18.307 PI: Laura Hammitt

Safety and Immunogenicity of V114 in Adults at Risk for Pneumonoccal Disease (Adult PCV15 Study) Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2023 - September 30, 2023 period

9. 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 July 1, 2023 - September 30, 2023 period

10. 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 July 1, 2023 - September 30, 2023 period

PI: Laura Hammitt 11. NNR-20.376

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 July 1, 2023 - September 30, 2023 period

PI: Laura Hammitt 12. NNR-20.381

A Phase 1/2/3 Placebo-Controlled, Randomized, Observer-Blind, Dose-Find Study to Evaluate the Safety, Tolerability, Immunigenicity, 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 July 1, 2023 - September 30. 2023 period Page 4

13. 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 July 1, 2023 - September 30. 2023 period

14. NNR-21.414 PI: Laura Hammitt

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

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2023 - September 30. 2023 period

15. 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 July 1, 2023 - September 30. 2023 period

16. 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 July 1, 2023 - September 30. 2023 period

17. 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 July 1, 2023 - September 30, 2023 period

18. 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 July 1, 2023 - September 30, 2023 period

19. 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 July 1, 2023 - September 30, 2023 period

20. 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 July 1, 2023 - September 30, 2023 period

21. 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 July 1, 2023 - September 30, 2023 period

22. 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 July 1, 2023 - September 30, 2023 period

23. 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 July 1, 2023 - September 30, 2023 period

24. 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 July 1, 2023 - September 30, 2023 period

25. 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 July 1, 2023 - September 30, 2023 period

26. 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

27. 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 July 17, 2023 - October 17, 2023 period

28. NNR-18.322 PI: Vincent Werito

Developing Community Partnerships Through Research to Define Community Well-Being from a Dine' Centered Perspective with Three (Dine') Navajo Communities in New Mexico

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 16, 2023 - August 16, 2023 period

29. NNR-19.355 PI: Sally Davis

Healthy Places-Healthy People

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering August 20, 2023 - November 19, 2023 period

30. 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 Reports covering 1) February 1, 2023 - April 30, 2023; 2) May 1, 2023 - July 31, 2023; 3) August 1, 2023 - October 31, 2023 periods

31. NNR-20.373 PI: Vincent Werito

Cultural Characteristics of Successful Aging from a Dine Perspective: The Significance of Dine Elder knowledge in Achieving Long-Life Happiness as community well-being

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 12, 2023 - August 12, 2023 period

32. NNR-20.391 PI: Heidi Brown

Impact of the COVID-19 Pandemic on Navajo Adults and Health Care Providers Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2023 - September 30, 2023 period

<u>33. NNR-21.401 PI : Jennifer Ri</u>chards

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 July 1, 2023 - September 30, 2023 period

34. 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 July 1, 2023 - September 30, 2023 period

35. NNR-21.428 PI: Vincent Werito

Wide Engagement for Assessing Vaccine Equity in New Mexico (WEAVE NM) Reason on Agenda: Quarterly Review Description: Request Review and Acceptance of Quarterly Report covering May 16, 2023 - August16, 2023 period

36. 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 July 1, 2023 - September 30, 2023 period

37. NNR-22.445 PI: Joshuaa Allison-Burbank

Piloting + Connection is Medicine Reason on Agenda: Quarterly Review Description: Request Review and Acceptance of Quarterly Report covering July 1, 2023 - September 30, 2023 period

38. NNR-22.449 PI: Ashley Lee

Dine' Household Water Survey Reason on Agenda: Quarterly Review Description: Request Review and Acceptance of Quarterly Report covering July 1, 2023 - September 30, 2023 period

<u>39. NNR-22.452 PI: Suzanne Singer</u>

Transportation Behaviors Related To Food & Energy In Rural Navajo And Hopi Communities Reason on Agenda: Quarterly Review Description: Request Review and Acceptance of Quarterly Report covoring June 4, 2023 August 3, 2023 pc

Description: Request Review and Acceptance of Quarterly Report covering June 4, 2023 - August 3, 2023 period

40. NNR-23.463 PI: Leonela Nelson

Family Spirits Strengths Reason on Agenda: Quarterly Review

41. 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 July 1, 2023 - September 30, 2023 period

42. 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 July 1, 2023 - September 30, 2023 period

43. 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 July 1, 2023 - September 30, 2023 period

NEW PRESENTATION(S)

1. NNR-23.480 PI: LaNaya Cook

Teacher's Experiences in Motivating and Helping Navajo Students Academically and Developing or Improving Self-Efficacy: A Qualitative Descriptive Study

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 08/29/2023

2. NNR-23.481 PI: Vera Johnson

Describing Work-Family balance (WFB) in the Lives of Traditional Dine Woman

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 10/05/2023

3. NNR-23.485 PI: Harrison Cayatineto

microRNA Based Inhibition against the Nucleocapsid Protein Synthesis in Bovine Viral Diarrhea Virus: A Surrogate Model for Hepatitis C. Virus Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 10/10/2023

RETURNING PRESENTATION(S)

1. NNR-22.454 PI: Elana Begay

How do Tribal Judges Understand Indigenous Peacemaking as Crime Control Tools, and their Varying Notions of Accountabilit

Reason on Agenda: Final Report - Thesis

Description: Request Acceptance and Approval to Final Thesis Report and Close Study.

2. NNR-18.311b PI: Nancy Whitesell

Multisite Implementation Evaluation of Tribal Home Visiting (MUSE) Reason on Agenda: Approval for Dissemination Description: Request Acceptance and Approval of public dissemination from Study.

