

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

DATE: November 29, 2016

TIME: 9:00 AM

PLACE: NDOH Conference Room  
Window Rock, AZ

**MEMBERS:**

Dr. Mark C. Bauer, Ph.D. - Scientific Education  
Beverly Becenti-Pigman, Board Chair - 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, MPH – Medicine  
Dr. Kalvin White, Ph.D. - Scientific Education

**OLD BUSINESS:**

- I. Meeting Call to Order
- II. Roll Call
  - Invocation
  - Introductions
- III. Review and Approval of Agenda
- IV. Review and Approval of August 16, 2016 Meeting Minutes

**NEW BUSINESS:**

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

Navajo Nation Human Research Review Board  
IRB 11/29/2016 Meeting Agenda

**NEW PRESENTATION(S)**

1. NNR-16.259T PI: Kahn-John, Michelle Ph.D., RN

**The Depression in Din'e (Navajo) Adults who Participate in the Din'e Hochxo'iji (Navajo Evil Way/Ghost Way) Ceremony**

**Reason on Agenda:** New Title

Description: Request Review and Approval of New Study

2. NNR-16.262T PI: Clark, Damon J.

**Din'e entrepreneurship**

**Reason on Agenda:** New Title

Description: Request Review and Approval of New Study

3. NNR-16.263T PI: Oren, Eyal Ph.D.

**Helicobacter Pylori Infection and Stomach Cancer**

**Reason on Agenda:** New Title

Description: Request Review and Approval of New Study

**RETURNING PRESENTATION(S)**

1. NNR-02.094 PI: Knowler, William MD

**Action for Health in Diabetes Look AHEAD**

**Reason on Agenda:** Annual Report

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

**Reason on Agenda:** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1 - September 30, 2016 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 July 1 - September 30, 2016 period.

3. NNR-02.106 PI: Dabelea, Dana MD

**SEARCH for Diabetes in Youth Study**

**Reason on Agenda:** Quarterly Review;

Description: Request Review and Acceptance of Quarterly Report covering July - September 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:** Annual Report

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

5. NAR-96.013 PI: Santosham, Mathuram MD  
**Epidemiology and Immunology of Respiratory Syncytial Virus Infections in Navajo and Apache Infants.**  
**Reason on Agenda:** Continuation Request  
Description: Request Acceptance and Approval of Request for Continuation of Study covering December 9, 2016 - December 9, 2017
6. 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:** Annual Report  
Description: Request Acceptance and Approval of Annual Report covering September 6, 2015 - September 6, 2016 period.
7. NNR-07.216 PI: Reid, Raymond MD  
**Rapid-response investigation of pediatric cases of invasive Haemophilus influenzae in Navajo American Children**  
**Reason on Agenda:** Annual Report  
Description: Request Acceptance and Approval of Annual Report covering September 18, 2015 - September 18, 2016 period.
8. 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:** Annual Report  
Description: Request Acceptance and Approval of Annual Report covering August 18, 2015 - August 18, 2016 period.
9. NNR-02.105 PI: Reid, Raymond MD  
**Epidemiology Study of Pneumonia among Navajo and White Mountain Apache Adults**  
**Reason on Agenda:** Continuation Request  
Description: Request Acceptance and Approval of Continuation Request covering December 17, 2016 - December 17, 2017 period
10. 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 April 1 - June 30, 2016 period.  
**Reason on Agenda:** Continuation Request  
Description: Request Acceptance and Approval of Continuation Request covering December 21, 2016 - December 21, 2017 period.
11. 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 July 16 - October 15, 2016 period.  
**Reason on Agenda:** Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering July 16 - October 15, 2016 period.

