

Navajo Nation Human Research Review Board Institutional Review Board Meeting Agenda

Meeting February 16, 2016
Time: 9:00: AM
Location: NNDOH East Conference RM,
Window Rock, AZ

Chairperson:
Ms. Beverly Becenti-Pigman

MEMBERS:

Dr. Mark C. Bauer, PhD. - Scientific Education
Beverly Becenti-Pigman - Community
Dr. David Begay, PhD. - Scientific Education
Rebecca Izzo-Manymules, MPH, PhD. (C) – Education
Ursula Knoki-Wilson. MSN, MPH – Nursing
Ronald Maldonado - Non-Scientific
Wallace McGilbert - Community
Dr. Raymond Reid, MD - Medicine
Dr. Kalvin White, PhD. - Scientific Education

OLD BUSINESS:

- I. Meeting Call to Order:
- II. Roll Call:
 - Invocation:
 - Introduction:
- III. Review and Acceptance of Agenda:
- IV. Review and Approval of November 17, 2015 Meeting Minutes:

NEW BUSINESS:

- V. Serious Adverse Events (SAEs):
- VI. Quarterly Reports:
- VII. New Presentations:
- VIII. Returning Presentations:
- IX. Manuscripts / Abstracts:
- X. Noon Hour Discussions: 1) NNDOH and NNHRRB Genetic Research Moratorium.
Ms. Ramona Antone-Nez, NDOH (A)
- XI. Announcements / Adjournment:

Navajo Nation Human Research Review Board
IRB 2/16/2016 Meeting Agenda

VII. NEW PRESENTATION(S)

1. NNR-15.229T PI: Carre, Nancy C. ***TABLED ITEM Use items from Dec. 15, 2015 Meeting Packet.***

The Effect of Educational Narratives on High School Persistence among Navajo Girls

Reason on Agenda: New Title

Description: Request Review and Approval of New Title

2. NNR-16.237 PI: Tapaha, Oliver Ed.M.

Dine' (Navajo) Elementary Teachers' Perspectives on Dine'k'ehgo Nanitiin Idine' Based Instruction): An Ethnographic Study

Reason on Agenda: New Title

Description: Request Review and Approval of New Protocol.

3. NNR-16.238T PI: Hammitt, Laura M.D.

Active Bacterial Surveillance for Staphylococcus aureus on the Navajo and White Mountain Apache Reservations.

Reason on Agenda: New Title

Description: Request Acceptance and Approval of New Protocol

4. NNR-16.239T PI: Chee, Donald B.A.

Integrated HIV/AIDS & Substance Abuse Prevention Project for the Navajo Nation

Reason on Agenda: New Title

Description: Request Review and Acceptance of New Title

VIII. RETURNING PRESENTATION(S)

1. NNR-02.094 PI: Knowler, William MD

Action for Health in Diabetes Look AHEAD

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October 1, - December 31, 2015 period.

2. NNR-02.110 PI: Knowler, William MD

Diabetes Prevention Program Outcomes Study (DPPOS)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October 1, - December 31, 2015 period.

3. NNR-03.121 PI: Bitsui, Natasha

2003 Navajo Youth Behavior Survey (YRBS)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October 1 - December 31, 2015 period.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering January 1, 2015 - December 31, 2015 period.

4. NNR-05.165 PI: Reid, Raymond M.D., Laura Hammitt, MD

Long Term Impact of the Pneumococcal Conjugate Vaccine on Pneumococcal Nasopharyngeal Colonization and Immune Correlates for Disease Protection

Reason on Agenda: Conference Presentation

Description: Request Review and Approval of Abstract to be used for Request Conference Presentation at International Symposium on Pneumococci and Pneumococcal disease (ISPPD) in June 26-30, 2016 in Glasgow, Scotland.

Title; Threshold Levels of Anticapsular IGG that Correlate with Protection Against Pneumococcal Acquisition

5. NNR-09.253 PI: Reid, Raymond M.D., Laura Hammitt, MD

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

Reason on Agenda: Conference Presentation

Description: Request Review and Approval of Abstract to be used for Request Conference Presentation at International Symposium on Pneumococci and Pneumococcal disease (ISPPD) in June 26-30, 2016 in Glasgow, Scotland.

Titled: 1) Impact of PCR, Colonization Density, and Age on Detection of Streptococcus Pneumoniae in the Nasopharynx of Healthy American Indians; Title 2) Characterization of Serotype-Specific Pneumococcal Colonization Prevalence and Density Among American Indians in the PCV13 era Using PCR and Microarray.