3. NNR-15.231 PI: Sara Selig

Engaging Patients and Stakeholders to Improve Cancer Outcomes in Navajo Nation

Reason on Agenda: Continuation Request

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

Reason on Agenda: Quarterly Review Description: Request Review and Acceptance of Quarterly Report covering June 15, 2023 - September 15, 2023 period

4. NNR-15.199 PI: Carmen George

REACH for Healthy Navajo Communities.

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination Materials: 1) Increasing access to Healthy Foods through COPE Navajo Fruit and Vegetable Prescription Program, 2) Produce Prescriptions on the Navajo Nation, 3) Trail Enhancements on Navajo Nation, 4) Establishing Certification for Community Health Workers on Navajo Nation

5. 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 June 19, 2023 - September 19, 2023 period

Reason on Agenda: Continuation Request

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

Helicobacter Pylori Infection and Stomach Cancer

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering December 1, 2023 - November 30, 2024 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering 1) December 1, 2022 - February 28, 2023, 2) March 1, 2023 - March 31, 2023, 3) June 1, 2023 - August 30, 2023 period

7. 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 July 1, 2023 - September 30, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 1, 2022 - September 30, 2023 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 1, 2023 - September 30, 2024 period

8. NNR-18.330 PI: Laurie Hudson

Thinking Zinc

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments 1) Revision of Protocol, 2) Revision of Consent. TABLED FROM October 24th Meeting.

Reason on Agenda: Consent Modification

Description: Request Acceptance and Approval of Consent Modification to be part of a Research Study

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments to Protocol: 1) New funding from N Higher Education Department, 2) Expansion of Geographical study area, 3) increase in the number of maximum from 100-200, 4) Increase amount of compensation, 5) Increase amount of blood collected from 1-2 tablespoons of blood, 6) De-identified urine sample to be sent to Columbia University for analysis, 7) addition of 24-hour food recall to help with nutrient intake assessment.

9. NNR-19.349 PI: Tasha Seneca Keyes

Restorative Justice practices for improving school-based relationships

Reason on Agenda: Annual Report Description: Request Acceptance and Approval of Annual Report covering July 17, 2022 - July 24, 2023 period

Reason on Agenda: Continuation Request Description: Request Acceptance and Approval of Continuation Request covering July 17, 2023 - July 16, 2024 period

10. 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 June 18, 2023 - September 17, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 18, 2022 - September 17, 2023 period

11. 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 July 1, 2023 - September 30, 2023 period

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Updated IHS-810 Form Release of Information Form.

12. 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: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering December 20, 2023 - December 20, 2024 period

Reason on Agenda: Annual Report Description: Request Acceptance and Approval of Annual Report covering December 20, 2022 - December 20, 2023 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2023 - September 30, 2023 period

13. 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

Reason on Agenda: Annual Report Description: Request Acceptance and Approval of Annual Report covering December 15, 20222 - December 15, 2023 period

Reason on Agenda: Continuation Request

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

14. NNR-20.392 PI: Laura Hammitt

Protecting Native Families from COVID-19

Reason on Agenda: Continuation Request

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

Reason on Agenda: Annual Report

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

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2023 - September 30, 2023 period

15. 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 Parent Permission for Child Development Sceening typo From Consent to Parent Permission.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2023 - September 30, 2023 period

16. NNR-21.425 PI: Wayne Morgan

Healthy Hooghans Pilot Project

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 19, 2022 - October 18, 2023 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering June 27, 2023 - June 26, 2024 period

17. 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 Review and Acceptance of Quarterly Report covering June 25, 2023 - September 24, 2023 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering December 31, 2023 - December 31, 2024 period

18. NNR-22.456 PI: Dornell Pete

Navajo ABID Study II: Helicobacter pylori risk and treatment experiences in Navajo Adults Reason on Agenda: Consent Modification

Description: Request Acceptance and Approval of updated Consent Form, Phone Script, Outreach Material Consent, REDcap intake form.

19. NNR-22.458 PI: James McKenzie

Dine Language and Culture Revitalization-Focused Schools

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) April 1, 2023 - June 30, 2023, 2) July 1, 2023 - September 30, 2023 periods

Reason on Agenda: Continuation Request Description: Request Acceptance and Approval of Continuation Request covering January 10, 2024 - January 10, 2025 period

Reason on Agenda: Consent Modification

Description: Request Acceptance and Approval of Revised Consent Form for Continuation Request 2024-20.

20. NNR-21.398 PI: Karletta Chief

Assessing Navajo COVID-19 Risks and Increasing Indigenous Resilience

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to change of Institution for Dr. Ricky Camplian from NAU to Indiana University.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to add new Nenahnezad and UpperFruitland Chapters to Study.

21. NNR-19.359 PI: Angelina Castagno

Strengthening Teaching in Native Serving Schools Through Long-Term, Culturally Responsive Professional Development

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering September 18, 2023 - September 18, 2024 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 18, 2022 - September 18, 2023 period

22. NNR-21.430 PI: Elise Christopher

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

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 20, 2023 - October 20, 2024 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report cover October 20, 2022 - October 19, 2023 period

23. 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: Conference Presentation

Description: Request Acceptance and Approval of Conference Presentation titled: Migration Adjusted Cox Model for Electronic Health Records: An Application in the Indian Health Service and Tribal Health Programs Data.

SERIOUS ADVERSE EVENT

1. NNR-02.110 PI: Vallabh Shah

Diabetes Prevention Program Outcomes Study (DPPOS) Reason on Agenda: Primary - Off Site SAE Description: Diagnosis: COVID-19

Reason on Agenda: Primary - Off Site SAE Description: Diagnosis: Osteoarthritis Right Knee Replacement <u>NNR-20.374</u> 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: Broken Femur

Last Page and End of Agenda