

**Navajo Nation Human Research
Review Board**

**Institutional Review Board
Meeting Agenda**

Meeting Date: Tuesday, September 21, 2021

Meeting Time: 9:00 AM

Location: Teleconference

Teleconference Dial-in Number: 978-990-5350, Access Code: 5891214

Members:

Mrs. Beverly Becenti-Pigman - Community
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, Bio-Ethics
Dr. Rebecca Izzo-Manymules, Ph.D. - **Chairperson** - Education
Dr. Sonya Shin, MD - Medicine
Ms. Ursula Knoki-Wilson, MSN, MPH - Nursing

OLD BUSINESS:

- I. Meeting Call to Order:
- II. Roll Call:
 - Invocation:
 - Introduction:
- III. Review and Approval of Agenda:
- IV. Review and Approval of May 18, 2021 Minutes:
-

NEW BUSINESS:

V. Review and Acceptance of Quarterly Reports:

VI. New Presentations:

VII. Returning Presentations:

VIII. Serious Adverse Events (SAEs):

IX. Noon Hour Discussions: 1) Review and Approval of 2021 Navajo Research Conference Abstracts, 2) Review and Acceptance of 3 Manuscripts, 3) 2021 Research Conference Update - Dr. Mark Bauer

X. Abstract to Submit NN Research Application: 1) Project Co-STEM - Coconino County Education Services Agency, 2) Tribal Home Visiting Continuous Quality Improvement Collaborative Process Study - Tribal Evaluation Institute.

XI. Announcements / Adjournment:

New Presentation(s)

1. NNR-21.420 PI: Guy, Martha S. MA, BA
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Sacred learners in Navajo Head Start: What Teachers Need to Know for Working with Children with Disabilities

Reason on New

Description: Remarks: Request Review and Approval of New Study; Date Received - 08/30/2021

2. NNR-21.421 PI: Burgess, Jeff MD, MS, MPH
-

Arizona Healthcare Emergency Response and other Essential Workers Surveillance (AZ-HEROES) COVID-19 Study

Reason on New

Description: Remarks: Request Review and Approval of New Study; Date Received - 08/31/2021

3. NNR-21.422 PI: Glaser, Katherine MD, MPH
-

Assessment of Efficacy and Acceptability of Home Blood Pressure Monitoring for Pregnant Women Living on the Navajo Nation.

Reason on New

Description: Remarks: Request Review and Approval of New Study; Date Received - 09/01/2021

4. NNR-21.423 PI: Gupta, Akash MD
-

Evaluating the Impact of the Gallup COVID-19 Respiratory Shelter

Reason on New

Description: Remarks: Request Review and Approval of New Study; Date Received - 09/02/2021

Quarterly Reports

1. NNR-02.106 PI: Dabelea, Dana M.D.
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SEARCH for Diabetes in Youth Study

Reason on Quarterly Review -

Description: Request Review and Acceptance of Quarterly Reports covering 1) December 18, 2020-March 18, 2021; 2) March 18, 2021-June 18, 2021; 3) June 18, 2021-September 18, 2021 periods

2. NNR-11.342 PI: O'Connell, Joan M. Ph.D.
-

Comparative Effectiveness of Healthcare Delivery Systems for American Indian and Alaska Native using Enhanced Data Infrastructure

Reason on Quarterly Review -

Description: Request Review and Acceptance of Quarterly Reort covering May 16, 2021 - August 15, 2021 period

Quarterly Reports

3. NNR-14.185 PI: Yazzie, Sheldwin CNMT
-

Assessing Indoor Radon Exposure on the Navajo Nation.

Reason on Quarterly Review -

Description: Request Review and Acceptance of Quarterly Report covering May 1, 2021 - July 31, 2021 period

4. NNR-14.192 PI: deHeer, Hendrik Ph.D., MPH
-

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

Reason on Quarterly Review -

Description: Request Review and Acceptance of Quarterly Reports covering: 1) December 17, 2020 - March 16, 2021; 2) March 17, 2021 - June 16, 2021 periods

5. NNR-17.293 PI: Davis, Jonathan MAS, MA
-

Evaluating Geodesign as a Planning Framework for Navajo Nation Chapters

Reason on Quarterly Review -

Description: Request Review and Acceptance of Quarterly Reports covering 1) January 16, 2021 - April 16, 2021, 2) April 16, 2021 - July 16, 2021 periods

6. NNR-18.330 PI: Hudson, Laurie G PhD
-

Thinking Zinc

Reason on Quarterly Review -

Description: Request Review and Acceptance of Quarterly Report covering April 22, 2021 - July 21, 2021 period

