

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

Date: October 20, 2020, Time 1:00 – 4:00 PM

Teleconference Call-In Number: **978-990-5350**, Access Code: **5891214**

Confidentiality – NNHRRB respectfully requests that the meeting not be audio/video recorded by participants. Thank You.

MEMBERS:

Beverly Becenti-Pigman, Chairperson - Community
Dr. David Begay, Ph.D. - Scientific Education
Dr. Nanibaa' Garrison, Ph.D. - Genetics, Bio-Ethics
Dr. Rebecca Izzo-Manymules, Ph.D. - Education
Ursula Knoki-Wilson, MSN, MPH - Nursing
Dr. Kalvin White, Ph.D. - Scientific Education
Dr. Sonya Shin, MD - Medicine
Delvin Yazzie, MPH – Epidemiology

OLD BUSINESS:

- I. Meeting Call to Order:
- II. Roll Call:
 - Invocation:
 - Introduction:
- III. Review and Approval of October 20, 2020 Agenda:
- IV. Review and Approval of August 18, August 27, 2020 Meeting Minutes.

NEW BUSINESS:

- V. Quarterly Reports:
- VI. New Presentations:
- VII. Returning Presentations:
- VIII. Serious Adverse Events:
- IX. Noon Hour Discussion: 1) NNHRRB Chair Selection, 2) NN Health Command Operation Center COVID-19 update - Dr. Jill Moses, MD
- X. Abstracts Review and Acceptance
- XI. Announcement and Adjournment:

NEW PRESENTATION(S)

1. NNR-20.382T PI: Johnson, Debralee
Diabetes Standards of Care and Clinical Practice on Foot Care
Reason on New Title
Description: Request Review and Acceptance of New Study
2. NNR-20.383T PI: Lee, Murlynn Crystal PhD, MPH
Identifying Sociocultural Levels of Attitudes Towards Acceptability of COVID-19 Public Health Videos and Associated Public Health Recommendation Levels of Adherences to Reduce COVID-19 among the Navajo Nation
Reason on New
Description: Request Review and Acceptance of New Study
3. NNR-20.384T PI: Pete, Dornell MPH
Assessing the Gut MicroBiota and Individual Diet in the Navajo ('Abid Study)
Reason on New Title
Description: Request Review and Approval of New Study
4. NNR-20.385T PI: Garrity, Geraldine, MA
A Study on the Bureau of Indian Education (BIE) Navajo Language Immersion Programs
Reason on New Title
Description: Request Review and Approval of New Study
5. NNR-20.386T PI: Haskie, Miranda J. Ph.D.
Observing PPE Use in One Navajo Nation Community during COVID-19 Pandemic
Reason on New Title
Description: Request Review and Approval of New Study
6. NNR-20.387T PI: Hammitt, Laura MD
Protecting Native Families from COVID-19
Reason on New Title
Description: Requesting Review and Approval of New Study

RETURNING PRESENTATION(S)

1. NNR-02.106 PI: Dabelea, Dana MD
SEARCH for Diabetes in Youth Study
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering June 18, 2020 - September 18, 2020 period
2. NNR-05.175 PI: Mohs, Kimberly MD
Navajo Area Indian Health Services - Cardiovascular Risk Reduction Demonstration Project
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering ending October 2020 period
3. NNR-10.287 PI: Gittelsohn, Joel Ph.D.
Multilevel Obesity Prevention Trial for American Indian Community (OPREVENT)
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July, August, September 2020 period

