

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

Meeting: December 15, 2015
Time: 9:00 AM
Location: NN Education Center large Confer. Rm
Window Rock, AZ

MEMBERS:

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

OLD BUSINESS:

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

NEW BUSINESS:

- V. Serious Adverse Events (SAEs)
- VI. Quarterly Reports:
- VII. New Presentations:
- VIII. Returning Presentations:
- IX. Manuscripts / Abstracts:
- X. Noon Hour Discussion: NNHRRB Two day Work Session
 - 1) Revise NN Health Codes; 2) Revise NNHRRB Bylaws;
 - 3) Revise NNHRRB Plan of Operations.
- XI. Announcements / Adjournment

**Navajo Nation Human Research Review Board
IRB 12/15//15 Meeting Agenda**

NEW PRESENTATION(S)

1. NNR-15.223T PI: Richards, Jennifer MPH

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

Reason on Agenda: Revised New Protocol

Description: Request Acceptance and Approval of Revised Protocol and Revised Consent Forms of New Application. (Tabled on 10-20-15 Mtg.)

2. NNR-15.228T PI: Warner, Elizabeth K. ***TABLED ITEM Use items from November 17, 2015 Meeting Packet.***

Enforcement of Tribed Environmental Law

Reason on Agenda: New Title

Description: Request Review and Approval of New Title

3. NNR-15.229T PI: Carre, Nancy C.

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

4. NNR-15.230T PI: LaPahe, Nelda

Navajo Nation Takes Control: A Blueprint of a Dream

Reason on Agenda: New Title

Description: Request Review and Approval of New Protocol.

5. NNR-15.231T PI: Selig, Sara M.D.

Engaging Patients and Family Members to Improve Cancer Outcomes in Navajo Nation

Reason on Agenda: New Title

Description: Request Review and Approval of New Protocol

6. NNR-15.232T PI: Hammitt, Laura M.D.

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

Reason on Agenda: New Title

Description: Request Review and Approval of New Protocol.

7. NNR-15.233T PI: Prouix, Jeffrey A. Ph.D.

Is Mindful Meditation Effective and Culturally Relevant for Native People?

Reason on Agenda: New Title

Description: Request Review and Approval of New Protocol

RETURNING PRESENTATION(S)

1. NNR-03.121 PI: Bitsui, Natasha

2003 Navajo Youth Behavior Survey (YRBS)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Two Quarterly Reports covering 1) April 1 - June 30, 2015; 2) July 1 - September 30, 2015 period.

2. NNR-04.145 PI: Lewis, Johnnye L. Ph.D.

Dine Network for Environmental Health Project (DiNEH)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 20 - October 19, 2015 period.

3. NNR-07.198 PI: McGrath, Jane W. M.D.

Envision New Mexico Pediatric Overweight Learning Collaborative

Reason on Agenda: Quarterly Review

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

4. NNR-08.225 PI: English, Kevin C. Dr. PH

Tribal Community Health Representative (CHR) Breast and Cervical Health Education and Community Outreach Project Dissertation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June 20 - September 19, 2015 period.

5. 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 July 21 - October 21, 2015 period.

6. NNR-13.113 PI: English, Kevin C. Dr. PH

Tribal FOBT Study

Reason on Agenda: Quarterly

Description: Request Review and Acceptance of Two Quarterly Reports: 1) May 22 - August 21, 2015 period, 2) August 22 - November 21, 2015 periods.

7. 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 May 19, - August 19, 2015 period.

8. 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: Annual Report;

Description: Request Acceptance and Approval of Annual Report covering October 16, 2014 – October 16, 2015 period.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Request for Continuation from October 16, 2015 – October 16, 2016

9. NNR-10.287 PI: Gittelsohn, Joel Ph.D.

Multilevel Obesity Prevention Trial for American Indian Community (OPREVENT)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Two Quarterly Reports covering 1) April, May, June; 2) July, August, September 2015 period.

