Supporting Statement
For OMB Review and Approval of

Agency for Toxic Substances and Disease Registry (ATSDR)
A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation

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SECTION A. Justification

Date 8 March 2012

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A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR) for the Agency for Toxic Substances and Disease Registry (ATSDR) "A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation" (U01).

The program requests Office of Management and Budget (OMB) approval for three years.

Background

This Information Collection Request (ICR) is a new data collection request involving pregnant mothers, their infants and fathers within the Navajo Nation. The Navajo Nation encompasses 16 million acres of New Mexico, Utah and Arizona, and is the largest Alaska Native/American Indian Reservation in the United States. From 1948 to 1986, hundreds of uranium mining and milling operations were conducted in the Navajo Nation. These mining and milling operations have left a legacy of uranium contamination through abandoned uranium mines/mills, drinking water and soil, and homes and structures built with mining waste. Uranium is a heavy metal and may cause adverse health effects due to both its radiological and chemical properties. As a heavy metal, uranium primarily damages the kidneys and urinary system. The kinetics, metabolism, and toxic effects of uranium on kidney function are well established. However, there is limited epidemiological and toxicological data regarding uranium exposure and adverse birth and reproductive health outcomes. Identification and mitigation of early exposures to uranium may aid in preventing potential adverse child and maternal health outcomes.

In the Navajo Nation, congenital anomalies remain the leading cause of infant deaths. The infant mortality rate among the Navajo people is 8.5 deaths per 1000 live births, compared to 6.9 deaths per 1000 live births among all races. The postnatal mortality rates for Navajo infants are 2.1 times higher than the US for all races. There is strong evidence linking the early and consistent use of prenatal care with positive reproductive results. However, only 61% of Navajo mothers with live births received prenatal care in the first trimester as compared to 83% of all U.S. mothers. Early and regular prenatal care is a significant predicator of positive birth outcomes. Therefore, it is imperative that Navajo women and their families are educated about the importance of prenatal care and the potential adverse health risks associated with exposure to uranium.

The U.S. House of Representatives Committee on Oversight and Government Reform requested that federal agencies develop a plan to address health and environmental impacts of uranium contamination in the Navajo Nation. In response to the Congressional charge, ATSDR awarded a research cooperative agreement to University of New Mexico Community Environmental Health Program (UNM-CEHP) entitled "A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation (U01)," in August 2010. In order to carry out the study,

ATSDR and UNM-CEHP are collaborating with the Navajo Area Indian Health Service (NAIHS), Navajo Nation Division of Health (NNDOH), Navajo Nation Environmental Protection Agency (NNEPA), and Navajo culture and language specialists to carry out the study. Study participants will be recruited from five NAIHS clinics/ Public Law 93-638 (PL-638) healthcare facilities on the reservation. Through an interagency agreement with ATSDR, NAIHS will hire project coordinators at each of the five clinics and will conduct medical screenings and provide prenatal care to study participants. Through a sole-source contract with ATSDR, NNDOH Community Health and Environmental Research Specialists (CHERs) will provide survey administration, community education, training and outreach for the study.

The study will evaluate reproductive outcomes in pregnant women, follow and assess their children at birth, 2 months, 6 months, 9 months and up to1 year of age to evaluate the impact of uranium exposure on biological and psychosocial endpoints. Due to the infant mortality rate in this population, we may not obtain follow-up information on all children at each age point. Also, follow-up information may be limited due to miscarriages or participant fatigue. However, extensive training and outreach will be conducted to maximize participant response rate and minimize participant fatigue (See Part B.3). OMB approval is requested to conduct the biological sample analysis, surveys, and developmental screenings that will be performed during this research period for each participant.

The study will provide broad public health benefits for Navajo communities through outreach and education on the importance of prenatal care, environmental prenatal risks and earlier assessment and referral for known developmental delays.

ATSDR is authorized by the Comprehensive Environmental Response, Compensation and Liability Act of 1980 and Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9604(i)(1)(E), (7), (9), (15) and 9626(a)] to collect this study data. Please see Attachment 1 for Authorizing Legislation.

The 60-day Federal Register Notice of the proposed information collection (IC) was published on November 22, 2011. (See Attachment 2).