4. NNR-11.319 PI: Patten, Christi A. PhD.
Family Cancer Literacy to Promote Mammography Screening among Navajo Women
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering 1) November 23, 2019 - February 22, 2020, 2) May 23, 2020 - August 22, 2020. Attached copy Published Manuscript
5. NNR-18.296 PI: Bauer, Mark C. Ph.D.
Secondary Data Analysis of American Indian students' resilience through digital storytelling and final projects in the Din'e College Summer Research Enhancement Program Curriculum.
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering May 20, 2020 - August 20, 2020 period
6. NNR-19.368 PI: Colling, Lisa M. Ph.D.
Parent Kit Evaluation Study
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering June 23, 2020 - September 22, 2020 period
7. NNR-16.245 PI: Gittelsohn, Joel Ph.D.
Engaging Tribal Policy Makers to Sustain Improvements to the Food and Physical Activity in American Indian Communities (OPREVENT2)
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July, August, September 2020 period
8. NNR-20.373 PI: Werito, Vincent Ph.D.
Cultural Characteristics of Successful Aging from a Din'e Perspective: The Significance of Din'e Elder knowledge in Achieving Long-Life Happiness as community well-being
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering May 12, 2020 - August 12, 2020 period
9. NNR-09.259 PI: Santosham, Mathuram MD
Menu for Life - Assessing Food Security Risk among At-Risk Southwestern Native Americans
Reason on Final Report
Description: Request Acceptance and Approval of Final Report covering 2009 - 2020 period
10. NNR-17.273 PI: Dayle John, Kelsey Ph.D.
What can the Navajo Horse teach us about decolonizing education.
Reason on Close Study
Description: Request Acceptance and Approval to Close-out Study. (Graduated, NN IRB approved Dissertation, Final Report)
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering April 18, 2019 - April 18, 2020 period
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering 1) January 18, 2020 - April 18, 2020, 2) April 18, 2020 - July 18, 2020 period
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering April 18, 2020 - April 18, 2021 period

11. NNR-15.223 PI: Richards, Jennifer Ph.D.
Formative Research to Inform the Development of an Intergenerational Strengths-Based Program for American Indian Girls as they Transition to Adulthood.
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering December 15, 2020 - December 15, 2021 period
12. NNR-15.232 PI: Hammitt, Laura MD
Etiology of pneumonia and burden of pneumococcal pneumonia in hospitalized American Indian adults
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering November 17, 2020 - November 17, 2021 period
13. NNR-16.264 PI: Reid, Raymond MD
Preventing Early Childhood Obesity, Part I: Family Spirit Nurture, 3-9 Months, Part II: 18 Months
Reason on Continuation Request
14. NNR-11.346 PI: Reid, Raymond MD
Together on Diabetes Study: Evaluation of a pilot Diabetes Prevention and Management Program for American Indian Youth.
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering December 21, 2020 - December 21, 2021 period (Part I)
15. NNR-02.110 PI: Knowler, William MD
Diabetes Prevention Program Outcomes Study (DPPOS)
Reason on Amendment
Description: Request Acceptance and Approval of Amendment to Revised Study (V4.6) Phase 3 final year, and pending NIH Continuation Approval Letter, Revised Consent Form, to add 2 Co-PIs.
Reason on Add/Change Co-Investigators
Description: Request Acceptance and Approval of adding 2 Co-PI: Dr. Sara Michaels and Dr. Kevin McDermott at Northern Shiprock Medical Center.
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering August 19, 2020 - August 19, 2021 period
16. NNR-04.151 PI: Hammitt, Laura MD
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 Annual Report
Description: Request Acceptance and Approval of Annual Report covering September 21, 2019 - September 21, 2020 period
17. NNR-05.165 PI: Reid, Raymond MD
Long Term Impact of the Pneumococcal Conjugate Vaccine on Pneumococcal Nasopharyngeal Colonization and Immune Correlates for Disease Protection
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering September 6, 2019 - September 6, 2020 period

