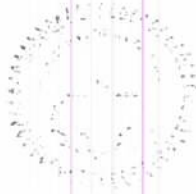


THE NAVAJO NATION



BEN SHELLY PRESIDENT
REX LEE JIM VICE PRESIDENT

January 31, 2013

Johnnye Lewis, Ph.D.
Principal Investigator, Navajo Birth Cohort Study
Director, Community Environmental Health Program
University of New Mexico Health Science Center
Albuquerque, New Mexico 87131

Dear Dr. Lewis:

This is to notify you that I have had the Navajo Nation Human Research Review Board review the changes to the outreach materials requested by the Federal Office of Management and Budget. The board has no objections to the requested changes.

We assume this will remove the final barrier to the issuance of a control number for the project by OMB. We look forward to the start of enrollment at Chinle Hospital in February. As you know, this project has the full support of Vice-President Rex Lee Jim, as well as Tribal Council and the Attorney General of Navajo Nation.

Please contact me if you have questions.

Sincerely,

Beverly Becenti-Pigman
Chair, Navajo Nation Human Research Review Board



THE UNIVERSITY OF NEW MEXICO
HEALTH SCIENCES CENTER

Human Research Review Committee

MSC 08 4560 BMSB Room B71

1 University of New Mexico~Albuquerque, NM 87131-0001

(505) 272-1129 Facsimile (505) 272-0803

<http://hsc.unm.edu/som/research/hrrc/>

07-Jun-2012

Lewis, Johnnye L, Ph.D.
College of Pharmacy

SUBJECT: HRRC Approval of Research - Amendment

Project Title: The Navajo Birth Cohort Study (A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation)

HRRC#: 11-310

Type of Review: Expedited Review

Approval Date: 06-Jun-2012

Expiration Date: 13-Jun-2013

Dear Dr. Lewis:

The Human Research Review Committee (HRRC) has **approved*** the above mentioned research protocol action based on review of the following:

1. Investigator Protocol version 05/16/2012;
2. UNM HSC Mother's Consent version 05/16/2012;
3. UNM HSC Father's Consent version 05/16/2012;
4. Biological Specimen Table submitted 05/25/2012;
5. Food Frequency Questionnaire submitted 05/25/2012;
6. NBCS Eligibility Questionnaire submitted 05/25/2012;
7. Recruitment Materials submitted 05/25/2012;
8. Approval Process for future informational videos.

PI requests acknowledgment of the following:

1. Navajo HRRB Letter dated 04/19/2012;
2. NBCS Mother Consent Translational Guide submitted 05/25/2012;
3. Participant Timeline English version submitted 05/25/2012;
4. Initial Version Participant Timeline Navajo Translation Guide submitted 05/25/2012;
5. Initial Version HIPAA Navajo Translation Guide submitted 05/25/2012;
6. NBCS Introduction submitted 05/25/2012;
7. Reference Document for Malcolm Benally.

Consent Decision:

Amended consent(s) attached.

HIPAA Authorization on record; signed HIPAA required

VA Studies Only:

If a consent is required, we have attached a date stamped consent that must be used for consenting participants during the above noted approval period.

If HIPAA Authorization is required, the HIPAA Authorization version noted above should be signed in conjunction with the consent form.

This study is approved to enroll only the number of subjects listed in the application, current protocol and consent form(s). If the PI wants to enroll additional subjects, it is the responsibility of the PI to submit an Amendment Request to the HRRC before the approved number of enrolled subjects is exceeded. If increased enrollment is requested the application, protocol and/or consent form(s) must also be amended to include the new target.

When consent is required, it is the responsibility of the Principal Investigator (PI) to ensure that ethical and legal informed consent has been obtained from all research participants.

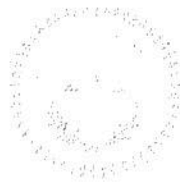
Sincerely,

A handwritten signature in black ink, appearing to read 'Mark Holdsworth', written over a light blue horizontal line.

Mark Holdsworth, PharmD
Executive Chair
Human Research Review Committee

* Under the provisions of this institution's Federal Wide Assurance (FWA00003255), the HRRC has determined that this proposal provides adequate safeguards for protecting the rights and welfare of the subjects involved in the study and is in compliance with HHS Regulations (45 CFR 46), FDA Regulations (21 CFR 50, 56).

THE NAVAJO NATION

BEN SHELLY
REX LEE JIM

December 6, 2011

Johnnye L. Lewis, PhD
College of Pharmacy - MSC09 5360
University of New Mexico
Albuquerque NM 87101-0001

Dear Dr. Lewis:

This is to advise you that Study #NNR-10.84T "Navajo Birth Cohort Cohort Study (NBCS)" was presented to Navajo Nation Human Research Review Board on August 23, 2011 and considered the initial submission of your protocol and the Board took the following actions:

- We have assigned a permanent ID# NNR-10.323 to be used as a reference for all documents pertinent to the study;
- The Board approved the study effective from August 23, 2011 to August 23, 2012 with all standard conditions;
- The following actions are to be implemented, if they have not been done: 1) PI change to and not or; 2) Insurer to be done for cost of injury and document to be sent to Department of Justice for legal review; 3) Contact NNHRRB and UMHSC; 4) Risk change or to read and; and 5) Submit original copy of document.

Additional contingencies are:

The Navajo Nation Human Research Review Board has added a very important additional contingency regarding failure to comply with NNHRRB rules, regulations, and submittal of reports which could result in sanctions being placed against your project. This could also affect your funding source and the principal investigator. **Under Part Five: Certification**, please note paragraph five wherein it states: "I agree not to proceed in the research until the problems have been resolved or the Navajo Nation Human Research Review Board has reviewed and approved the changes." Therefore, it is very important to submit quarterly and annual reports on time and if continuation is warranted submit a letter of request sixty (60) days prior to the expiration date.