12. 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 Reports covering 1) March 20 - June 19, 2016; 2) June 20 - September 19, 2016 periods.
13. 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 Reports covering 1) April 22 - July 21, 2016; 2) July 22 - October 21, 2016 periods.
14. NNR-10.268 PI: Batliner, Terrence DDS  
**Preventing Caries in Preschoolers: Testing a Unique Service Delivery Model in American Indian Head Start Programs**  
**Reason on Agenda:** Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering May 1 - August 31, 2016 period.
15. NR-11.351 PI: McElyea, Virginia B  
**Arizona Ready-for-Rigor**  
**Reason on Agenda:** Annual Report  
Description: Request Acceptance and Approval of Annual covering March 1, 2015 - June 30, 2016 period. Attachments; Grant Findings power point presentation, Chinle Chapter Planning Meeting (9-21-16) (9-6-16) agenda, sign in sheet, minutes.
16. NNR-13.105 PI: Necefer, Len Ph.D.  
**Public Perceptions of Energy and the Environment on the Navajo Nation**  
**Reason on Agenda:** Annual Report  
Description: Request Acceptance and Approval of Annual Report covering March 2015 - March 2016 period.  
**Reason on Agenda:** Quarterly Review  
Description: Request Review and Acceptance of Quarterly Reports covering: 1) January 2016 - April 2016; 2) October 2015 - December 2015; 3) July 2015 - September 2015; 4) April 2015 - June 2015; 5) January 2015 - March 2015 periods.  
**Reason on Agenda:** Final Report  
Description: Request Acceptance and Approval of Final Report covering 2013 – 2016 study period.  
**Reason on Agenda:** Close-out Study  
Description: Request Acceptance and Approval to Close Project.
17. NNR-14.188 PI: Pindus, Nancy M.  
**Study of the Food Distribution Program on Indian Reservations.**  
**Reason on Agenda:** Close Out Study  
Description: Request Acceptance and Approval of Transfer of Data (CD-ROM) and Close-out Protocol.
18. NNR-15.197 PI: DeAngelis, Margaret Pharm.D.  
**Retinal Screening Program UNHS and Moran Eye Center Collaboration.**  
**Reason on Agenda:** Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering March 18 - October 17, 2016 period

19. NNR-15.199 PI: Shin, Sonya MD

**REACH for Healthy Navajo Communities.**

**Reason on Agenda:** Amendment

Description: Request Review and Approval of Amendments of UPDATED FORMS: 1.1 CHT Team Deelopment Measure Questionnaire (V2; 2) 1.2 CHT Module 1 Assessment (Sessions 02) [v2]. NEW FORMS: 1) 1.9 CHT Module 1 Assessment (sessions 3-5); 2) 1.10 CHT Team Directions Worksheet; 3) 1.11 CHT Roles & Responsibilities Worksheet; 4) 1.12 CHT Process Map Worksheet; 5) 1.13 CHT Process Map & Patient Engagement Worksheet.

**Reason on Agenda:** Addition of Co-Investigator

Description: Request Review and Approval to Add Co-Investigators; 1) Onagh MacKenzie, MPH Candidate, 2) Marc Emerson, PhD Candidate. Attachments; Letter of Interest, CV, Part V certifications, IRB Letters.

20. 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 October 18 - November 19, 2016 period.

21. 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 Quarterly Report covering July 1 - September 30, 2016 period.

22. NNR-15.223 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:** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2016 period.

**Reason on Agenda:** Continuation Request

Description: Request Acceptance and Approval of Continuation Request of Study covering December 15, 2016 - December 15,

23. NNR-15.226 PI: Yazzie, Benjamin B.

**Interpreting Navajo Cultural Strata**

**Reason on Agenda:** Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 20, 2015 - October 20,, 2016 period.

24. NNR-16.242T PI: Begay, Shawna L. MFA

**Developing a Navajo Educational Media Guide: A Community Perspective.**

**Reason on Agenda:** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 8 - October 19, 2016 period.

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

**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 covering February 21, 2016 - February 21, 2018 period.

26. NNR-15.232 PI: Hammitt, Laura MD

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

**Reason on Agenda:** Continuation Request

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

27. NNR-16.258T PI: Swaim, Randall C. Ph.D.

**Substance use among American Indian Youth attending schools on or near Reservation**

**Reason on Agenda:** Consent Revision (New Title)

Description: Request Review and Approval of Revised of Consent Form Per Directive of IRB Board on 10-18-16 meeting

28. NNR-16.249 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:** Addendum

Description: Request Review and Approval of Addendum of Two Supporting Resolution from Northern and Fort Defiance Agency Council.

**Reason on Agenda:** Conference Presentation

Description: Request Review and Approval of Conference Presentation at 15th National Indian Nations Conference on December 7, 2016.

## IX. Noon Hour Discussions

## X. Manuscripts Review

- *Pneumococcal protein antigen serology varies with age and may predict antigenic profile of colonizing isolates (NNR-05.165): Azarian T, Grant LR, Georgieve M, Hammitt LL, Reid R, Bentley SD, Goldbatt D, Santosham M, Weatherholtz B. Goklish N, Thompson CM, Hanage WP, O'Brien KL, Lopsitch M.*
- *Understanding the Influence of cultural impact information in a decision tool for energy resource management (NNR-13.105): Len Necefer, Gaberielles Wong-Parodi, Mitchell J. Small*

### Abstracts Review

- *What the Navajo can teach us about making – Steve Orlando*

- *The processes of Food Sovereignty in the Navajo Nation – Eugénie Clémenti Picos (France)*

## XI. Announcements / Adjournment

*Last page and end of Agenda*