18. NNR-07.216 PI: Reid, Raymond MD
Haemophilus Influenzae among southwestern American Indian Children
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering September 18, 2019 - September 18, 2020 period
19. NNR-16.254 PI: Reid, Raymond MD
Evaluation of NativeVision Year Round Program
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering September 20, 2019 - September 20, 2020 period
20. NNR-06.182 PI: Wallerstein, Nina Dr.PH
Listening to Each Other Curriculum Development Research Project
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering October 21, 2019 - October 21, 2020 period
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering October 21, 2020 - October 21, 2021 period.
Attached UNM HRRC Approval letter.
21. NNR-11.323 PI: Lewis, Johnnye L. Ph.D.
Navajo Birth Cohort Study (NBCS)
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering May 23, 2020 - August 22, 2020 period
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering August 23, 2019 - August 22, 2020 period
22. NNR-14.175 PI: Lombard, Kevin A. Ph.D.
Where Health and Horticulture Intersect: A Navajo Wellness Collaboration
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering June 11, 2019 - June 13, 2020 period
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering: 1) December 18, 2019 - March 17, 2020, 2) March 18, 2020 - June 16, 2020 periods
Reason on Continuation Request;
Description: Request Acceptance and Approval of Continuation Request covering April 15, 2020 - April 15, 2021 period
23. NNR-16.257 PI: Lombard, Kevin A. Ph.D.
Engaging Family and School in Navajo Gardening for Health
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering September 20, 2019 - September 20, 2020 period
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Reports covering: 1) September 18, 2019 - December 17, 2019; 2) December 18, 2019 - March 17, 2020; 3) March 18, 2020 - June 16, 2020; 4) June 17, 2020 - September 15, 2020
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering September 20, 2020 - September 20, 2021 period

24. NNR-19.333 PI: Lombard, Kevin A. Ph.D.

Engaging Navajo Elementary Schools in Randomized Controlled Trial of Y'eeego! Healthy Eating & Gardening

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February 21, 220 - May 19, 2020 period

Reason on Add/Change Co-Investigators

Description: Request Acceptance and Approval to Add Ms. Heather Wilcox as Co-PI to Study. Attachments Part 5 Certification and CV

25. NNR-15.199 PI: Shin, Sonya MD

REACH for Healthy Navajo Communities.

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering 1) March 17, 2020 - June 17, 2020, 2) June 17, 2020 - September 17, 2020 periods

Reason on Approval for Dissemination

Description: Request Acceptance and Approval of 5 Store Dissemination Materials, and Beverage Purchasing Trends on Navajo Nation

26. NNR-16.263 PI: Harris, Robin B. Ph.D., MPH

Helicobacter Pylori Infection and Stomach Cancer

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June 1, 2020 - August 31, 2020 period

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering November 29, 2018 - November 29, 2019 period

Reason on Conference Presentation

Description: Request Acceptance and Approval of Power point Slides Presentation at Annual Meeting of the American Public Health Association (APHA) Conference "Creating the Healthiest Nation Preventing Violence" on October 24-28, 2020, Virtual Conference.

27. NNR-17.277 PI: Moore, Kelly R MD

Stopping Gestational Diabetes in Daughters and Mothers - Phase 2

Reason on Conference Presentation

Description: Request Acceptance and Approval of Power Point Presentation at Diabetes Mellitus Interagency Coordinating Center Committee Meeting on October 30, 2020 at Bethesda, Maryland.

28. NNR-17.281 PI: Garrison, Nanibaa' Ph.D.

Perspectives on Genetic Research in the Navajo Nation

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering 1) January 26, 2020 - April 26, 2020, 2) April 25, 2020 – August 20, 2020 periods.

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 20, 2019 - August 20, 2020 period

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 20, 2020 - August 20, 2021 period