6. NNR-97.018 PI: Santosham, Mathuram MD., Laura Hammitt, 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: Conference Presentation

Description: Request Review and Approval of Abstract to be used for Request Conference Presentation at International Symposium on Pneumococci and Pneumococcal disease (ISPPD) in June 26-30, 2016 in Glasgow, Scotland. Titled: 1) Impact of PCV13 on invasive pneumococcal disease among American Indians Less than 5 years of age living on the Navajo Nation; Title 2) Indirect Impact of PCV13 Vaccination on Adults living on the Navajo Nation; Title 3) Impact of PCV13 on Acute Otitis Media in American Indians Less than 5 Years of Age Living on the Navajo Nation Reservation.

7. NNR-06.188 PI: Gittelsohn, Joel Ph.D.

Expanding and Sustaining a Successful Food-Store Based Program to Improve Diet and Risk for Obesity and Other Chronic Disease in American Indians

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October - December 2015 period.

8. NNR-06.195 PI: Deaton, James

National Indian Education Study 2007

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October 16, 2015 - January 15, 2016 period.

9. NNR-07.198 PI: McGrath, Jane W. MD

Envision New Mexico Pediatric Overweight Learning Collaborative

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 17, 2015 - December 16, 2015 period.

10. NNR-08.225 PI: English, Kevin C. Dr.PH
Tribal Community Health Representative (CHR) Breast and Cervical Health Education and Community Outreach Project Dissertation - Doctoral Candidate
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering September 20, 2015 - December 19, 2015 period.
11. NNR-10.277 PI: English, Kevin C. Dr.PH
Tribal Community Colorectal Health Education and Navigation Project
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering October 22, 2015 - January 22, 2016 period.
12. NNR-11.152 PI: Leischow, Scott J. PhD
Networks among Tribal Organizations for Clean Air Policies
Reason on Agenda: Amendment
Description: Request Acceptance and Approval of Amendments to Protocol to include: 1) Mayo IRB Approval Letter; 2) Flyer, 3) Email Script; 4) January 2016 clean and tracked changes; 5) Summary of Change to protocol.
Reason on Agenda: Conference Presentation
Description: Request Acceptance and Approval of Conference Presentation at Society for research on Nicotine & Tobacco Annual Conference in Chicago, IL on March 2-5, 2016.
13. NNR-11.319 PI: Patten, Christi A. PhD
Family Cancer Literacy to Promote Mammography Screening among Navajo Women
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Reports covering 1) May 23, - August 22, 2015 period, 2) August 23 – November 22, 2015 periods.
Reason on Agenda: Annual Report
Description: Request Acceptance and Approval of Annual Report covering August 23, 2014 - August 22, 2015 study period.
14. NNR-11.321 PI: Samuel-Nakamura, Christine, PhD
Uranium in the plant-animal-human food chain near abandoned mining sites and structures in an American Indian community in Northwestern New Mexico
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering August 21 - November 21, 2015 period.
15. NNR-01.81 PI: Bauer, Mark C. Ph.D
Making a Difference: The Role of Family Support in Navajo Diabetics' Selfcare
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering January - March 2015 period.
Reason on Agenda: Annual Report
Description: Request Acceptance and Approval of Annual Report covering March 2014 - March 2015 period.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) April - June 2015, 2) July - September 2015, 3) October - December 2015 periods

Reason on Agenda: Progress Report

Description: Request Review and Acceptance of Progress Report for Fall 2015.

16. NNR-11.324 PI: Bauer, Mark C. Ph.D

Cross-Site Evaluation of the Dine College HIV Prevention Demonstration Project for the Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) January 01, - March 31, 2015; 2) April 1, June 30, 2015; 3) July 1 - September 20, 2015; 4) September 20, - December 20, 2015 periods

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 20, 2014 - September 20, 2015 study period.

17. 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 Reports covering 1) February 1 - April 30, 2015; 2) April 17 - July 17, 2015 periods, 3) July 17, - October 17, 2015 periods.

18. 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 Reports: 1) March 17, - June 17, 2015; 2) June 18 - September 18, 2015; 3) September 17 - December 17, 2015 periods.