Privacy Impact Assessment

Overview of the Data Collection System

The ATSDR study “A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation” will be conducted by interview and by the collection of blood and urine specimens for analytical measurements. The information collection (IC) will be implemented in five phases: sampling; eligibility screening; enrollment and informed consent; interviews using a structured questionnaire and follow-up. The burden tables in Section A.12 reflect the data flow of the collection forms developed by the principal investigator at UNM-CEHP.

- Sampling: Potential Study participants must be eligible to receive prenatal care services from the following NAIHS/ PL-638 Clinics: Northern Navajo Medical Center, Chinle Comprehensive Health Care Facility, Gallup Indian Medical Center, Tuba City Regional Health-Care Corporation, or Tséhootsooí Medical Center. Please refer to Part B.1 for Respondent Universe and Sampling Methods.
- Eligibility screening: Interviewers will administer and document eligibility screening using paper and pencil form. Any paper copies will be stored and managed in a record keeping system in a locked file in the office of Dr. Johnnye Lewis (Principal Investigator) at UNM-CEHP. Participants are pregnant woman who are at least 14 years of age and have lived on the Navajo reservation for at least 5 years.
- Enrollment and informed consent: Informed consent will be documented on a paper and pencil form (Attachment 4). Any paper copies will be stored and managed in a record keeping system in a locked file in the office of Dr. Lewis.
- Interview: A computer assisted personal interview (CAPI) will be conducted to ascertain the respondent's contact information. CDC's rapid data collector (RDC) will be used for questionnaire responses
- Follow-up: The study will examine reproductive outcomes in pregnant woman and follow and assess their children from birth to 1 year of age

ATSDR requests OMB approval to collect biological and survey information from pregnant Navajo women, fathers, and their children over a three-year period. . Survey instruments were specifically designed to collect demographic information, assess potential environmental, health risks, and mother-child interactions. The survey instruments were developed based on previous surveys conducted by UNM-CEHP's Dine' Network for Environmental Health (DiNEH) Project, the National Children's Study, and by other birth cohort studies in other indigenous populations. The final format of the survey instruments was modified based on review and input from the Navajo Nation community liaison group, and associated Navajo staff who addressed issues such as cultural sensitivity, comprehension and language translation.

Each study participant will be given a unique study ID number. Information and/or specimens collected as part of the study will be labeled with this assigned study number. Information (without participant's name) will be entered into the Rapid Data Collector (RDC), a secure web-based computer database maintained on CDC servers. Data will be stored for three years following conclusion of the study, and then de-identified data will be turned over to the Navajo Nation per the Navajo Nation Human Research and Review Board protocols.

Items of Information to be Collected

The IC will acquire information in identifiable form (IIF) permitting sampling, screening, recruitment, and results reporting to respondents. The IIF will be stored and managed in the Principal Investigator's record system. The categories of directly identifiable information to be collected include: names, date of birth, street address, mailing address, phone numbers, email addresses, and biological specimens. All IIF will be maintained and processed in the established record keeping system and managed by the Principal Investigator at UNM-CEHP and lead research team members. Lead research team members include the UNM Project Coordinator/ Database Manager, Navajo Nation Division of Health Project Coordinator, and the Clinical Liaisons at each of the five Navajo Area Indian Health Service (NAIHS)/ PL-638 health facilities. No other staff or trained contractors will have access to this system.

The project deliverables include results for chemical analytes in blood and urine specimens. The laboratory analysis for the project will be provided by in-house and by the National Center for Environmental Health (NCEH), Division of Laboratory Sciences (DLS), Inorganic and Radiation Analytical Toxicology Branch at CDC. Blood and urine specimens will be labeled by study ID only. Laboratory personnel will not handle any records with IIF.

A secondary purpose of the IC is to obtain demographic factors and lifestyle information on factors that can potentially contribute to a higher exposure including: age, sex, education and income level, dietary patterns, hobbies, land, water and drug use, occupational and employment history, residential history and household exposure (Attachment 3: Data Collection Instruments).

The data will be collected by the ATSDR contractor, Navajo Nation Division of Health (NNDOH). Identifiers must be maintained because of repeated contacts needed with the parent during pregnancy and when the baby is 2, 6, 9, and 12 months in accordance with study plans to assess developmental levels of the child. However, all data will be identified by study ID# only and the list linking name and study ID # will be stored in a locked file at UNM-CEHP with access limited to the UNM-CEHP and the lead research team. Data will be de-identified by the principal investigator prior to delivery to ATSDR, through a secure and encrypted file transfer protocol that is described in Section A.10.

