

Navajo Nation Human Research Review Board Institutional Review Board Meeting Agenda

Date: March 15, 2016

Time: 9:00 AM

Location: NDOH Conference Rm
Window Rock, AZ

Chairperson: Beverly Becenti-Pigman

MEMBERS:

Dr. Mark C. Bauer, Ph.D. - Scientific Education

Beverly Becenti-Pigman - 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, M.D. - 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 December 15, 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;

XI. Announcements / Adjournments;

**Navajo Nation Human Research Review Board
IRB March 15, 2016 Meeting Agenda**

VII. NEW PRESENTATION(S)

1. NNR-16.240T PI: McCarroll, Meghan B.A.
Examining the Impacts of the Gold King Mine Spill within Local Communities
Reason on Agenda: New Title
Description: Request Review and Approval of New Study

VIII. RETURNING PRESENTATION(S)

1. NNR-02.094 PI: Knowler, William MD
Action for Health in Diabetes Look AHEAD
Reason on Agenda: Amendment
Description: Request Acceptance and Approval of Amendments to Protocols to include: 1) Revised Protocol Tracked and Clean - Extension (Version 15); 2) Consent to Participate Tracked and Clean.
2. NNR-06.195 PI: Deaton, James
National Indian Education Study 2007
Reason on Agenda: Annual Report
Description: Request Acceptance and Approval of Annual Report covering April 15, 2015 - April 14, 2016 period.
Reason on Agenda: Continuation Request
Description: Request Acceptance and Approval for Request Continuation from April 14, 2016 - April 14, 2017 study period.
3. NNR-09.241 PI: Overman, Barbara Ph.D.
Giving Voice to Health Values from within the Navajo Culture
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Reviews covering 1) August 1, 2015 - October 31, 2015, 2) November 1, 2015 - January 31, 2016 periods.
4. 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 August 19, 2015 - November 19, 2015 period.
5. NNR-14.185 PI: Yazzie, Sheldwin A. MPH
Assessing Indoor Radon Exposure on the Navajo Nation.
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering November 1, 2015 - January 30, 2016 period.

6. NNR-10.268 PI: Braun, Patricia MD

Preventing Caries in Preschoolers: Testing a Unique Service Delivery Model in American Indian Head Start Programs

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report (5) covering November 9, 2013 - November 10, 2014 period.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Year 6 2nd Quarterly Report.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Year 6 3rd Quarterly Report.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Year 6 Annual Report covering November 11, 2014 - November 11, 2015 period.

7. NNR-11.150 PI: Shin, Sonya MD

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

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering December 15, 2015 - March 15, 2016 period.

Reason on Agenda: Progress Report

Description: Request Review and Acceptance of Progress Report of Community Health Advisory Panel (CHAP) Meeting Summary

Reason on Agenda: Conference Presentation

Description: Request Review and Approval of 3 Abstract for Conference Presentation: 1) Cultural Elements Underlying the Community Health Representative - Client Relationship in Navajo Nation 2) Impact of Integrated community health worker outreach to individual with diabetes on the Navajo Nation; 3) Strengthening the role of Community Health Representatives in the Navajo Nation.

Reason on Agenda: Consent Modification

Description: Request Acceptance and Approval of 2 Consent Modifications.

8. 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 December 17, 2015 - March 17, 2016 period.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering March 17, 2015 - March 17, 2016 period.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment of 2 additional Forms: 1) Interview Guide for Food Distributors Associated with Healthy Stores Initiatives; 2) Interview Guide for Navajo Farmers associated with Healthy Stores

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment Change of Survey Forms associated with process evaluation.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request from March 17, 2016 - March 17, 2017 study period.

9. NNR-11.152 PI: Leischow, Scott J. Ph.D.

Networks among Tribal Organizations for Clean Air Policies

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Conference Presentation at the World indigenous Cancer Conference in Queensland, Australia on April 12-14, 2016. (presentation approved in September 2014)

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

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

Reason on Agenda: Quarterly Review

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

Reason on Agenda: Addendum

Description: Request Acceptance and Approval for addendum of Supporting Resolutions for study: 1) Fort Defiance Agency Council; 2) Northern Navajo Agency Council; 3) Eastern Agency Council; 4) Western Navajo Agency Council; 5) Shiprock chapter resolution; 6) Tse Daa K'aan Chapter resolution; 7) Upper Fruitland Chapter resolution; 8) Leupp Chapter

11. NNR-11.318 PI: Gordon, Paul H. MD

Parkinson Disease among the Navajo

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 23, 2015 – December 31, 2015 period.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of 2015 Annual Report.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval Continuation Request from February 2016 - February 2017 study period.

12. NNR-13.106 PI: Gordon, Paul H. MD

Neurological Disease among the Navajo

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 23, - December 31, 2016 period.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of 2015 Annual Report.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval for Request Continuation of Study

13. NNR-11.319 PI: Patten, Christi A. Ph.D.

Family Cancer Literacy to Promote Mammography Screening among Navajo Women

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Unanticipated Event Letter to participants.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 23, 2015 - February 22, 2016 period.

