DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date February 16th, 2012

From James Peterson, PhD
IRB-D Administrator, Human Research Protection Office

Subject CDC Approval of Reliance on a Non-CDC IRB for CDC Protocol #6149.0, "A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation"

To Steve Dearwent, PhD
ATSDR/DHS

CDC's Human Research Protection Office reviewed and approved the request to allow reliance on a non-CDC IRB for protocol #6149.0, "**A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation**" in accordance with 45 CFR 46.114. The protocol has been reviewed and approved by the University of New Mexico Health Sciences Center IRB for the maximum allowable period of twelve months and the **IRB's approval will expire on 6/13/2012.**

CDC study activities <u>may begin</u> with the following collaborators as current IRB approval has been received by CDC's Human Research Protection Office (HRPO):

1. **Navajo Division of Health**
2. **Navajo Area Indian Health Service**

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB along with available IRB approvals from all collaborators. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. **To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request along with all completed supporting documentation at least six weeks before the protocol's expiration date of 6/13/2012.**

Any problems of a serious nature must be brought to the immediate attention of the CDC IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for CDC IRB approval <u>before</u> they are implemented.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office (404) 639-4721 or e-mail: huma@cdc.gov.

cc:
NCEH/ATSDR Human Subjects
Angela Ragin, PhD

THE UNIVERSITY OF NEW MEXICO
HEALTH SCIENCES CENTER

IRB Authorization Agreement

Institution Providing IRB Review: University of New Mexico Health Sciences Center

Designated IRB Registration No.:
IRB00000591 UNMHSC/School of Medicine IRB #1
IRB00000592 UNMHSC/School of Medicine IRB #2
IRB00001775 UNMHSC/School of Medicine IRB #3
IRB00001776 UNMHSC/School of Medicine IRB #4

Federal Wide Assurance ("FWA") No.: FWA00003255

Name of Organization Relying on the Designated IRB: Centers for Disease Control and Prevention (CDC)

Organization's OHRP Federal Wide Assurance ("FWA") No.: FWA00001413

The Regents of the University of New Mexico, for its public operation known as the Health Sciences Center ("HSC"), specifically for its Human Research Review Committee ("HRRC"), and Centers for Disease Control and Prevention (CDC) ("Organization") agree that, subject to the following conditions, Organization may rely upon the designated IRB for review and continuing oversight of the following research projects ("Studies"):

> Studies in which the Principle Investigator ("PI") is a salaried University of New Mexico Health Sciences Center faculty member

Organization shall provide the Operations Manager, Office of Human Research Protections, Basic Medical Sciences Building, Room B71, University of New Mexico, with evidence sufficient to confirm that Organization has a current and valid Federal Wide Assurance.

As applicable, Organization shall pay all HRRC fees of HSC. The initial review fee shall be due and payable at the time the protocol for the Study is submitted for HRRC review.

In performing their obligations under this Agreement, Organization and the PI will comply with all applicable laws, and, to the extent not in conflict with applicable federal law, regulations, policies and procedures, will abide by all policies and requirements of HSC concerning research, patient rights, and patient privacy. Organization and the PI will also be familiar with and, to the extent not in conflict with applicable federal law, regulations, policies and procedures, comply with the "HRRC Manual for Conducting Human Subject Research" (the "Manual"), and the HRRC Policy Regarding the Use of the UNMHSC Human Research Review Committee. PI acknowledges receiving the Manual and the policy. To the extent permitted by applicable federal law, Organizations shall: 1) remain solely responsible for ensuring compliance with the HRRC's determinations and with the terms of its OHRP-approved FWA and other contractual obligations; provide HRRC information, as requested, including medical and other

records, pertaining to the Study,; allow representatives of the HRRC access to its records; promptly report any suspected or known failure to comply, or other problem, including debarment of researchers, and adverse events, occurring during Studies, as well as any audit of the Studies; provide a copy to the HRRC of all audit reports and all correspondence with governmental agencies concerning the Studies; and, cooperate with the HRRC in all investigations related in any manner to the Studies.

