Navajo Nation Human Research Review Board
Meeting Agenda

DATE: September 19, 2017
TIME: 9:00 AM
PLACE: NDOH West Conference Room, Window Rock, AZ

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, (C) Ph.D. - Education
Ursula Knoki-Wilson, MSN, MPH - Nursing
Wallace McGilbert - Community
Dr. Raymond Reid, MD – 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 of June Meeting Minutes:

NEW BUSINESS:
V. Quarterly Reports:

VI. Serious Adverse Events (SAEs)

VII. New Presentations:

VIII. Returning Presentations:

IX. Noon Hour Discussion
   - 2017 Annual Research Conference Abstracts Approval

X. Manuscripts and Abstract to submit NNHRRB Application

XI. Announcements and Adjournment

Report Date Tuesday, September 12, 2017
NEW PRESENTATION(S)

1. NNR-17.285T  PI: Arviso, Merlee  M.Ed. MPA
   How Has Navajo Community College (now Din'e College) Impacted the Local Communities?
   Reason on: New Title
   Description: Request Review and Approval of New Study

2. NNR-17.286T  PI: Whyte, Ayn N.  MS
   American Indian/Alaska Native Health Equity Initiative
   Reason on: New Title
   Description: Request Review and Approval of New Study

3. NNR-17.283T  PI: Russell, Maureen  Ph.D., OTR/L
   Sleep Interventions for Caregivers and their Young Children in Part C Programs
   Reason on: New Title
   Description: Request Review and Approval of New Study

FINAL REPORT

1. NNR-16.255  PI: Radovanovic, Sonja D Ph.D., M.A.
   First Things First Navajo Regional Partnership Council
   Reason on: Final Report
   Description: Request Acceptance and Approval of Final Report, Dissemination Plan, Publication of Report

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: Quarterly Review
   Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

2. NNR-01.081  PI: Bauer, Mark C. Ph.D
   Making a Difference: The Role of Family Support in Navajo Diabetics' Self Care
   Reason on: Quarterly Review
   Description: Request Review and Acceptance of Quarterly Reports covering: 1) January - March 2017, 2) April - June 2017 periods

3. NNR-01.085  PI: Reid, Raymond  M.D.
   Effect of Pneumococcal Conjugate Vaccine on Nasopharyngeal Colonization among Adult Household Contacts of Vaccinated
   Reason on: Quarterly Review
   Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period
4. NNR-02.094   PI: Knowler, William MD  
**Action for Health in Diabetes Look AHEAD**  
**Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

5. NNR-02.099   PI: Santosham, Mathuram MD  
**Safety and Efficacy of Pentavalent (G1, G2, G3, G4, and P1) Human-Bovine Reassortant Rotavirus Vaccine in Healthy Infants**  
**Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

6. NR-02.105   PI: Reid, Raymond M.D.  
**Epidemiology Study of Pneumonia among Navajo and White Mountain Apache Adults**  
**Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

7. NNR-02.110   PI: Knowler, William MD  
**Diabetes Prevention Program Outcomes Study (DPPOS)**  
**Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

8. NNR-02.111   PI: Reid, Raymond M.D.  
**Effects of Maternal Influenza Vaccination on Respiratory Disease among Infants**  
**Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

9. 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**  
**Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

10. NNR-05.165   PI: Reid, Raymond M.D.  
**Long Term Impact of the Pneumococcal Conjugate Vaccine on Pneumococcal Nasopharyngeal Colonization and Immune Correlates for Disease Protection**  
**Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

11. NNR-05.174   PI: Reid, Raymond M.D.  
**In-home Prevention of Substance Abuse Risk in Navajo Teen Families**  
**Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

12. NNR-05.175   PI: Mohs, Kimberly MD  
**Navajo Area Indian Health Services - Cardiovascular Risk Reduction Demonstration Project**  
**Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly ending in September 2017 period
13. NNR-09.253 PI: Reid, Raymond M.D.
Impact of 13-valent pneumococcal conjugate vaccine (PVC13) on pneumococcal disease and colonization among Native American communities
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017

14. NNR-09.255 PI: Reid, Raymond M.D.
Pilot Study of the Association between Acute Gastroenteritis and Water Quality, Availability, and Handling Practices on the Navajo Nation
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

15. 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 Quarterly Review
Reason on Final Report
Description: Request Acceptance and Approval of Final Report

16. 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 Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

17. 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 Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

18. NNR-13.166 PI: Hilgert, Uwe PhD.
Cultivating Diverse Talent in STEM (CDTIS)
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Review

19. NNR-14.177 PI: Duran, Bonnie G. Dr.PH.
Tribal Colleges and Universities Behavioral Health Adaptation of an Evidence-Based Intervention
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering January 2017 - June 2017 period

20. NNR-15.214 PI: Lewis, Johnnye L. Ph.D.
Wood Stove Interventions and Child Respiratory Infections in Rural Communities
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering April 21 - July 20, 2017 period
21. 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 Quarterly Review
   Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period.

22. NNR-15.231 PI: Selig, Sara MD
   Engaging Patients and Stakeholders to Improve Cancer Outcomes in Navajo Nation
   Reason on Quarterly Review
   Description: Request Review and Acceptance of Quarterly Report covering June 16 - September 15, 2017 period.

23. NNR-15.232 PI: Hammitt, Laura M.D.
   Etiology of pneumonia and burden of pneumococcal pneumonia in hospitalized American Indian adults
   Reason on Quarterly Review
   Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period.

24. NNR-16.238 PI: Hammitt, Laura M.D.
   Active Bacterial Surveillance for Staphylococcus aureus on the Navajo and White Mountain Apache Reservations.
   Reason on Quarterly Review
   Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period.