The survey instruments for pregnant mothers will include the following: Enrollment Survey (Attachment 3a), Ages and Stages Questionnaire (Attachment 3c), Mullen Stages of Early Development (Attachment 3d), Postpartum Surveys (Attachment 3e, 3f, 3g) and Eligibility Form (3h). Fathers will also be given an enrollment survey (Attachment 3b). Information in Identifiable form (IIF) will be maintained at cooperative agreement study partner, University of New Mexico (UNM) includes: mailing address, medical information and notes, biological specimens, phone number, and email address. However, this information will be de-identified

prior to transmission to the RDC on CDC server. In compliance with the federal Health Insurance Portability and Accountability Act (HIPAA), all participants will sign a HIPAA Authorization to Use and Disclose Protected Health Information for Research Purposes Form (Attachment 4). This purpose of this form is to get participants' permission (authorization) to use health information about them that is created by or used in connection with this research. Please see Section A.10 for further details.

Using the Rapid Data Collector data entry system, Community Health and Environmental Research Specialists (CHERs) will administer an enrollment survey to enrolled mothers and fathers to identify demographic information, characteristics of the home environment, land use patterns including foods locally raised, and potential exposures. The enrollment survey will include questions involving use of prescription, over-the-counter, and recreational drugs, stress, physical activity, water usage, food behaviors, occupation, and activities conducted in the home which might create potential health risks.

Developmental assessments will utilize two standardized instruments: The Ages and Stages Questionnaire I (ASQ-I) and the Mullen Stages of Early Learning (MSEL). The ASQ-I (Attachment 3c) is a population screening measure that is used to assess a child's development between the ages of 1 month and 5 ½ years of age. The ASQ-I is a nationally validated assessment of a child's function in a number of domains, including communication, gross and fine motor skills, problem solving and personal social skills. Since Native Americans were underrepresented in the ASQ-I national sample, ASQ-I has never been specifically validated in the Navajo population. However, the ASQ is routinely used for screening Navajo children. The MSEL (Attachment 3d) is a standardized measurement of early intellectual development and is used for children from birth to 5 years old. The MSEL is comprised of five (5) scales: Gross Motor, Fine Motor, Visual Reception, Expressive Language, and Receptive Language. The Fine Motor, Visual Reception, Expressive Language, and Receptive Language scales combine to form an Early Learning Composite scores. Attachment 12 details the Manual of Procedures for the ASQ-I and MSEL.

CHERs will administer postpartum surveys to mothers after birth and when the baby age is 2, 6, 9, and 12 months in conjunction with the ASQ-I. The postpartum survey that is administered after birth (Attachment 3e) will assess risk factors during pregnancy such as diet, medication and change in location. The postpartum surveys at 2,6,9 (Attachment 3f) and 12 months (Attachment 3g) will assess breastfeeding behaviors, depression, and child-parent interactions using standardized instruments, including the Kessler 6 depression scales (Kessler et al, 2002), the HOME screening tool (Bradley and Caldwell, 1977), and the Edinburgh postpartum depression scale (Watts et al, 2007). The postpartum survey at 12 months includes a food frequency questionnaire.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The information collection does involve web-based data collection methods, and there is no website with content directed at children under 13 years of age. Eligible participants must be at least 14 years of age to participate in the study. The data collection system utilizes a security controlled internal website; therefore, public access and the potential for cookies do not exist.

A.2. Purpose and Use of the Information Collection

The ATSDR and its cooperative agreement partner, UNM-CEHP, will oversee the collection of this data by the contractor, Navajo Nation Division of Health. The information collected will be used to determine if Navajo mothers and their infants have elevated exposure to uranium. The primary objective of this study is to evaluate the health effects of non-occupational exposure to uranium among Navajo mothers and their infants- particularly during prenatal, perinatal, and early postnatal life periods. Additionally, the study will provide health education and outreach to increase prenatal care utilization and mitigation of environmental uranium exposure.

