

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

Meeting Date: 2022-09-27 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:
 - Introduction:
- III. Review and Approval of Agenda:
- IV. Review and Approval of April 19, 2022 Meeting:

NEW BUSINESS:

- V. Review and Approval of Quarterly Reports:
- VI. New Presentations:
- VII. Returning Presentations:
- VIII. Serious Adverse Events (SAEs)
- IX: Noon Hour Discussion:
- X. Review and Acceptance of Manuscripts: 1) A Policy, systems and Environment approach to decreasing sugar..... -NNR-16.264; 2) Phase 3 Trial to Evaluate the Safety, Tolerability, and Immunogenicity of V114.....NNR-18.307; 3) Association of diabetes subgroups with cognitive status and assessment NNR-02.094; 4) Weight changes during COVID Shutdown in Older Individuals with Type 2 Diabetes: NNR-

02.094; 5) The Association of Total Knee Arthroplasty with Weight Loss in the Look AHEAD Clinical Trial - NNR-02.094; 6) Association of Timing of Moderate-to-Vigorous Physical Activity; 7) Chronic Community Exposure to Environmental Metal Mixtures ... NNR-11.323.

XI. Announcement / Adjournment of Meeting:

QUARTERLY REPORTS

1. NNR-14.179 PI: Shawn Jordan

Engineering Design Across Navajo Culture, Community and Society

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 21, 2022 - August 20, 2022 period

2. NNR-15.199 PI: Carmen George

REACH for Healthy Navajo Communities.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering March 17, 2022 - June 17, 2022 period

3. NNR-16.263 PI: Robin Harris

Helicobacter Pylori Infection and Stomach Cancer

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering March 1, - May 31, 2022 period

4. NNR-19.337 PI: Crystal LoudHawk-Hedgepeth

Kresge Inquiry Project

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) January - March 2022; 2) April-June 2022; 3) July-August 2022; 4) updated July-August 2022 periods

5. NNR-19.355 PI: Sally Davis

Healthy Places-Healthy People

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance and Approval of Quarterly Report covering April 1, 2022 - June 30, 2022 period

6. 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 MedWatch Safety Report (202200012540) July 8, 2022. Data Safety Monitoring Committee - Recommendation (July 12, 2022)

7. 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: (Other)

Description: Request Review and Acceptance of MedWatch Safety Report (202200012540) July 8, 2022. Data Safety Monitoring Committee - Recommendation (July 12, 2022).

8. NNR-21.412 PI: Joel Gittelsohn

Formative Research to Improve WIC Participation in Three Diverse Native American Communities

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports: 1) June 15,-September 15, 2021; 2) September 15, 2021 - December 15, 2021; 3) December 15, 2021 - March 15, 2022 periods

9. NNR-21.423 PI: Akash Gupta

Evaluating the Impact of the Gallup COVID-19 Respiratory Shelter

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 1, 2022 - August 1, 2022 period

10. NNR-21.428 PI: Vincent Werito

Wide Engagement for Assessing Vaccine Equity in New Mexico (WEAVE NM)

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 16, 2022 - October 16, 2023 period

NEW PRESENTATION(S)

1. NNR-22.450 PI: Candi Running Bear

Culturally Relevant Dialogic Reading to Increase Vocabulary in Navajo Preschoolers with Disabilities

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 08/22/2022

2. NNR-22.451 PI: Christine Ami

Dilji nidaiilah (today, we butche): Dine Lessons from Sheep on Life, death, and re-memembering

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Stud; Date Received - 08/26/2022

3. NNR-22.452 PI: Suzanne Singer

Transportation Behaviors Related To Food & Energy In Rural Navajo And Hopi Communities

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 09/01/2022

RETURNING PRESENTATION(S)

1. NNR-18.312 PI: Laura Brown

Lactation and Technology for Community Health (LATCH)

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final Report covering August 21, 2018 - August 16, 2022 period. enclosed is Published manuscript and Raw data.

2. NNR-21.425 PI: Wayne Morgan

Healthy Hooghans Pilot Project

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 19, 2022 - October 19, 2023 period

3. NNR-02.094 PI: Mary Hoskin

Action for Health in Diabetes Look AHEAD

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 16, 2021 - October 16, 2022 period

4. NNR-16.247 PI: Bruce Bender

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

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation request covering September 20, 2022 - September 20, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 20, 2021 - September 20, 2022 period

5. NNR-16.258 PI: Randall Swaim

Substance use among American Indian Youth attending schools on or near Reservation

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments for 7-12th grade surveys: 1) delete related COVID-19 questions; 2) Delete of other questions; 3) Add new questions; 4) shorten of survey by 38 items.

6. NNR-17.266 PI: Jani Ingram

Mutton Consumption Survey

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February 22, 2022 - May 21, 2022 period

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Poster to be presented at National Meeting of the Society for the Advancement of Chicanos and Native Americans in San Juan, Puerto Rico, on October 27-29, 2022, or American Indian Society for Engineering and Science in Palm Springs, CA on October 6-8, 2022. Co-Presented by Dr. Ingram and student Ashley Hale and Andee Lister.