7. NNR-20.373T 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, 2021 - September 12, 2021 period

Renewal

1. NNR-18.311b PI: Whitesell, Nancy Ph.D,

Multisite Implementation Evaluation of Tribal Home Visiting (MUSE)

Reason on Continuation Request -

Description: Request Acceptance and Approval of Continuation Request covering August 20, 2021 - August 19, 2022 period

2. NNR-19.360 PI: MacKenzie, Debra Ph.D.

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

Reason on Continuation Request -

Description: Request Acceptance and Approval of Continuation Request covering September 17, 2020 - September 16, 2022 period

Returning Presentation(s)

2. NNR-05.174 PI: Reid, Raymond MD

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

Reason on Continuation Request -

Description: Request Acceptance and Approval of Continuation Request covering October 17, 2021 - October 17, 2022 period

Reason on Annual Report -

Description: Request Acceptance and Approval of Annual Report covering October 17, 2020 - October 17, 2021 period

3. NNR-09.253 PI: Reid, Raymond MD

Impact of 13-valent pneumococcal conjugate vaccine (PVC13) on pneumococcal disease and colonization among Native American communities

Reason on Annual Report -

Description: Request Acceptance and Approval of Annual Report covering August 18, 2020 - August 18, 2021 period

6. 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, 2021 - August 22, 2021 period

Reason on Continuation Request -

Description: Request Acceptance and Approval of Continuation Request covering August 23, 2021 - August 22, 2022 period, Updated Consent and Assent Forms.

Reason on Annual Report -

Description: Request Acceptance and Approval of Annual Report covering August 23, 2020 - August 22, 2021 period

Returning Presentation(s)

7. NNR-15.223 PI: Richards, Jennifer Ph.D., MPH
-

Formative Research to Inform the Development of an Intergenerational Strengths-Based Program for American Indian Girls as they Transition to Adulthood.

Reason on Annual Report -

Description: Request Acceptance and Approval of Amendments: 1) Revised documents - JHU IRB Research Plan v6 8/19/21, Child Outcomes Assessment v6 8/12/21, 2) New Documents - Poster v1, 8/19/21, Business Cards v1 8/12/21, Self-Referral Form v1, 8/12/21.

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

Helicobacter Pylori Infection and Stomach Cancer

Reason on Quarterly Review -

Description: Request Review and Acceptance of Quarterly Report covering March 1, 2021 - May 21, 2021 period

Reason on Amendment -

Description: Request Acceptance and Approval of Amendment to use 300 DNA samples obtain from de-identified gastric biopsies to detect the presence of antibiotic resistance genes (clarithromycin, metronidazole, levofloxacin) in the bacterium Helicobacter pylori.

10. NNR-17.278 PI: Morrell, Erica Ph.D.
-

Navajo Nation Breastfeeding Coalition - First Food Justice Study

Reason on Annual Report -

Description: Request Acceptance and Approval of Continuation Request covering July 18, 2019 - July 18, 2020 period. TABLED at August 17, 2021 Meeting. Please use documents from August 17th Meeting agenda item.

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

Perspectives on Genetic Research in the Navajo Nation

Reason on Amendment -

Description: Request Acceptance and Approval of Amendment 1) to conduct deliberation over Zoom in 3 hour session (instead of 1.5 day, 2) will offer compensation of \$375 down to \$124/session, 3) updated consent form for deliberation, 4) updated budget, 5) add Ms. Carissa Sherman and Ms. Amanda Skenadore to Study

Reason on Annual Report -

Description: Request Acceptance and Approval of Annual Report covering August 20, 2020 - August 17, 2021 period

Reason on Quarterly Review -

Description: Request Review and Acceptance of Quarterly Reports covering: 1) November 28, 2020 - February 23, 2021, 2) February 24, 2021 - May 18, 2021, 3) May 19, 2021 - August 17, 2021 periods

Returning Presentation(s)

Reason on Continuation Request -

Description: Request Acceptance and Approval of Continuation Request covering August 20, 2021 - August 20, 2022 period

15. NNR-17.282 PI: Hammitt, Laura M.D.

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 Annual Report -

Description: Request Acceptance and Approval of Annual Report covering August 15, 2020 - August 15, 2021 period

18. NNR-17.289 PI: Redhouse, Eudora

Youth Builders

Reason on Quarterly Review -

Description: Request Review and Acceptance of Quarterly Reports covering: 1) January 1, 2021 - March 31, 2021, 2) April 1, 2021 - June 30, 2021 periods

Reason on Continuation Request -

Description: Request Acceptance and Approval of Continuation Request covering October 17, 2021 - October 17, 2022 period

Reason on Add/Change Co-Investigators -

Description: Request Acceptance and Approval to Change Co-Investigator from Ms. Rivas (Resigned) to Ms. Kareen Torres, CV attached.