Reason on Agenda: Annual

Description: Request Acceptance and Approval of Annual Report covering December 18, 2014 - December 2015 period.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Request for Continuation covering December 18, 2015 - December 18, 2016 period (original approval date 12-21-2010)

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to add Social Media and Sustainability Interviews.

10. NNR-11.150 PI: Shin, Sonya M.D.

Evaluating the Navajo Community Outreach and Patient Empowerment (COPE) Program

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to Protocol, additional secondary analysis of study data

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

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

Reason on Agenda: Quarterly Review

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

12. NNR-11.318 PI: Gordon, Paul H. M.D., MPH

Parkinson Disease among the Navajo

Reason on Agenda: Quarterly Review .

Description: Request Review and Acceptance of Quarterly Report covering May 22 - September 22, 2015 period.

13. NNR-13.106 PI: Gordon, Paul H. M.D., MPH

Neurological Disease among the Navajo

Reason on Agenda: Quarterly

Description: Request Review and Acceptance of Quarterly Report covering May 22 - September 22, 2015 period.

14. NNR-11.322 PI: Baumbach, Joan M.D., MPH
Evaluating the Effectiveness of a 13-Valent Pneumococcal Conjugate Vaccine among Children
Reason on Agenda: Annual Report
Description: Request Acceptance and Approval of Annual Report covering August 24, 2014 - August 23, 2015 period.
Reason on Agenda: Continuation Request
Description: Request Acceptance and Approval of Continuation Request from August 23, 2015 - August 23, 2016 period.
15. NNR-11.323 PI: Lewis, Johnnye L. Ph.D.
Navajo Birth Cohort Study (NBCS)
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering August 23 - November 22, 2015 period.
16. NNR-11.325 PI: Campbell, James J. M.D.
Study of a vaccine for reducing ear and lung infections in children
Reason on Agenda: Continuation Request
Description: Request Acceptance and Approval of Continuation Request from February 21, 2016 - February 21, 2017 period.
17. 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
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering September - November 2015 period.
18. NNR-11.346 PI: Reid, Raymond M.D.
Together on Diabetes Study: Evaluation of a pilot Diabetes Prevention and Management Program for American Indian Youth.
Reason on Agenda: Amendment
Description: Request Acceptance and Approval of Amendments to Protocol: 1) John Hopkins Amendment Notice; 2) Add Primary AIM 3; 3) Research Plan; 4) HIPAA waiver approval.
19. NNR-13.102 PI: Jones, Rachelle G. Ph.D. ***TABLED ITEM Use items from November 17, 2015 Meeting Packet.***
Maintaining Hozho: Preceptions of Physical Activity, Physical Education and Healthy Living Among Navajo High School Students
Reason on Agenda:
Description: Request Acceptance and Review of ASU IRB Continuation Request for Study to December 17, 2015.
Reason on Agenda: Annual Report
Description: Request Acceptance and Approval of 2014 Annual Report covering May 21, 2013 - May 21, 2014 period.
Reason on Agenda: Annual Report
Description: Request Acceptance and Approval of 2015 Annual Report covering May 21, 2014 - May 21, 2015 period.
Reason on Agenda: Continuation
Description: Request Acceptance and Approval of Request Continuation of Study from December 17, 2015 - December 17, 2016

20. NNR-13.108 PI: Selvage, W. David

Evaluation of the Effectiveness of Tdap Vaccination Strategies at Preventing Infant Pertussis

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering June 2014 - June 2015 period

Reason on Agenda: Continuation

Description: Request Acceptance and Approval of Continuation Request from May 2015 - May 2016 period.

21. NNR-13.166 PI: Hilgert, Uwe Ph.D.

Cultivating Diverse Talent in STEM (CDTIS)

Reason on Agenda: Quarterly Review

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

22. NNR-14.172 PI: Willie, Christine M

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.

