

Navajo Nation Human Research Review Board Institutional Review Board Meeting Agenda

DATE: July 19, 2016
TIME: 9:00 AM
PLACE: NDOH Conference Rm,
Window Rock, AZ

OLD BUSINESS:

MEMBERS:

Dr. Mark C. Bauer, Ph.D. - Scientific Education
Beverly Becenti-Pigman, **Chairperson** - Community
Dr. David Begay, Ph.D. - Scientific Education
Rebecca Izzo-Manymules, MPH, Ph.D.(C) - Education
Ursula Knoki-Wilson, MSN, MPH - Nursing
Wallace McGilbert - Community
Dr. Raymond Reid, MD - Medicine
Dr. Kalvin White, Ph.D. - Scientific Education

- I. Meeting Call to Order
- II. Roll Call
 - Invocation
 - Introductions
- III. Review and Approval of Agenda
- IV. Review and Approval of March 15 Meeting Minutes

NEW BUSINESS:

- V. Serious Adverse Events (SAEs)
- VI. Quarterly Reports
- VII. New Presentations
- VIII. Returning Presentations
- IX. Noon Hour Discussion
- X. Manuscripts / Abstracts
- XI. Announcements / Adjournment

Navajo Nation Human Research Review Board
IRB 7/19/16 Meeting Agenda

NEW PRESENTATION(S)

1. NNR-16.241T PI: Sepanski, Ashley RN, MSN . **USE PACKET FROM MARCH 15th MEETING.**
Disruptive Behavior in the Healthcare Setting
Reason on Agenda: New
Description: Request Review and Approval of New Study
2. NNR-16.243T PI: Nakamura, Lisa Ph.D. . **USE PACKET FROM APRIL 19th MEETING.**
Oral History Interviews of Navajo Electronics Workers of their close associates employed at Fairchild Semi Conductor, Shiprock, NM 1965-1975
Reason on Agenda: New Title
Description: Request Review and Approval of New Study
3. NNR-16.247T PI: Bender, Bruce G. Ph.D. **USE PACKET FROM JUNE 21st MEETING.**
Creating an asthma collaboration to reduce childhood asthma disparities on the Navajo Nation
Reason on Agenda: New Title ***(Re-submit with revisions)***
Description: Request Review and Approval of New Study
4. NNR-16.249T PI: Melton, Ada Pecos MPA
The National Baseline Study (NBS) Examining Violence Against American Indian and Alaska Native Women Living in Indian Country and Alaska Native Villages.
Reason on Agenda: New Title
Description: Request Review and Approval of New Study
5. NNR-16.250T PI: Facemire, Challie MA
Grand Canyon Case Study
Reason on Agenda: New Title
Description: Request Review and Approve New Study
6. NNR-16.251T PI: Frank, Daniel MS
Investigating Culturally-Contextualized Making with the Navajo Nation
Reason on Agenda: New Title
Description: Request Review and Approval of New Study.

RETURNING PRESENTATION(S)

1. NAR-96.013 PI: Santosham, Mathuram MD
Epidemiology and Immunology of Respiratory Syncytial Virus Infections in Navajo and Apache Infants.
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2016 period.

2. NNR-97.018 PI: Santosham, Mathuram MD
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, 2016 period.
3. NNR-09.259 PI: Santosham, Mathuram MD
Menu for Life - Assessing Food Security Risk among At-Risk Southwestern Native Americans
Reason on Agenda: Quarterly Review
 Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2016 period.
4. NNR-04.151 PI: Santosham, Mathuram 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 Agenda: Quarterly Review
 Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2016 period.
5. NNR-01.085 PI: Reid, Raymond MD
Effect of Pneumococcal Conjugate Vaccine on Nasopharyngeal Colonization among Adult Household Contacts of Vaccinated
Reason on Agenda: Quarterly Review
 Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2016 period.
6. NNR-02.105 PI: Reid, Raymond MD
Epidemiology Study of Pneumonia among Navajo and White Mountain Apache Adults
Reason on Agenda: Quarterly Review
 Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2016 period
7. NNR-02.111 PI: Reid, Raymond MD
Effects of Maternal Influenza Vaccination on Respiratory Disease among Infants
Reason on Agenda: Quarterly Review
 Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2016 period.
8. 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 Agenda: Quarterly Review
 Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2016 period
9. 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 Agenda: Quarterly Review
 Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2016 period.