29. NNR-17.283 PI: Russell, Maureen Ph.D.
Sleep Interventions for Caregivers and their Young Children in Part C Programs
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Reports covering: 1) December 19, 2019 - March 19,2020; 2) March 19, 2020 - June 19, 2020; 3) June 19, 2020 - September 19, 2020 periods.
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering September 19, 2019 - September 19, 2020 period
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering September 19, 2020 - September 19, 2021 period
30. NNR-17.288 PI: Dabelea, Dana MD
Tribal Turning Point (TTP)
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 2020-September 2020 period
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering October 16, 2019 - October 16, 2020 period
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering October 16, 2020 - October 16, 2021 period, Attached Consent Form to support continuation period
31. NNR-17.289 PI: Ritter, Lois
Youth Builders
Reason on Change in Investigators
Description: Request Acceptance and Approval of Change of PI from Ms. Lois Ritter to Ms. Eudora Redhouse, attachments from Ms. Debbie Oftedal, President and CV and Part 5 Certification
32. NNR-17.292 PI: Montoya, Lupita Ph.D.
Impact of Heating Stove Replacement on Indoor and Outdoor Pollutants and Respiratory Health in Shiprock, NM Navajo Nation
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Reports covering 2020 periods
Reason on Conference Presentation
Description: Request Acceptance and Approval of Conference Presentation Titled: US Environmental Protection Agency's Household Energy Output Research Webinar, on September 22, 2020.
33. NNR-18.301 PI: Eakins, Danielle Ph.D.
Sexual Assault among American Indian/Alaska Native Tribal Colleges Students: a Secondary Data Analysis Assessing Risk and Resiliency Factors to Inform Prevention and Intervention Methods
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering April 17, 2019 - April 17, 2020 period
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering April 17, 2020 - April 17, 2021 period
34. NNR-18.302 PI: Bauer, Mark C. Ph.D.
Navajo NARCH Partnership: Evaluation of the Student Enhancement Program
Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering; 1) April 17, 2019 - July 17, 2019, 2) July 17, 2019 – October 17, 2019, 3) October 17, 2019 - January 17, 2020, 4) January 17, 2020 - April 17, 2020, 5) April 17, 2020 - July 17, 2020 periods

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering April 17, 2019 - April 17, 2020 period

Reason on Amendment

Description: Request Acceptance and Approval of 10 Amendments: 5 Revised Consent Forms: 1-ISEP Parental Consent Form, SREP Consent Form, 3-BSPH Consent Form, 4-MPH Consent Form, 5-SREP Practicum Mentor Consent Form. and 5 Revised Surveys: 1-ISEP Pre-Survey, 2-ISEP Post-Survey, 3-BSPH Exit Survey, 4-MPH Exit Survey, 5-SREP Practicum Mentor Survey.

35. NNR-18.322 PI: Werito, Vincent Ph.D.

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 Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 16, 2019 - October 16, 2020 period

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 16, 2020 - October 16 2021 period

36. NNR-19.355 PI: Davis, Sally Ph.D.

Healthy Places-Healthy People

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 20, 2019 - August 20, 2020 period

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 20, 2020 - August 20, 2021 period

37. NNR-19.359 PI: Castagno, Angelina E Ph.D.

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

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering September 18, 2020 - September 18, 2021 period

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 18, 2019 - September 18, 2020 period

Reason on Conference Presentation

Description: Request Acceptance and Approval of Conference Presentation on April 2021 meetings.

Reason on Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) September 18, 2019 - December 18, 2019, 2) December 18, 2019 - March 18, 2020, 3) March 18, 2020 - June 18, 2020 periods

38. NNR-19.350 PI: Hammitt, Laura MD

Surveillance for RSV and Other Respiratory Infections among Native American Children and Pregnant Women

Reason on Amendment

Description: Request Acceptance and Approval of Amendments of Main Study; 1) Revise Research Plan, 2) Informed Consent v4; 3) Data Collection Forms, 4) Recruitment Materials. Sub-Study New Materials: 1) Informed Consent, 2) Data Collection Forms, 3) Recruitment Material. Sub-study new materials: 1) Informed Consent, 2) Data Collection Forms, 3) Recruitment Material, 4) other RSV SuNA Antibody Test Results Letter to Adult or Child.