19. NNR-11.333 PI: Vining, Christine B. **TABLED ITEM use from January 19th, meeting packet**

Socializing English-Speaking Navajo Children to Story Telling

Reason on Agenda: Progress Report

Description: Request Acceptance and Approval of Conference Presentation Progress Report from December 15, 2015, Navajo Nation Parent Conference, Navajo Nation Museum, Window Rock, AZ

20. NNR-11.351 PI: McElyea, Virginia B

Arizona Ready-for-Rigor

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 1, - November 30, 2015 period.,

21. NNR-14.171 PI: Henderson, Davis E

CELF - 4 and PPVT - 4 among Navajo Students

Reason on Agenda: Revised Protocol

Description: Request Review and Acceptance of Quarterly Report covering October - December 2015 period.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 2015 - February 2016 period.

22. NNR-15.215 PI: Henderson, Davis E
Dynamic Assessment of Narratives among Navajo Preschooler
Reason on Agenda: Modification
Description: Request Acceptance and Approval of Modification Request to Add new site to Study at Borrego Pass School. 1) Borrego Pass School Principal Approval Letter.
23. NNR-14.172 PI: Willie, Christine M **TABLED ITEM use from Dec. 15th, 2015 and January 19th, meeting packets**
Sheep is Life and Dine' Decolonization
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering March - May 2015 period.
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering June - August 2015 period.
Reason on Agenda: (Other)
Description: Request Review and Acceptance of Dissertation Titled: A study of Navajo Traditional Sheep Butchering. Submitted in partial satisfactory of the requirement for the degree of Doctor of Philosophy.
24. NNR-14.182 PI: Pindus, Nancy M.
Assessment of American Indian Alaska Native and Native Hawaiian Housing Needs
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering September 2015.
25. NNR-14.188T PI: Pindus, Nancy M.
Study of the Food Distribution Program on Indian Reservations.
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report ending September 2015.
Reason on Agenda: Annual Report
Description: Request Review and Acceptance of U.S. Department of Agriculture Draft Final Report on Study of the Food Distribution Program on Indian Reservations. With Technical Appendix.
26. NNR-15.199 PI: Shin, Sonya MD
REACH for Healthy Navajo Communities.
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering September 17 - December 17, 2015 period.
27. NNR-15.231T PI: Selig, Sara MD
Engaging Patients and Stakeholders to Improve Cancer Outcomes in Navajo Nation
Reason on Agenda: Amendment
Description: Request Acceptance and Approval of Amendments to Protocol to include new sites Gallup Indian Medical Center, 1) Eastern Navajo Agency Council Resolution.
28. NNR-15.202 PI: King, Farina
The Journey of Dine' Students in Four Directions: Navajo Educational Experiences in the Twentieth Century.
Reason on Agenda: Conference Presentation
Description: Request Review and Approval of Conference Presentation on April 08, 2016 at Organization of American Historians.

29. NNR-15.214 PI: Lewis, Johnnye, PhD. D.A.B.T.

Wood Stove Interventions and Child Respiratory Infections in Rural Communities

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October 21, 2015 - January 20, 2016 period.

30. NNR-11.323 PI: Lewis, Johnnye, PhD. D.A.B.T.

Navajo Birth Cohort Study (NBCS)

Reason on Agenda: Dissemination Approval - Media

Description: Request Review and Approval to conduct Media Interview participate and staff on study by Navajo Times Newspaper.

31. NNR-15.196 PI: Spoonemire, Jr. Steven, DPT, OCS

Dry Needling for Plantar Heel Pain: A Case Series with Long Term Follow-up.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of 2015 Annual Report. 1) Approved Manuscript for Publication

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final Report.

32. NNR-15.224 PI: Watanabe, Kohei

Ethnography of Laughter: Laughter of Dine and Creation of Hozo

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October 22, 2015 - January 22, 2016 period.

33. NNR-16.234T 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: Consent Modification

Description: Request Acceptance and Approval of Revised Consent Form, Update Focus Group Questions and Recruitment Materials.

FINAL REPORT

34. NNR-11.320 PI: Carter, Susan L. PhD

NIYLP Web of Life Teenage Pregnancy Prevention

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final Report covering 2011 to 2015 study years

IX. Manuscripts / Abstracts:

1) The title of the project is Disruptive Behavior in the Healthcare Environment (Kayenta I.H.S.) - *Ashley Sepanski, RN, MSN, C-NE*

X. Noon Hour Discussions: 1) NNDOH and NNHRRB Genetic Research Moratorium. Ms. Ramona Antone-Nez, NDOH (A)

XI. Announcements / Adjournment:

Last page and end of Agenda