25. NNR-16.260 PI: Eddie, Regina S. MS, RN
   A Socio-Ecological Analysis of Childhood Obesity and School Nutrition Policies and Practices in Select Elementary and Middle Schools on the Navajo Reservation.
   Reason on Quarterly Review
   Description: Request Review and Acceptance of Quarterly Report covering June - August 2017 period.

26. NNR-16.261 PI: Hammitt, Laura M.D.
   Evaluation of maternal immunization and interventions to increase uptake of vaccines among expectant American Indian women
   Reason on Quarterly Review
   Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period.

27. 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 Quarterly Review
   Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period.

28. NNR-03.121 PI: Bitsui, Natasha
   2003 Navajo Youth Behavior Survey (YRBS)
   Reason on Annual Report
   Description: Request Acceptance and Approval of Annual Report covering July 20, 2016 - July 19, 2017 period.
   Reason on Quarterly Review
   Description: Request Review and Acceptance of Quarterly Report covering April - Jul 2017 period.
29. NNR-07.216 PI: Reid, Raymond M.D.
Rapid-response investigation of pediatric cases of invasive Haemophilus influenzae in Navajo American Children
Reason on Amendment
Description: Request Acceptance and Approval of Amendment of Protocol Title to: Haemophilus Influenzae among southwest American Indian Children.

29. NNR-09.259 PI: Santosham, Mathuram MD
Menu for Life - Assessing Food Security Risk among At-Risk Southwestern Native Americans
Reason on Continuation Request
Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period

30. NNR-11.150 PI: Shin, Sonya MD
Evaluating the Navajo Community Outreach and Patient Empowerment (COPE) Program
Reason on Quarterly Review

30. NNR-15.199 PI: Shin, Sonya MD
REACH for Healthy Navajo Communities.
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering Mary 17 - June 17, 2017 period
Reason on Amendment
Description: Request Acceptance and Approval of Amendment Request of 1) Fruits and Vegetable Prescription Intake Survey, Monthly Check in and Exit Survey Forms
33. NNR-11.323 PI: Lewis, Johnnye L. Ph.D.

Navajo Birth Cohort Study (NBCS)

Reason on Conference Presentation
Description: Request Review and Approval of Conference Presentation of 1) Poster Titled: Examining Norms of an Early Developmental Screening Took in Navajo Children, at UNM Southwest Conference on Disability on October 11-13, 2017.

34. NNR-14.185 PI: Yazzie, Sheldwin A. Ph.D, MPH

Assessing Indoor Radon Exposure on the Navajo Nation.

Reason on Abstract Submission
Description: Request Review and Acceptance copy of Dissertation.

35. 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 Conference Presentation
Description: Request Acceptance and Approval of Abstracts for Conference Presentation at National Native Health Research Training Initiative Conference

Reason on Progress Report
Description: Request Review and Acceptance of 1) Household Summary report back sheet, 2) An updated CHR Flip Chart; 3) University of Arizona Approval for CHR Flip Chart and Household Summary report back sheet.

Reason on Approval for Dissemination
Description: Request Review and Acceptance of Two (2) Power Point Presentations of 1) Teach-In-Study Results, 2) A Dietary Patterns Pre and Post GKMS

Reason on Addendum
Description: Request Review and Approval of Addendums of Adam Settimoss NAU Master’s Thesis. Supporting documents: Mariette Marsh UA IRB, UA IRB Waiver of Human Research Subjects Approval, Initial UA IRB project approval, NAU-UA IRB Agreement, Letter from Dr. Jani Ingram, NAU

36. NNR-16.239 PI: Chee, Donald B.A.

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

Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering February 16 - May 16, 2017 period
Reason on: Consent Modification
Description: Request Acceptance and Approval of Consent Form Modification.
37. NNR-16.245  PI: Gittelsohn, Joel  Ph.D.

Engaging Tribal Policy Makers to Sustain Improvements to the Food and Physical Activity in American Indian Communities (OPREVENT2)
Reason on: Approval for Dissemination
Description: Request Review and Approval dissemination of Informational Flyer, Posters, educational displays, Labels and booklets.
38. NNR-16.254  PI: Reid, Raymond  M.D.

Evaluation of Native Vision Year Round Program
Reason on: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period
Reason on: Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering September 20, 2017 - September 20, 2018 period
39. NNR-16.257  PI: Lombard, Kevin A. PhD

Engaging Family and School in Navajo Gardening for Health
Reason on: Annual Report
Description: Request Acceptance and Approval of Annual Report covering September 2016 - August 2017 period
Reason on: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering May - August 2017 period,
40. NNR-17.273  PI: Dayle John, Kelsey  B.A.

What can the Navajo Horse teach us about decolonizing Education.
Reason on: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering April 18 - August 17, 2017 period
Reason on: Addendum
Description: Request Acceptance and Approval to add the Approved Navajo Nation Historic Preservation Permit to Protocol.

IX. Noon Hour Discussion
-2017 Annual Research Conference Abstracts Approval

X. Manuscripts and Abstract to submit NNHRRB Application
1-Tribal Turning Point – Dr. Dana Dabelea, MD,PhD., Dr. Katherine Sauder, PhD.
2-Diné Power Plate for Healthy Eating Challenge – Caroline Trapp, DNP, ANP-BC, CDE
3-Ethnographic Study of Woodland Resources Collection and use by Members of Navajo Nation – Brian F. Codding
4-Effectiveness of School Gardening across the Schools on Navajo Reservation – Jordan Jones

XI. Announcements and Adjournment

Last page and end of Agenda