The study is being conducted in response to Navajo community requests conveyed to Congress, which resulted in a Congressional allocation for ATSDR to conduct this epidemiological study. Study funds were requested for the three year study period (2010-2012). The results of the study will answer long-standing questions on whether or not exposures to uranium wastes and other environmental contaminants are associated with adverse birth outcomes or developmental delays on the Navajo Reservation. Answers to these questions will benefit the Navajo individuals, Navajo families and the federal government. An understanding of the risks associated with uranium exposure can reduce stress associated with the current lack of knowledge. For participating families, risks or developmental delays will be identified early and these families will be referred to support services to ensure early intervention and reduce the impacts of developmental delays. Since these studies are being conducted under Congressional mandate and include federal agencies responsible for removal of source contamination, the improved understanding of risks will help in guiding policies that prioritize remedial actions to remove contamination sources from these communities.

Privacy Impact Assessment

The IC will acquire information in identifiable form (IIF) permitting sampling, screening, recruitment, and results reporting to respondents. The IIF will be stored and managed by ATSDR's research cooperative agreement partner and principal investigator at the UNM-CEHP. IIF will be stored and managed using a record system stored in a locked file in the principal investigator's office. The categories of directly identifiable information to be collected include: names, date of birth, street address, mailing address, phone numbers, email addresses, and biological specimens. The principal investigator at UNM-CEHP will be working in collaboration with the Navajo Area Indian Health Service (NAIIHS) and Navajo Nation Division of Health (NNDOH). NAIHS and NNDOH will provide support for project activities such as recruitment

and enrollment of eligible participants, scheduling appointments, administering the questionnaire, sample collection and medical consultation.

The information in identifiable form (IIF) will be used for the purpose of 1) follow up of participants for home and prenatal care visits at the Indian Health Service clinics and healthcare facilities contracted with Navajo Nation Division of Health through Public Law 93-638 (PL-638) providers and 2) recording and clarifying information that has been provided by the Community Health and Environmental Research Specialists (CHERs).

Information that might be considered sensitive by a portion of the general public is being collected, so there could be an effect on the respondent's privacy if there were a breach of privacy. Accordingly, very stringent safeguards have been put into place as described in Section A.10.

A.3. Use of Improved Information Technology and Burden Reduction

Electronic reporting will be used to collect all questionnaire data for this program. This study will use the Rapid Data Collector (RDC) CAPI development tool which is provided through the CDC Secure Data Network. The RDC allows for design of a data collection form which can be used via Windows application to rapidly collect and store questionnaire data in the field. The data is stored locally using XML format and can be uploaded into a centralized data store in SQL Server 2005 via Web Services when user has access to the CDC LAN. Data collected can be aggregated, reported and exported using a variety of formats including XML and Microsoft Excel. Trained Community Health Environmental Representatives (CHERs) will administer surveys in the field and record responses in RDC. The RDC CAPI will be deployed on laptop computers to collect data. RDC is a CDC-database management system that is C&A approved.

A.4. Efforts to Identify Duplication and Use of Similar Information

ATSDR efforts to identify duplication of the proposed IC included reviews of existing reports, peer reviewed publications, abstracts presented at international, national and tribal meetings. ATSDR also worked with the principal investigator at UNM-CEHP to identify whether the proposed IC is duplicated for 1) proposed population of interest; 2) specific area of concern; and 3) proposed chemical contaminants.

There is a paucity of studies focused on uranium contamination in the Navajo Nation; therefore, the U.S. House Committee on Oversight and Government Reform requested that government agencies prepare a plan to address Health and Environmental Impacts of Uranium Contamination in the Navajo Nation. This study is a result of the House Committee's Request for an epidemiological study focused on environmental uranium contamination in the Navajo Nation.

Literature searches, data base searches, and consultations with Navajo Nation Division of Health, Navajo Nation Environmental Protection Agency, New Mexico Department of Health, and Arizona Department of Health were also conducted to determine that a similar data collection is not being conducted by another institution. This is the only epidemiological study that combines both uranium biomonitoring of pregnant Navajo women and fathers with the applied public health benefit of prenatal educational outreach.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

In order to gather data relevant to prenatal, perinatal, and postnatal time periods, data must be collected during pregnancy, as well as, post-pregnancy. If data is not collected data during these critical time periods, information on health effects of environmental uranium exposure on the infant cannot be determined. Please see Attachment 10: Recruitment Poster, Brochure, and Template Examples which details frequency of participant interactions. There are no legal obstacles to reduce the burden

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. 60-day Federal Register Notice was published on November 22, 2011 in volume 76, page 72206 (Attachment 2). We received no public comments.