The following are requirements that apply to all research studies:

1. The Navajo Nation retains ownership of all data obtained within its territorial boundaries. The Principal Investigator shall submit to the NNHRRB a plan and timeline on how and when the data/statistics will be turned over to the Navajo Nation;
2. Only the approved informed consent document(s) will be used in the study;
3. Any proposed future changes to the protocol or the consent form(s) must again be submitted to the Board for review and approval prior to implementation of the proposed change;
4. If the results of the study will be published or used for oral presentations at professional conferences, the proposed publication, abstract and/or presentation materials must be submitted to the Navajo Research Program for Board review and prior approval;
5. Upon Board approval, three (3) copies of the final publication must be submitted to the Navajo Research Program;

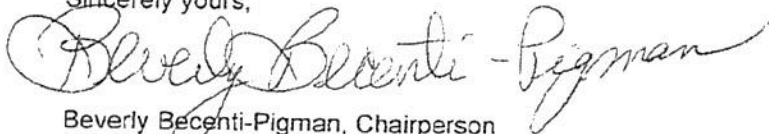
6. All manuscripts must be submitted to the Navajo Research Program for Board Review and prior approval;
7. The Principal Investigator must submit a dissemination plan on how the results of the study and how these results will be reported back to the Navajo Nation. The Principal Investigator must share specifically how these results will generally benefit or improve the health of the Navajo people. This can be completed by:
 - a. Conducting an educational in-service for the community people and health care providers on the Navajo Nation and present the findings. Provide documentation of these in-services presented.
 - b. Developing educational materials for use by the health care providers and the community people and providing the training on how to use the materials; and
 - c. Presenting and sharing the results of the study at a research conference sponsored by the Navajo Nation for its health care providers and the Navajo people.
8. The Principal Investigator is expected to submit documentation on 7a, b, & c.
9. The Principal Investigator must submit quarterly and annual reports as scheduled.

This approval will automatically expire on **August 23, 2012** unless sooner suspended, revoked or terminated by action of the Board. A continuation of the research project may be requested by submitting a written request at least sixty (60) days prior to the expiration date to the:

Navajo Division of Health – Research Program
Post Office Box 1390
Window Rock, Arizona 86515

If you have any questions, please call the Navajo Research Program at (928) 871– 6650.

Sincerely yours,



Beverly Becenti-Pigman, Chairperson
Navajo Nation Human Research Review Board

Cc: Beverly Becenti-Pigman
NNR-10.323
Chrono



August 23, 2012

Johnnye L. Lewis, PhD
College of Pharmacy - MSC09 5360
University of New Mexico
Allbuquerque NM 87101-0001

Dear Dr. Lewis:

This is to advise you that **Study #NRR-11.323 "Navajo Birth Cohort Study (NBCS)"** was presented to Navajo Nation Human Research Review Board on June 19, 2012 and considered the quarterly and annual report, request for continuation and de-identified data sharing to validate ASG-1 for Navajo. The Board initiated the following actions:

- Approved the Quarterly Report covering February 23 to May 22, 2012;
- Approved the Annual Report covering August 23, 2011 through May 17, 2012;
- Approved the request for Continuation effective **August 23, 2012 through August 23, 2013**; and
- Approved consideration of de-identified data sharing to validate ASQ-1 for Navajo.

Additional contingencies are:

The Navajo Nation Human Research Review Board has added a very important additional contingency regarding failure to comply with NNHRRB rules, regulations, and submittal of reports which could result in sanctions being placed against your project. This could also affect your funding source and the principal investigator. **Under Part Five: Certification**, please note paragraph five wherein it states: *"I agree not to proceed in the research until the problems have been resolved or the Navajo Nation Human Research Review Board has reviewed and approved the changes."* Therefore, it is very important to submit quarterly and annual reports on time and if continuation is warranted submit a letter of request sixty (60) days prior to the expiration date.

The following are requirements that apply to all research studies:

1. The Navajo Nation retains ownership of all data obtained within its territorial boundaries. The Principal Investigator shall submit to the NNHRRB a plan and timeline on how and when the data/statistics will be turned over to the Navajo Nation;
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5. Upon Board approval, three (3) copies of the final publication must be submitted to the Navajo Research Program;
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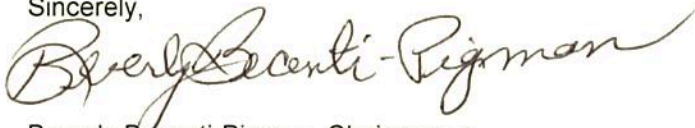
- a. Conducting an educational in-service for the community people and health care providers on the Navajo Nation and present the findings. Provide documentation of these in-services presented.
 - b. Developing educational materials for use by the health care providers and the community people and providing the training on how to use the materials; and
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8. The Principal Investigator is expected to submit documentation on 7a, b, & c.
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This Approval will automatically expire on August 23, 2013 unless sooner suspended, revoked or terminated by action of the board. A continuation of the research project may be requested by submitting a written request at least sixty (60) days prior to the expiration date to the:

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If you have any questions, please call the Navajo Research Program at (928) 871- 6650.

Sincerely,



Beverly Becenti-Pigman, Chairperson
Navajo Nation Human Research Review Board

Cc: Beverly Becenti-Pigman
NNR-11.323
Chrono