23. NNR-14.175 PI: Lombard, Kevin A. Ph.D.

Where Health and Horticulture Intersect: A Navajo Wellness Collaboration

Reason on Agenda: Quarterly Review

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

24. NNR-14.177 PI: Duran, Bonnie G. Dr.PH

Tribal Colleges and Universities Behavioral Health Adaptation of an Evidence-Based Intervention

Reason on Agenda: Modification

Description: Request Acceptance and Approval of 15 Modifications of Study: 1) The inclusion of 3 questions about student's Facebook contract; 2) Revised invitation letter to increase Participation among students without a reliable email address; 3) Revised recruitment poster and flyer for stages 1 & 2. 4) Update and clarification of the suicide, depression and alcohol abuse protocol; 5) An alcohol referral letter included as update to the suicide, depression and alcohol abuse protocol; 6) A depression Referral letter included as an update to the suicide, depression and alcohol abuse protocol; 7) A request for secondary data analysis conducted by University of Washington School of Social Work Doctoral Student Kate Schultz; 8) The inclusion of 5 additional email contacts to study participants; 9) Provide telephone-based BASICS

25. NNR-14.185 PI: Yazzie, Sheldwin A. MPH, Ph.D. (C)

Assessing Indoor Radon Exposure on the Navajo Nation.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 30 - October 30, 2015 period, with Power point presentation from NNHRRB Conference .

26. NNR-14.186 PI: Emord, Patty

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

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Plan to Disseminate Findings to Navajo Nation.

27. NNR-15.199 PI: Shin, Sonya M.D.

REACH for Healthy Navajo Communities.

Reason on Agenda: Quarterly Review

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

28. NNR-15.202 PI: King, Farina ***TABLED ITEM Use items from November 17, 2015 Meeting Packet.***

The Journey of Dine' Students in Four Directions: Navajo Educational Experiences in the Twentieth Century.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report.

Reason on Agenda: Addendum

Description: Request Acceptance and Approval the Navajo Nation Cultural Resources Investigation Permit for Study.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Release Form to have Phillip Fund to Dissemination Study data.

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval off Conference Presentation Abstract and Draft Presentation.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report from Navajo Oral History Recording.

29. NNR-15.208 PI: Pollari, Lynette

Dine Cultural Sustainability through Settlement Form: "Finding Patterns for New Navajo Neighborhoods:

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering August 19 - November 20, 2015 period.

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Conference Request Abstract and Power point Presentation at AISA 17th Annual Conference on February 4-5, 2016 in Tempe, AZ

30. NNR-11.337 PI: Nielsen, Erik Dr.

Integrating Traditional Ecological Knowledge in Watershed Restoration at Canyon de Chelly National Monument, Chinle, AZ

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final Report included: 1) Final Dissemination Plan; 2) Student Thesis with Appendices; 3) Group Interview Transcripts.

MANUSCRIPTS

1. Absence of Fluoride Varnish-Related Adverse Events in Caries Prevention Trials in Young Children (NNR-10.268), Authors: Raul I. Garcia, DMD, Steven E. Gregorich, PhD, Francisco Ramos-Gomez, DDS, MS, MPH, Patricia Braun, MD, MPH, Anne Wilson, DDS, MS, Judith Albino, PhD; Tamanna Tiwari, DSm MDDS, MPH, Terry Batliner, DDS MBA, Nancey F. Cheng, MS, MS, William Santo, BS, Michelle Henshaw, DDS, MPH, Stuart A. Ganksy, DrPH.
2. Cultural Elements Underlying the Community Health Representative – Client Relationship in Navajo Nation (NNR-11.150). Authors: Vikas Gampa, Casey Smith, Caroline King, Olivia Musket, Hannah Sehn, Jamy Malone, Cameron Curley, Mae-gilene Begay, Sanya Shin, MD, MPH, Adrienne Katrina Nelson, MPH, MSC.

ABSTRACTS (proposed to submit new protocol)

1. Multi-level Obesity Prevention Trails for North American Indian Communities (OPREVENT2), Dr. Joel Gittelsohn, PI.

Last page and end of Agenda