B. Efforts to consult with persons outside of the agency

In September 2009, ATSDR representatives met with several Navajo agency and department representatives (NNDOH, NNEPA), NAIHS, EPA, community members, and local university researchers to gain further understanding of previous research activities conducted in the Navajo Nation, to summarize current activities, and to discuss knowledge gaps in environmental uranium exposure and potential health effects. In addition, NNEPA staff led ATSDR representatives on a tour through parts of the reservation to observe some of the abandoned mine areas and three of the four milling sites. The study coincides with the Health and Environmental Impacts of Uranium Contamination in the Navajo Nation 5 Year Plan requested by the House of Representatives Committee on Oversight and Government Reform. Therefore, we have conducted yearly congressional briefings to the Rep. Henry A. Waxman Committee in consultation with the Environmental Protection Agency, Bureau of Indian Affairs, Nuclear

Regulatory Commission, Navajo Area Indian Health Service, and the Department of Energy. The following primary individuals were consulted to obtain their views on the availability of the data, the clarity of instructions, disclosure, questionnaire development, language interpretation, analyte selection, cultural sensitivity regarding the study. A full detailed list of individuals consulted is in Attachment 7. Please see Attachment 8 for Community Outreach Chronology and Attachment 9 for ATSDR Timeline of Interactions.

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A.9. Explanation of Any Payment or Gift to Respondents

In consultation with the Community Liaison Group, (see Attachment 7 –Individuals Consulted), the following incentive plan was determined to be most appropriate. Participants will receive a token of appreciation at the time of enrollment, during prenatal visits, birth and during postnatal follow-ups. Appropriate delivery and developmental incidentals such as diaper bags, sleepers, baby books, etc., or gift cards may be provided as tokens of appreciation during prenatal and postnatal visits.

Since this study is being done at the request of the communities and will serve to benefit the communities directly, we were unsure if compensation was appropriate. However, substantial time and travel for participants is involved because of repeated visits and therefore the consensus decision was to provide gifts that will be useful in childrearing. A series of baby books written in Navajo, “diaper” or incidental bags with the study logo, age appropriate toys, etc. are planned for distribution to the participating families during repeat appointments. In some cases such as the 12-month Mullen administration, the token of appreciation may be in the form of a gift card.

A.10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the NCEH/ATSDR Privacy Officer who determined that the Privacy Act does apply. Data will be primarily collected by the ATSDR contractor Navajo Nation Division of Health (NNDOH) and identifiers must be maintained because of repeated contacts needed with the parent during pregnancy and when the baby is 2, 6, 9, and 12 months old in accordance with study plans to assess developmental levels of the child. The applicable Privacy Act System of Records Notice (SORN) is 09-19-0001, "Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances."

Surveys questions that involve information in identifiable form (IFF) include name, mailing address, medical information and notes, biological specimens, phone number, and email address. The contact information is necessary for scheduling and follow-up of prenatal visits and home visits. Biological specimens are critical for evaluating uranium and other contaminant levels. Information and /or specimens collected as part of the study will be labeled with an assigned study ID number.

The master list linking participant identifiers and project numbers will be stored and maintained in the Principal Investigator's (Dr. Johnnye Lewis) locked files, maintained at the University of New Mexico. Dr. Lewis and her research associates will maintain access to participants study information by participant ID number. Dr. Lewis and the lead research team (UNM Project Coordinator/Database Manager, Navajo Nation Division of Health Project Coordinator, and the Clinical Liaisons at each of the five Navajo Area Indian Health Service / PL-638 health facilities) will be the only ones with access to information *linking participants' names to their participant numbers.* Information in identifiable form (IIF) will be used for the purpose of 1) follow up of participants for home and prenatal care visits at the Indian Health Service clinics and healthcare facilities contracted with Navajo Nation Division of Health through Public Law 93-638 (PL-638) providers and 2) recording and clarifying information that has been provided by the Community Health and Environmental Research Specialists (CHERs) for data quality and control purposes.

Information in identifiable form (IIF) will be provided to CHERs for home and prenatal care visits and follow-ups. IIF will be provided in a limited manner sufficient to accomplish the task, and destroyed once the task is complete. Lead research team members may also use IIF to verify correct data entry by CHERs during periodic data quality and control checks. Data will be stored for 3 years following conclusion of the study, and then de-identified data will be turned over to the Navajo Nation per the Navajo Nation Human Research Code (1996).