19. NNR-17.292 PI: Montoya, Lupita

Impact of Heating Stove Replacement on Indoor and Outdoor Pollutants and Respiratory Health in Shiprock, NM Navajo Nation

Reason on Addition of Co-Investigator -

Description: Request Acceptance and Approval to add new researcher Ms. Sarah Zelasky to Study team

21. NNR-18.302 PI: Bauer, Mark C.

Navajo NARCH Partnership: Evaluation of the Student Enhancement Program

Reason on Amendment -

Description: Request Acceptance and Approval of Amendments: 1) Additional Questionnaire, 2) On-line Survey, with Consent Form.

Reason on Quarterly Review -

Description: Request Review and Acceptance of Quarterly Report covering April 17, 2021 - July 17, 2021 period

Returning Presentation(s)

22. NNR-18.312 PI: Brown, Laura MD

Lactation and Technology for Community Health (LATCH)

Reason on Annual Report -

Description: Request Acceptance and Approval of Annual Report covering August 21, 2020 - August 21, 2021 period. TABLED from August 17, 2021 Meeting. Please use documents from 8/17/21 Meeting agenda items.

24. NNR-18.316 PI: Hunter, Deidre Ph.D.

Cultural Responsive Project Based Learning STEM Curriculum for Native American Classrooms

Reason on Annual Report -

Description: Request Acceptance and Approval of Annual Report covering September 18, 2020 - September 17, 2021 period

Reason on Continuation Request -

Description: Request Acceptance and Approval of Continuation Request covering September 18, 2021 - September 18, 2022 period

26. NNR-18.319 PI: Jones Brayboy, Bryan M PhD

Culturally Responsive Making: Developing High-Low Tech Maker Activities in Local and Mobile Spaces for Supporting American Indian Youth

Reason on Annual Report -

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

Reason on Quarterly Review -

Description: Request Review and Acceptance of Quarterly Reports covering: 1) March 18, 2021 - June 18, 2021, 2) June 18, 2021 - September 18, 2021 periods

27. NNR-19.347 PI: Henderson, Davis E Ph.D., CCC-SLP

Navajo Children with and without Speech Sound Disorders

Reason on Amendment -

Description: Request Acceptance and Approval of Amendments to Protocol: 1) Updated Flyer to recruit participants for dissemination social media platform, 2) Option to use Zoom (password Protect), 3) Phone Script and Eligibility Screening, 4) Parent Consent, 5) Parent Questionnaire, 6) Child Assent, 7) Incentive Cards

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

Healthy Places-Healthy People

Reason on Continuation Request -

Description: Request Acceptance and Approval of Continuation Request covering August 20, 2021 - August 19, 2022 period

Returning Presentation(s)

Reason on Annual Report -

Description: Request Acceptance and Approval of Annual Report covering August 20, 2020 - August 19, 2021 period

30. NNR-19.357 PI: Hammitt, Laura M.D.

A Phase 3 Randomized, Double, Placebo-controlled Study to evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody with an Extended Half-Life Against respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants (MELODY)

Reason on Annual Report -

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

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

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

Reason on Conference Presentation -

Description: Request Acceptance and Approval of Abstract for Conference Presentation at American Educational Research Association (AERA) April 2022 meeting. Titled: Strengthening STEM Teaching in Rural, Indigenous-serving Schools through Long-term Culturally responsive Professional Development

Reason on Conference Presentation -

Description: Request Acceptance and Approval of Abstract for Conference Presentation at Association for Science Teacher Education (ASTE), at January 2022 Meeting. Titled: Developing and piloting a tool to access culturally responsive principles in STEM instruction in School serving Indigenous students.

Reason on Conference Presentation -

Description: Request Acceptance and Approval of Abstract for Conference Presentation on April 22, 2022, at American Educational Research Association (AERA) meeting. Titled: Piloting a Tool to Access Culturally Responsive Principles of Instruction in Schools Serving Indigenous Students

Reason on Annual Report -

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

Reason on Continuation Request -

Description: Request Acceptance and Approval of Continuation Request covering September 18, 2021 - September 18, 2022 period

37. NNR-19.369 PI: Tarazi, Chelsey L. B.S.

Exploring Navajo Mothers Experiences When Giving Birth to and Caring for a Premature Infant in Rural NICU

Reason on Amendment -

Description: Request Acceptance and Approval to Change Research Title to: Exploring the Psychological Experiences and Resiliency Practices of Navajo Mothers who Give Birth to and Care for a Premature infant in a Rural-Serving Neonatal Intensive Care Unit. Attached Northern Arizona Healthcare IRB approval Letter.