39. NNR-20.376 PI: Hammitt, Laura MD
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 (*The Coronavirus Treatment Study*)
Reason on Amendment
Description: Request Acceptance and Approval of Amendment to Study: 1) Revise inclusion criteria the initial positive SARS-CoV-2 test to allow additional types of test, 2) Revise the diary to collect information through day 14, 3) Revise the amount of plasmato be delivered to minimum of 175 mL to align with Investigational Product Manual, 4) Revised the AE grading system to use Med DRA system, 5) Revise the Statistical Analysis section, 6) Include information about the appointment for second Medical monitor, 7) other minor revisions to align our site-specific of the main trial, 8) Consent Form, I.H.S. 810, Diary Card, Pulse Ox imager Handout, Initial Consent Form.
40. NNR-20.379 PI: Hammitt, Laura MD
Convalescent Plasma to Stem Coronavirus: A Randomized Controlled Double Blinded phase 2 Study Comparing the Efficacy and Safety of Human Coronavirus Immune Plasma (HCIP) vs. Control (SARS-CoV-2 non-immune plasma) among Adults Exposed to COVID-19 (*The Coronavirus Prevention Study*)
Reason on Amendment
Description: Request Acceptance and Approval of Amendments: 1) Increase Sample size 150-500, 2) Revise Definition of "high risk exposure; 3) Revised inclusion criteria for the initial negative SARS-CoV-2, 4) Revise the exclusion criteria to add history of prior COVID-19 infection; 5) Revise the amount of plasma to align with Investigational Product Manual; 6) Revise the AE grading to MedDRA system; 7) Revise Statistical Analysis section, 8) Include information about appointment of second medical monitor, 9) Other minor revision to align our site-specific protocol of the main trial, 10: Revise Consent Form, HIS-810, Consent Flipchart, Initial Consent Form.
41. NNR-20.381T PI: Hammitt, Laura MD
A Phase 1/2/3 Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding 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)
Reason on Amendment
Description: Request Acceptance and Approval of Amendment to Protocol: 1) Reduce the Volume of Blood draws to 20 ml.; 2) Increase sample size for Phase 2/3 to 43,998; 3) Remove exclusion criterion 2 for phase 3 and added criteria for HIV positive participants; 4) Expand age range for inclusion in Phase 2/3 to older adolescents and over 85 years of age,(Navajo Nation only enroll adults into this study); 5) Revised Informed Consent to reflect Protocol changes, 6) Protocol Administrative Change Letter, Amendment 5; 7) Protocol Administrative Change Letter - Amendment 6; 8) Community engagement update; 9) Study Budget.
42. NNR-19.331 PI: Donaldson, Cathron MS,
Understanding Navajo Parents' Beliefs about Cradling and Early Mobility Practices
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Reports covering : 1) February 19 - May 19, 2020, 2) May 19 - August 19, 2020. Copy of Published Manuscripts attached.

43. NNR-02.094 PI: Knowler, William, MD

Action for Health in Diabetes Look AHEAD

Reason on Amendment

Description: Request Acceptance and Approval of Amendments: Protocol v23 Telephone Script-Epidemic-Pandemic Impacts Inventory

Reason on Addition of Co-Investigator

Description: Request Acceptance and Approval of Add Dr. Sara Michaels as Co-Investigator at Northern Navajo Medical Center. Attached CV and Part V Certification

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 23, 2020 - October 15, 2021 period

44. NNR-11.319 PI: Patten, Christi A. PhD

Family Cancer Literacy to Promote Mammography Screening among Navajo Women

Reason on Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 23, 2019 - 2020 period

Reason on Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 23, 2020 - 2021 period

SERIOUS ADVERSE EVENTS

1. NNR-02.110 PI: Knowler, William MD
Diabetes Prevention Program Outcomes Study (DPPOS)
2. NNR-11.323 PI: Lewis, Johnnye L. Ph.D.
Navajo Birth Cohort Study (NBCS)

- IX. Noon Hour Discussion: 1) NNHRRB Chair Selection, 2) NN Health Command Operation Center COVID-19 update - *Dr. Jill Moses, MD*
- X. Abstracts Review and Acceptance
- XI. Announcement and Adjournment:

Last page and end of Agenda