10. NNR-09.255 PI: Reid, Raymond MD
Pilot Study of the Association between Acute Gastroenteritis and Water Quality, Availability, and Handling Practices on the Navajo Nation
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2016 period
11. NNR-07.216 PI: Reid, Raymond MD
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, 2016 period.
12. 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 Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2016 period.
13. NNR-05.174 PI: Walkup, John MD
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, 2016 period.
14. NNR-09.245 PI: Wiggins, Charles Ph.D.
Understanding lung cancer risk among Navajo former uranium miners
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering February 19, 2016 - May 19, 2016 period.
Reason on Agenda: Annual Report
Description: Request Acceptance and Approval of Annual Report covering June 2015 - May 2016 period.
15. NNR-14.185 PI: Yazzie, Sheldwin A. MPH
Assessing Indoor Radon Exposure on the Navajo Nation.
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering February 1, - April 30, 2016 period.
Reason on Agenda: Continuation Request
Description: Request Acceptance and Approve Continuation Request.
16. NNR-09.250 PI: Gittelsohn, Joel Ph.D.
Formative Research to Understand Key Barriers to Implementing a Farm-To-Table Program in the Navajo Nation
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2016 period.
17. NNR-11.150 PI: Shin, Sonya MD
Evaluating the Navajo Community Outreach and Patient Empowerment (COPE) Program
Reason on Agenda: Conference Presentation
Description: Request Acceptance and Approval of Conference Presentation of Abstract to be presented at 2016 New Mexico Community Health Worker Association Conference on August 4-5, 2016.

18. NNR-11.152 PI: Leischow, Scott J. Ph.D.

Networks among Tribal Organizations for Clean Air Policies

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering June 16, 2015 - June 16, 2016 period.

Reason on Agenda: Progress Report

Description: Request Acceptance and Approval of Mapping the Smoke-Free Status of U.S. Tribal Casinos.

Reason on Agenda: Conference Presentation

Description: Request Review and Approval of Conference Presentation of Power Point Presentation of Study to be used at I.H.S. National Webinar, SRNT Disparities Network Seminar, in Fall 2016.

Reason on Agenda: Progress Report

Description: Request Acceptance and Approval of Project Report on Smoke-free Policy Assessment Among Navajo Certified Chapter,

19. NNR-15.203 PI: Leischow, Scott J. Ph.D.

Standardized Tobacco Assessment for Retail Settings - Tribal Commercial Tobacco (STARS-TCT)

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval for Dissemination of Cover Letter and Summary Report to be sent to Navajo Nation Retailers, NDOH and Tax Office.

20. NNR-11.318 PI: Gordon, Paul H. MD

Parkinson Disease among the Navajo

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February 15 - May 15, 2016 period.

21. NNR-11.325 PI: Campbell, James J. MD

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, 2016 period.

22. NNR-11.332 PI: Speakman, Kristen MA. MPH

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 January 1 - March 31, 2016 period

23. NNR-01.081 PI: Bauer, Mark C. Ph.D.

Making a Difference: The Role of Family Support in Navajo Diabetics' Self care

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) January 27, - March 27, 2016. 2) April 27 - June 27, 2016 periods

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering March 27, 2015 - March 27, 2016 period.

24. NNR-11.349 PI: Bauer, Mark C. Ph.D

Navajo Gardening, Nutrition, and Community Wellness

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 17, - April 17, 2016 period.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering April 17 2015 - April 17, 2016 period.

25. NNR-15.201 PI: Bauer, Mark C. Ph.D

An Intervention to Promote Navajo Gardening, Nutrition, and Community Wellness

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering December 17, 2015 - March 17, 2016 period.

26. NNR-13.113 PI: English, Kevin Dr.PH

Tribal FOBT Study

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February 22, - May 21, 2016 period.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering May 22, 2015 - May 21, 2016 period.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering May 22, 2016 - May 21, 2017 period.

27. NNR-13.158 PI: Dabelea, Dana M.D.

Tribal Turning Point Program (TTPP) (A Feasibility Pilot Study)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering March - May 2016 period.

28. NNR-14.176 PI: Duran, Bonnie G. Dr.PH

Tribal Colleges and Universities Alcohol, Drugs and Mental Health Epidemiologic Study (TCU-ADME)

Reason on Agenda: Quarterly Review

Description: Request Review and Accept of Quarterly Report covering January - June 2016 period.

29. NNR-14.186 PI: Emord, Patty

An Evaluation of the B9 Vitamin Initiative for Navajo Women of Child Bearing Age

Reason on Agenda: (Other) Closure Transfer of Data to NN

Description: Request Acceptance and Approval of Affidavit of Transfer of Data to Navajo Nation, no NN Research data retained with March of Dimes.