Returning Presentation(s)

Reason on Annual Report -

Description: Request Acceptance and Approval of Annual Report covering January 21, 2021 - September 21, 2021 period

38. NNR-20.376 PI: Hammitt, Laura M.D.

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 Annual Report -

Description: Request Acceptance and Approval of Annual Report covering July 30, 2020 - July 30, 2021 period

39. NNR-20.379 PI: Hammitt, Laura M.D.

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 Annual Report -

Description: Request Acceptance and Approval of Annual Report covering July 30, 2020 - July 30, 2021 period

41. NNR-20.380 PI: Eddie, Regina S. PhD.MS, RN

Examining School Wellness in American Indian Communities

Reason on Annual Report -

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

Reason on Continuation Request -

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

Returning Presentation(s)

42. NNR-20.381 PI: Hammitt, Laura M.D.

A Phase 1/2/3 Placebo-Controlled, Randomized, Observer-Blind, Dose-Fing Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-COV 2 RNA Vaccine Candidates Against COVID-19 in Healthy Adutls (Short Title: Pfizer COVID-19 Vaccine Study)

Reason on Amendment -

Description: Request Acceptance and Approval of Amendments v7: #1a. changed the analysis method for the within group comparison of seroresponse rates for Phase 3 booster and VOC immunogenicity assessment from the Miettinen and Nurminen method to the adjusted Wald interval to provide tighter CI and higher power for Ni in most cases. B. Claridired that any non-study coronavirus vaccines are to be recorded at anytime they are given during the study participation, C. Clarified tha participants who are randomized in the C4591031 study should be withdrawn from this study. #2. Investigator's Brochure v7 - additional information is gathered about the investigational vaccine of summary changes. #3. Summary of Changes to the Investigator's Brochure document - summary of changes from v6 to v7. #4. Data Safety Monitoring Committee - Recommendation Memo (6/29/21) has provided a memo stating that Data Safety Monitoring Committee met to review Phase 2/3 reactogenicity and adverse event data on (6/29/21) and recommended continuing the study per protocol. #5 Data Safety Monitoring Committee - Recommendation Memo (7/27/21)
Pfizer has provided a memo stating that Data Safety Monitoring Committee met to review Phase 2/3 reactogenicity and adverse event data on(7/27/21) and recommended continuing the study per protocol.

43. NNR-21.401T PI: Richards, Jennifer Ph.D., MPH

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

Reason on Amendment -

Description: Request Acceptance and Approval of Amendment 1) re-order study assessment, 2) adjust incentive schedule to reflect change in order of assessments, 3) Revise study documents to explain and reflect these changes and 4) add flyer and business card for study promotion.

44. NNR-21.414 PI: Hammitt, Laura M.D.

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

Reason on Amendment -

Description: Request Acceptance and Approval of Amendments:

45. NNR-21.419 PI: Allison-Burbank, Joshuaa PhD.

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

Reason on Amendment -

Description: Request Acceptance and Approval of Amendment: 1. Amend Research Plan - a. update Suicide Safety Protocol to indicate if a research program assstant idenfies a participant with increased suicide risk.

Serious Adverse Event

1. NNR-20.381 PI: Hammitt, Laura M.D.
-

A Phase 1/2/3 Placebo-Controlled, Randomized, Observer-Blind, Dose-Fing 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 Primary - Off Site SAE -

Description: <p>Diagnosis: Suicide, Fatal</p>

3. NNR-02.110 PI: Shah, Vallabh O.
-

Diabetes Prevention Program Outcomes Study (DPPOS)

Reason on Primary - Off Site SAE -

Description: <p>Diagnosis: Sepsis</p>

Reason on Primary - Off Site SAE -

Description: <p>Diagnosis: Positive COVID-19</p>

5. 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 Primary - Off Site SAE -

Description: <p>Diagnosis: Child dehydration, vomiting, diarrhea, low iron and Potassium</p>

Reason on Primary - Off Site SAE -

Description: <p>Diagnosis: Misscarriage</p>

6. NNR-18.307 PI: Hammitt, Laura M.D.
-

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

Reason on Primary - Off Site SAE -

Description: <p>Submission of SAEs Final Listing.</p>

Last Page and end of Agenda