For scheduling and medical record access, lead research team members will need linkage information for individual participants and entry of data. They will be asked to destroy that

linked information on completion of the interview, and no data collected in the field will be entered into the electronic data files by any identifier other than participant number. All members of the research team will be required to complete UNM (or NAIHS) privacy protection, confidentiality, and health information security trainings, as well as CITI training for research with human participants.

There should be no infringement on the privacy of the volunteer participants as recruitment will be through self-identification to a member of the research team. Consents will be obtained either in the home at an appointment scheduled with the participant, or in a private room in the clinic setting. If any consents are administered at other locations due to subject contact with the research team in a different venue, all staff will be trained to ensure the consent process is done in a private space beyond hearing of others. Follow-up will be conducted through the research team scheduling home appointments, and at 1 year arranging for a parent or guardian to bring a child into a designated location for testing. Again, these tests will be administered in a private space. Clinical staff providing care or accessing medical records will have access to identifiers in order to access the medical record. However, abstractions from the records will only be documented by participant ID numbers.

Staff will be trained in the protection of private medical information. Training will be through the on-line trainings mandatory for all UNM staff or through approved NAIHS training protocols as appropriate. For staff not affiliated with either of these institutions, the UNM HIPAA and CITI trainings as well as other mandatory trainings for Health Sciences Center staff on security and control of data and protection of PHI will be required. A scheduling tool will be used to create prompts for research team members to schedule appointments for individual participants in a timely manner, and this notification will contain contact information linked to the participant number in order for the research to enter data correctly. Again, these staff will be trained on participant privacy, and entry of data into the database or onto forms in their computers will be done only by participant ID numbers. The research team will be asked to destroy notifications linking names and numbers upon completion of the appointments.

All study partners will adhere to all federal, HHS, and/or CDC IT security policies. Systems development work shall comply with the HHS Enterprise Performance Life Cycle (EPLC) Framework as an IT Project Management requirement and shall perform Enterprise Performance Life Cycle (EPLC) requirements, objectives, responsibilities, and standards for managing information technology (IT) projects in conjunction with the government or on the behalf of the government. More details about the EPLC are available at: http://www.hhs.gov/ocio/eplc/.

Adequate administrative, operational, and technical security controls will be implemented to prevent unauthorized access to or disclosure of any personally identifiable information (PII) that will be accessed by the contractor. Electronic transfers of PII via Internet or portable media must utilize FIPS 140-2 compliant encryption. The final de-identified dataset with data collected

on all participants will be delivered to CDC/ATSDR, UNM, and NNDOH using excel files with encrypted, password coded spreadsheets through a password protected data sharing facility.

IRB Approval

UNM IRB approval was obtained on June 17, 2011 (HRRC#: 11-310). CDC/ATSDR IRB finalized agreement to rely on UNM IRB on August 4, 20111. The Navajo Nation Human Research Board approval was obtained in December 2011. (Attachment 5)

10.1 Privacy Impact Assessment

A. Subject to Privacy Act

This submission has been reviewed by the NCEH/ATSDR Privacy and Confidentiality Officer who determined that the Privacy Act does apply.

B. Describe how information will be secured

Access to information will be tiered to the roles and responsibilities of members of the research staff. Data will be collected using the CDC Rapid Data Collector, and stored in "virtual tables" on the CDC servers. Field research staff will have access to enter data based on participant study number; the database manager will have full privileges; statisticians and modelers will have authorization to read and export data; while team members with no data entry or manipulation responsibilities will have read-only privileges. The lead research team members who provide Quality Assurance/Quality Control (QA/QC) for the data will have time-limited access to edit specific datasets until QA is completed. Reports to team members with no responsibilities for data entry, QA, or analysis will be exported through requests to the database manager to ensure adequate metadata accompanies the report. To allow for system maintenance and software upgrades, the CDC IT/ITSO system administrator will have full access to the data.

Electronic reporting will be used to collect all questionnaire data for this program. This study will use the Rapid Data Collector (RDC) CAPI development tool which is provided through the CDC Secure Data Network. The RDC allows for design of a data collection form which can be used via Windows application to rapidly collect and store questionnaire data in the field. The data is stored locally using XML format and can be uploaded into a centralized data store in SQL Server 2005 via Web Services when user has access to the CDC LAN. Data collected can be aggregated, reported and exported using a variety of formats including XML and Microsoft Excel. Trained Community Health Environmental Representatives (CHERs) will administer surveys in the field and record responses in RDC. The RDC CAPI will be deployed on laptop computers to collect data in clinic locations. RDC is a CDC- database management system that is C&A approved. CHERs will receive extensive training on data entry and laptop security.