30. NNR-14.192 PI: deHeer, Hendrik Ph.D.

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

Reason on Agenda: Quarterly Review

Description: Request Review and Accept of Quarterly Report covering January 1 – March 31, 2016 period.

Reason on Agenda: Revised Protocol

Description: Request Review and Approval of Phase II of Protocol.

31. NNR-15.200 PI: Yonnie, Tammy

Traditional Navajo Storytelling as an Educational Strategy - Student Voices.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) March 17, 2015 - June 17, 2015 period; 2) June 17, 2015 - September 17, 2015; 3) September 17, 2015 - December 17, 2015; 4) December 17, 2015 - March 17, 2016

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering March 17, 2015 - March 17, 2016 period.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering March 17, 2016 - March 17, 2017 period.

32. NNR-15.212 PI: Solomon, Mark G.

2015 Safety Belt Use Estimates for the Indian Nations.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of 2 Quarterly Reports covering 1) July 1 - September 30, 2015, 2) October 1 - December 31, 2015 periods.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of 2015 Annual Report.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering 2016 - 2017 period.

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final Report.

33. NNR-15.231 PI: Selig, Sara MD

Engaging Patients & Stakeholders to Improve Cancer Outcomes in Navajo Nation

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of the following Amendment to Protocol; a) Circle of Life Consent Form; b) 2016 Cancer Conference Radio Ad (English); c) 2016 Navajo Times Cancer Conference Ad; d) 2016 Cancer Survivorship Conference Flyer; e) 2016 Cancer Survivorship Conference Agenda; f) 2016 Cancer Conference Resource Directory; g) 2016 Cancer Conference Evaluation Form; h) 2016 Cancer Conference Presenter Biographies.

34. NNR-15.215 PI: Henderson, Davis E

Dynamic Assessment of Narratives among Navajo Preschooler

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April - June 2016 period 2016 period.

35. NNR-15.232 PI: Hammitt, Laura M.D.

Etiology of pneumonia and burden of pneumococcal pneumonia in hospitalized American Indian adults

Reason on Agenda: Amendment

Description: Requesting Acceptance and Approve the Amendment of Inclusion and exclusion criteria (V1.3)

36. NNR-16.234 PI: Chief, Karletta Ph.D.

To Litso, the water is Yellow: Investigating short term exposure and risk perception of Navajo communities to the Gold King Mine toxic spill

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April - June 2016 period.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments and Modification of the following: 1) B. Informed Consent Forms for Household Sampling, B. Child Assent for children over 6 years; 2) A. Data Collection Tool - Household Questionnaires, B. Food Frequency for Adults and Children 2 years old, Food Frequency for Adults and Children over 2 years old, C. Food Frequency for Children less than 2 years old; 3) A. New Flyer, B. New Radio Script; 4) A. New Detailed Study Brochure for Household Sampling, B. New Lead Results Reporting and Follow-up Recommendations.

37. NNR-15.222 PI: Huyser, Kimberly R. Ph.D.

The American Indian Reservation as a source of Risk and Resilience against Psychological Distress: An Analysis of Two American Indian Tribes

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) January 1 – March 31, 2016, 2) April 1 - June 30, 2016 period.

38. NNR-15.220 PI: Laughter-Begay, Lucy

Healthy and Hunger Free Kids Act Food Access Navigation Project Study

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval on Continuation Request covering September 15, 2016 - September 15, 2017

FINAL REPORT

1. NNR-10.277 PI: English, Kevin C. Dr.PH

Tribal Community Colorectal Health Education and Navigation Project

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final Report of Study.

2. NNR-14.182 PI: Pindus, Nancy

Assessment of American Indian Alaska Native and Native Hawaiian Housing Needs

Reason on Agenda: Final Report

Description: Request Review and Approval to Final Report: Housing Needs of American Indians and Alaska Natives.

X. MANUSCRIPTS Review

1. Elevated arsenic and uranium concentrations in unregulated water sources on the Navajo Nation, USA – *Chris Shuey, Yolanda Barney, Johnnye Lewis, Joseph Hoover.*
2. American Indian Reservations as a Source of Risk and Resilience against Psychological Distress: An Analysis of Two American Indian Tribes – *Kimberly R. Huyser, Ronald J. Angel, Janette Beals, James H. Cox, Robert A. Hummer, Arthur Salamoto, Spero M. Manson, AI-SUPERPPF Team*

ABSTRACTS to submit Application

1. *Reconnecting NACNA with the Sacramento, Peyote – Joseph B. Walker*
2. *A Socio-Ecological Analysis of Childhood obesity and School Nutrition Policy and Practices – Regina S. Eddie*
3. *Stopping GDM – Kelly R. More*