The review and continuing oversight performed by the HRRC will meet the human subjects protection requirements of Organization's OHRP-approved FWA and other contractual obligations. The HRRC will follow written procedures in reporting its findings and actions to Organization. Representatives of Organization may review portions of HRRC minutes concerning the Study upon request.

In the event of injury or damage arising from the activities conducted pursuant to the study, HSC, the designated HRRC, and their officers, directors, employees, members, and agents may have recourse against the U.S. Government under the provision of the Federal Tort Claims Act (28 U.S.C. section 1346(b)) or other applicable federal law.

This Agreement shall be kept on file at HSC and Organization, and a copy shall be provided to OHRP upon request.

The parties have executed this Agreement effective as of August 4, 2011 at Albuquerque, New Mexico, and it shall remain in full force and effect until cancelled by either party upon not less than ninety (90) days prior written notice.

This Agreement constitutes the entire and integrated agreement of the parties with respect to the designation of the above-referenced IRB for review and continuing oversight of the Studies, and this Agreement shall supersede all prior discussions, representations, promises, and understandings of the parties as to the subject matter of this Agreement. The parties herein acknowledge that separate agreements may be in place between the parties with respect to other aspects of the study.

Facsimile or scanned copies of this Agreement including original, scanned or facsimile signatures shall be deemed original copies and shall each constitute an original executed agreement.

(Organization relying on FWA)
Centers for Disease Control and Prevention (CDC)

By: Barbara R. DeCausey Date: 8/4/2011
Barbara R. DeCausey, MPH, MBA
Chief,Human Research Protections ~~Office~~

Regents of the University of New Mexico, for the Health Sciences Center

By: _____ Date: 8/4/2011
Richard Larson, MD, PhD, Vice Chancellor for Research

NOTE: The Institution providing IRB review may need to be designated on the OHRP-approved FWA for the Organization.

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/

20-Jun-2011

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

SUBJECT: HRRC Approval of New Research Protocol
HRRC#: 11-310
Study Title: The Navajo Birth Cohort Study (A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation)
Type of Review: Full Committee Review
Approval Date: 17-Jun-2011
Expiration Date: 13-Jun-2012

Dear Dr. Lewis:

The Human Research Review Committee (HRRC) has reviewed and approved* the above-mentioned research protocol including the following:

1. HRRC Application, revised, received 061711 & All attachments submitted 052411 unless noted below
2. Protocol, v061611
3. Biological Specimen Table, received 061711
4. Recruitment Flyer/Announcement, received 061711
5. Photography Consent, v061611
6. UNMHSC Consent/Assent Form-Mother v061611
7. UNMHSC Consent/Assent Form-Father v061611
8. UNMHSC HIPAA Authorization v061611

Note: Revisions requested by the Full Committee on 6/14/11 were received and reviewed using Expedited review procedures.

ALSO NOTE: Navajo Nation IRB approval is required prior to beginning research. Please submit documentation of approval once received. Also, it is acknowledged that the infants name cannot be included on the consent at the time that the mothers consent is obtained. However, given the longitudinal nature of the study and the fact that the infant will be followed for a period of time and will undergo study procedures, the infants identity should be captured on the study documents such as the informed consent. As such, it is recommended to create a field for the infants name and to add the name once the infant is born. This will allow for adequate documentation of the infant's identity as a study subject. This recommendation can be incorporated with revisions made at the request of the Navajo Nation IRB and submitted to the HRRC when Navajo Nation IRB Approval documentation is submitted as an amendment.

Consent decision:

Requires a signed consent form
HIPAA Authorization on record; signed HIPAA required

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, protocol and consentform(s). If the PI wants to enroll additional subjects, it is the responsibility of the PI to submit an Amendment/Change 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.

Sincerely,

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
Allbuquerque 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