14. 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: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 1, 2013 - September 30, 2013 period.

Reason on Agenda: Continuation Request;

Description: Request Acceptance and Approval of Request for Continuation for January 2014 - December 2014 Study Period.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering; 1) January 1, 2014 - March 31, 2014; 2) April 1, - June 30, 2014; 3) July 1, 2014 - September 30, 2014 periods.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of 2014 Annual Report covering January 1, 2014 - December 31, 2014 study period.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Request for Continuation for January 2015 - December 2015 study period

Reason on Agenda: Quarterly Review

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

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Request Continuation for January 2016 - December 2016 study period.

Reason on Agenda: Quarterly Review

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

Reason on Agenda: Final Report - **PreviousTabled**

Description: Request Acceptance and Approval of Final Report included: 1) Final Dissemination Plan; 2) Student Thesis with Appendices; 3) Thesis without Appendices; 4) Group Interview Transcripts.

15. 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 December 2015 - February 2016 period.

16. NNR-14.176 PI: Duran, Bonnie G. Dr.PH

Tribal Colleges and Universities Alcohol, Drugs and Mental Health Epidemiologic Study (TCU-ADME)

Reason on Agenda: Quarterly Review

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

17. NNR-15.201 PI: Bauer, Mark C. Ph.D.

An Intervention to Promote Navajo Gardening, Nutrition, and Community Wellness

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Conference Presentation at March 4, 2016 in Chinle, AZ and on April 2, 2016 at Tuba City, AZ.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request of Study from March 17, 2016 - March 16, 2017 period.

18. NNR-01.081 PI: Bauer, Mark C. Ph.D.

Making a Difference: The Role of Family Support in Navajo Diabetics' Selfcare

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request of Study from March 27, 2016 - March 26, 2017 period

19. 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 November 19, 2015 - February 19, 2016 period.

Reason on Agenda: Dissertation Report

Description: Request Acceptance and Approval of Dissertation Report (Ph.D. candidate) covering February 2015 - February 2016

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Request Continuation for Study from May 19, 2016 - May 19, 2017 period.
Supporting Documents 1) ASU IRB approval Letter, 2) NN Historic Perservation Permit.

20. NNR-15.209T PI: Aruquete, Shing

A Case Study of the Teacher Advancement Program on a Native American Reservation.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report.

21. NNR-15.230T PI: LaPahe, Nelda

Navajo Nation Takes Control: A Blueprint of a Dream

Reason on Agenda: Addendum – New Title

Description: Request Acceptance and Approval of 1) Meeting Minutes for Supporting Documents to conduct Study in Tiis Naz Bas,
2) Permission Letter from Tiss Naz Bas School Board President and 3) Minutes from Aneth Community School Board Meeting

22. NNR-15.231 PI: Selig, Sara MD

Engaging Patients and Stakeholders to Improve Cancer Outcomes in Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 17, 2015 - February 17, 2016 period.

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

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

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment 1.4 version Request of 1) Adult Control Consent; 2) Adult Case Consent Forms.

24. NNR-01.085 PI: Reid, Raymond M.D.

Effect of Pneumococcal Conjugate Vaccine on Nasopharyngeal Colonization among Adult Household Contacts of Vaccinated

Reason on Agenda: Continuation Request

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

25. 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 Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering March 31, 2016 - March 31, 2017 period.

26. 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 Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstracts for Conference Presentations at International Symposium on Pneumococci and Penumococcal Disease (ISPPDD) on June 26-3-, 2016 in Glasgow, Scotland. Titled: Examination of Potential Rescued-Dose PCV Schedule Using a Mathematical Model of a S. Pneumoniae Colonization. (NNR-97.018, NNR-9.253)

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract or Conference Presentation Titled Identification of Latent Reservoirs of Pneumococcal Conjugated Vaccine (PCV) Serotypes after Extended Vaccination on June 26-30, 2016 in Glasgow, Scotland at International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD) (NNR-97.018, NNR-9.253)

27. 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 Acceptance of Updated version of Dissertation and Conference Presentation.

28. NNR-15.225 PI: Hee Kim, Sang

Achieving Success by Promoting Readiness for Education and Employment

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report.

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

Cultivating Diverse Talent in STEM (CDTIS)

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of 2015 Annual Report covering December 17, 2014 - December 16, 2015 study period.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval for Continuation Request covering December 17, 2016 - December 16, 2017 period.

ABSTRACTS

1. The title of the project is Disruptive Behavior in the Healthcare Environment (Kayenta I.H.S.) - Ashley Sepanski, RN, MSN, C-NE **(USE FROM FEBRUARY 16, MEETING PACKET)**
2. Developing a Navajo Educational Media Guide: A Community Perspective – Shawna L. Begay (Ph.D. Candidate)
3. Investigating Culturally-Contextualized Making with the Navajo Nation – Daniel Frank

Last page and end of Agenda