C. Opportunities for obtaining respondent consent

Because more than 20% of births on Navajo occur to women under 18, and the inclusion criteria include mothers as young as 14, consent will require a tiered process. For minors, regardless of state of residence, the consent of one parent for participation of their minor child as a parent in the birth cohort will be required, whether for a minor mother or minor father. A signature acknowledging the assent from the minor will also be obtained. However, the minor parent will be asked to consent for their child to be enrolled in the study and to be followed for a minimum of one year. Should the minor parent reach 18 during the study, she or he will be re-consented if additional data collections are scheduled. Copies of consent forms for the mother and the father are included in Attachment 4.

For parents over 18, the study consent will be required from the mother and from the father for their own participation, and the mother will be asked to consent for her child's participation through the first year. Because we are working to develop a sustainability plan for the cohort, the parents will also be informed that their data will be retained for up to three years past the end of the current project period.. They will be asked for consent to note in their medical and Growing in Beauty records that they are participants in the Navajo Birth Cohort Study, and to note whether they consent to be re-contacted. They will be retained in the active data system with successive 5-year consents for 20 years, but will be able at any time to refuse continuation in the cohort. Refusal will be noted in their files, and they will be withdrawn from any subsequent aspects of the project. In addition to these criteria, all participants will be informed of their right to refuse participation in particular components of the study without compromising their participation in others.

For specific parts of the study that may conflict with cultural practices, such as collection of meconium or destruction of unused biological specimens, they will specifically note their preference on the initial consent form. Consents will be administered by clinical staff dedicated to the project in each clinical service unit, by NNDOH field research staff in the home, or by the UNM DiNEH Project field staff. All team members administering consents will be mandated to maintain active CITI, HIPAA, and confidentiality trainings as provided by UNM, or their institutional equivalents submitted to the PI for review. Because UNM-CEHP have dedicated clinical staff on the project within the service units, we anticipate no difficulties in having the consents linked to the medical records — a process UNM-CEHP is currently doing in a collaborative project with NAIHS.

There will be two consent forms, one for the father and one for the mother of the unborn child (Attachment 4). Once the consent form is read and discussed with the potential participant, they will be asked to sign as appropriate on the consent/assent page where the following options will be available:

For participants 18 and over:

- Consent for participation of self and baby (mother) or self (father)

For participants under 18:

- Assent of interest to participate (mother and father)
- Consent of parent for participation of their minor child (mother and father)
- Consent of minor mom for participation of unborn child (mother only)

At the time of consenting, participants will also be given a brochure that outlines details and flow of the project with respect to each family member and endpoint, relative to prenatal, postnatal, and neonatal collections of data. Phone numbers for Navajo IRB, UNM IRB, DiNEH Project, NNDOH-CHR program, NNEPA and other agencies will be included in the brochure to enable participants to obtain information or to access available services (Attachment 10).

The informed consent procedures include a detailed description of the study as well as an assurance of the subject's freedom to withdraw from the study at any time without prejudice of any kind. Eligible subjects will be assured that their level of care will not be affected by participation or non-participation in the study. We will take all appropriate measures to ensure safeguarding of the data in order to minimize participant distress. Data collection and management will be carried out in a manner that ensures that sensitive data are handled appropriately with the utmost attention to privacy and security. Participation in the study involves answering questions about sensitive information of a personal nature. Interview questionnaires will be administered in a neutral and private setting to ensure the comfort of the participant. A list of available community social service resources will be provided to all participants for support and assistance. Research staff will be trained to administer interviews in a sensitive manner and to identify participants that may need referrals to outside agencies. Collaborating members of the research team include psychologists from the Center for Development and Disabilities and the Department of Pediatrics at UNM, as well as Navajo Nation's Growing in Beauty Program. Ongoing services will also be available through the Navajo Area Indian Health Service and PL-638 programs collaborating on the study and through Navajo Nation's Growing in Beauty Program which provides case management to families to ensure access to all available services.

Finally, the study partners includes several Navajo language and culture experts who will ensure that all questions are asked in a manner that is culturally appropriate, and that staff convey professional and cultural sensitivity to increase the confidence in safeguarding and professional management of information. All of these partners are also involved in ongoing, multidisciplinary training programs for all staff to ensure consistency regardless of the direct employment or reporting status. All staff are also completing HIPAA training and certification as well as completing the security and confidentiality trainings provided on line by the University of New Mexico for those in contact with patients.