7. NNR-17.277 PI: Denise Charron-Prochownik

Stopping Gestational Diabetes in Daughters and Mothers - Phase 2

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering July 19, 2022 - July 18, 2023 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April 1 - July 31, 2022 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering July 19, 2021 - July 18, 2022 period

8. NNR-17.289 PI: Eudora Redhouse

Youth Builders

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to conduct Community Needs and Resources Assessment among Central Consolidation District's Middle and High School students, parents, caregivers, school administrators, health clinic providers, and community members at Shiprock, Kirtland and Newcomb to begin October 1, 2022

9. NNR-19.360 PI: Debra MacKenzie

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

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Poster Titled: Validation of the CBCL and Achenback TOF from use with the Navajo Birth Cohort Study for the American Academy of Child and Adolescent Psychiatry (AACAP) Annual Meeting in October 17-22, 2022 in Toronto.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering September 18, 2022 - September 17, 2023 period. Includes update consent form reflecting continuation dates.

10. NNR-20.380 PI: Regina Eddie

Examining School Wellness in American Indian Communities

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 18, 2022 - August 18, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 18, 2021 - August 18, 2022 period

11. 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: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April 1, 2022 - June 31, 2022 period.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval to Add Two undergraduate students Erin Hill and Anna Leaf to study team. Attached CITI Certificates, NAU IRB approval Letter.

12. NNR-21.401 PI: Jennifer Richards

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

Reason on Agenda: Approval for Dissemination

Description: Request permission for a video to be played on Navajo Nation TV, include recruitment language who to contact if men want to learn more - Tabled from July 19, 2022 Meeting

13. NNR-21.409 PI: Carmen George

Expanding and Evaluating a community-based intervention to increase healthy beverage consumption by Navajo Preschool Children

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to Modify Caregiver Survey with additional questions. Track and Clean versions

14. NNR-21.398T PI: Karletta Chief

Assessing Navajo COVID-19 Risks and Increasing Indigenous Resilience

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of 2 Amendments to revise 1) Study Aims, Objectives, 2) methods and procedures

15. 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: Amendment

Description: Request Acceptance and Approval of Revision to Protocol: 1) Removal of (CES-D) The Center for Epidemiologic Studies Depression Scale, NIH Researcher explained CES-D is not particularly useful validating ASQs, Language was removed from research plan.(v4) 2) Revision of Informed Consent Form (V4) do not have certificate of confidentiality. 3) Participante Demographic Questinnaire was revised to add ifentifying whic community participants live in. New Study Document: 4) Recruitment Flyer (v1) creat new flyer for use in clinic based on the NIH recommendation researchers, 5) Columbia Suicide Severity Rating Scale (C-SSRS) Screener was previously submitted to NNHRRB, ASQ and PHQ (patient health questinnaire - screens for depression) 6) Suide Ideation Questionnire (SIQ and SIQ Jr), 7) Demographics Questionnaire - Decline, 8) Evaluation Questionnaire.

16. 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: Annual Report

Description: Request Acceptance and Approval of Anual Report covering October 16, 2021 - October 16, 2022 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Request Continuation covering October 16, 2022 - October 16, 2023 period

17. NNR-22.436 PI: Franklin Sage

The Changing Landscape and Climate of Dine'tah

Reason on Agenda: Amendment

Description: Request Acceptance and Approval to add Survey Component to Study.

18. 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: Annual Report

Description: Request Acceptance and Approval of Annual Report covering May 19, 2021 - May 19, 2022 period

19. 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: Amendment

Description: Request Acceptance and Approval of Protocol Amendment 10 pertaining to Sub-study D, which CAIH sites did

not participate, participants in Cohort 3 of Sub-study D has been changed from BNT162b2 OMI 30g to BNT162b2 30 ug.

20. 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: Conference Presentation

Description: Request Acceptance and Approval of Two (2) Abstracts for Conference Presentations: 1) Nirsevimab for the prevention of RSV disease in healthy late-preterm and term infants: follow-up through second RSV season and Nirsevimab for the prevention of RSV: Pooled efficacy from Phase IIb and Phase III trials in preterm and term infant at RSV 2022 Conference at Belfast, Northern Ireland on September 29-October 2, 2022,

The Safety and Efficacy of Nirsevimab for Medically attended RSV Lower Respiratory Tract Infection in all infants enrolled in the Phase 3 MELODY Trial at ID week 2022 on October 19-23, 2022 in Washington DC

21. 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: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 18, 2022 - October 18, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 18, 2021 - October 18, 2022 period

22. 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: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 19, 2022 - October 19, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 19, 2021 - October 19, 2022 period

23. NNR-05.174 PI: Allison Barlow

In-home Prevention of Substance Abuse Risk in Navajo Teen Families

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 17, 2022 - October 17, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual report coveing October 17, 2021 - October 17, 2022 period

24. 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 add a survey reminder to participant's outreach package.

25. NNR-22.449 PI: Ashley Lee

Dine' Household Water Survey

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Modified Research Plan updating household water questionnaire, update water quality testing consent form, and a new brochure.

26. NNR-18.302 PI: Mark Bauer

Navajo NARCH Partnership: Evaluation of the Student Enhancement Program

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Posters at meeting of the Academic Partnership in Research - Arizona Innovation Alliance. on September 27 and 28, 2022 at Flagstaff Moutain Campus

SERIOUS ADVERSE EVENT

1. 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: Pneumonia, febrile seizures, dehydration

2. 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: Seizures, COVID-19

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: Primary - Off Site SAE

Description:

Diagnosis: Undetermined (alcohol related)

Last Page and End of Agenda