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  Med, MPA
   How Has Navajo Community College Impacted the Local Communities? (now Din'e College)
   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
<table>
<thead>
<tr>
<th>No.</th>
<th>NNR-02.094</th>
<th>PI: Knowler, William  MD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Action for Health in Diabetes Look AHEAD</td>
<td></td>
</tr>
<tr>
<td>Reason on</td>
<td>Quarterly Review</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>NNR-02.099</th>
<th>PI: Santosham, Mathuram  MD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Safety and Efficacy of Pentavalent (G1, G2, G3, G4, and P1) Human-Bovine Reassortant Rotavirus Vaccine in Healthy Infants</td>
<td></td>
</tr>
<tr>
<td>Reason on</td>
<td>Quarterly Review</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>NR-02.105</th>
<th>PI: Reid, Raymond  M.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Epidemiology Study of Pneumonia among Navajo and White Mountain Apache Adults</td>
<td></td>
</tr>
<tr>
<td>Reason on</td>
<td>Quarterly Review</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>NNR-02.110</th>
<th>PI: Knowler, William  MD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Diabetes Prevention Program Outcomes Study (DPPOS)</td>
<td></td>
</tr>
<tr>
<td>Reason on</td>
<td>Quarterly Review</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>NNR-02.111</th>
<th>PI: Reid, Raymond  M.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Effects of Maternal Influenza Vaccination on Respiratory Disease among Infants</td>
<td></td>
</tr>
<tr>
<td>Reason on</td>
<td>Quarterly Review</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>NNR-04.151</th>
<th>PI: Santosham, Mathuram  MD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>Reason on</td>
<td>Quarterly Review</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>NNR-05.165</th>
<th>PI: Reid, Raymond  M.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Long Term Impact of the Pneumococcal Conjugate Vaccine on Pneumococcal Nasopharyngeal Colonization and Immune Correlates for Disease Protection</td>
<td></td>
</tr>
<tr>
<td>Reason on</td>
<td>Quarterly Review</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>NNR-05.174</th>
<th>PI: Reid, Raymond  M.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>In-home Prevention of Substance Abuse Risk in Navajo Teen Families</td>
<td></td>
</tr>
<tr>
<td>Reason on</td>
<td>Quarterly Review</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Request Review and Acceptance of Quarterly Report covering April 1 - June 30, 2017 period</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>NNR-05.175</th>
<th>PI: Mohs, Kimberly  MD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Navajo Area Indian Health Services - Cardiovascular Risk Reduction Demonstration Project</td>
<td></td>
</tr>
<tr>
<td>Reason on</td>
<td>Quarterly Review</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Request Review and Acceptance of Quarterly ending in September 2017 period</td>
<td></td>
</tr>
</tbody>
</table>
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.

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

30. 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 Acceptance and Approval of Continuation Request covering September 15, 2017 - September 15, 2018 period

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

31. NNR-11.150  PI: Shin, Sonya  MD

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

Reason on: Quarterly Review

Reason on: Annual Report
Description: Request Acceptance and Approval of Annual Report covering September 23, 2016 - September 19, 2017 period.

Reason on: Continuation Request
Description: Request Acceptance and Approval of Request for Continuation covering September 19, 2017 - September 18, 2018 period.

32. 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, Johnyne 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.

**Reason on**

**Conference Presentation**

**Description:** Request Review and Approval of Conference Presentation of the Following Abstracts Titled: 1) Working to understand the role of social determinants of health for minority and vulnerable communities in the United States on October 18, 2017 at 2017 International Society for Exposure Science Annual Meeting in Research Triangle Park NC, 2) Correlations between Immunologic Alterations and Metal Exposure within the Navajo Birth cohort Study on September 20-23, 2017 in Albuquerque, NM.

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.

**Reason on**

**Conference Presentation**

**Description:** Request Review and Approval of Abstracts for Conference Presentation: 1) Abstract Quantification of Dine activity patterns with the San Juan River in the wake of the Gold King Mine Spill; 2) Power Point Quantification of Dine activity patterns with the San Juan River in the wake of the Gold King Mine Spill; 3) Poster Slide Quantification of Dine activity patterns with the San Juan River in the wake of the Gold King Mine Spill; 4) Abstract for Community Driven University Partnerships to Assess Exposures and Risk Perceptions of Dine Communities following the Gold King Mine Spill; 5) Poster Slide for Community Driven University Partnerships to Assess Exposures and Risk Perceptions of Dine Communities following the Gold King Mine Spill.

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