D. Indicate whether respondents are informed about the voluntary or mandatory nature of their response

The consent and assent forms indicate that participation is completely voluntary and there is no untoward effect on the respondent if they decide not to respond to the data collection request. There are no plans to share identifiable data.

A.11. Justification for Sensitive Questions

Sensitive survey questions involve current medication and substance abuse, alcohol use, tobacco use, and stress. These questions provide information about critical confounders to identify any activities that would also result in adverse birth and reproductive health outcomes.

The purpose of the study is to evaluate the short- and long-term health and developmental effects of uranium exposure to mothers and infants living on the Navajo Nation. In order to characterize the effects of environmental exposures, it is essential to collect and control for information relating the individual and contextual factors that may be related to the exposures and outcomes of interest. To estimate the burden of uranium toxicity on the population-level, we need to collect individual-level information about complex, interdependent social variables and apply analytical approaches to model and control for the effects of these covariates.

The survey response data collected under this research study protocol that are generally considered sensitive by a majority of the population are central to evaluating the research questions and study hypotheses. Exposure to toxic chemicals, such as uranium, and other stressors commonly co-occur in disadvantaged populations. It is now recognized that contextual social factors may not only confound the relationship between environmental exposures and

negative health outcomes, but may also determine the degree of toxicity (Cooney, 2011). Animal studies have demonstrated that the joint impact of psychosocial stress and environmental exposure is synergistically more toxic than either factor alone. In addition, these studies also suggest that a positive social environment can mitigate toxicity of environmental exposures. Therefore, collecting information about the social environment is paramount to being able to appropriately and fully investigate the effects of environmental exposures, such as uranium, on maternal and child health. It is essential to simultaneously account for chemical environmental exposures as well as social conditions of the family which occur during critical windows of fetal and infant development. Such information includes, but is not limited to: parental education, family environment, psychosocial stress (parenting stress, depression, exposure to violence, chemical use and/or dependency), as well as educational and socio-economic information.

Information in identifiable form (IFF) such as name, mailing address, phone number, and email address will be collected. This contact information is necessary for scheduling and follow up of prenatal visits and home visits. Social security numbers will not be collected.

A.12. Estimates of Annualized Burden Hours and Costs

A. Burden hours are included in Table 1. Participants will include Native American mothers from age 14 to 45 with verification of pregnancy who have lived in the study area for at least 5 years. Also, participants must consent to receive prenatal care and deliver at one of the healthcare facilities (Northern Navajo Medical Center, Chinle Comprehensive Health Care Facility, Gallup Indian Medical Center, Tuba City Regional Health-Care Corporation, or Tséhootsooí Medical Center) that are taking part in the study. Fathers will be included in the study with consent regardless of age or residence. We estimate that 550 pregnant women and fathers per year must be enrolled in the study to obtain adequate statistical power. A 10% pregnancy loss will be assumed, which would result in 500 live births per year. Therefore, the total anticipated sample size is 1,500 mother-infant pairs over the three years of the study.

Table 1: Estimate of Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Response (Hours)	Total Burden (Hours)
Mother	Enrollment Survey	550	1	2	1100
	Ages and Stages Questionnaire (2,6,9 12 months)	500	4	15/60	500
	Mullen Stages of Early Development	500	1	15/60	125
	Postpartum Survey (0 months)	500	1	1	500
	Postpartum Survey (2,6,9 months)	500	3	15/60	375
	Postpartum Survey (12 months)	500	1	15/60	125
	Eligibility Form	550	1	5/60	46
Father	Enrollment Survey	550	1	90/60	825
				Total	3596

B. Burden costs are included in Table 2. The study participants will be members of the general public in the Navajo Nation. Recent government estimates of hourly-wages for the entire Navajo Nation were not yet available in the 2010 Census. Therefore, 2000 Census data was used.

According to 2000 Census data, the average weekly wage within the Navajo Nation is $406 or $10.15/hour assuming a 40 hour work week. This data is based upon the 2000 Census Demographic Data (http://censtats.census.gov/data/AZ/280042430.pdf).

Table 2: Estimate of Annualized Burden Costs

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Total Burden Cost(s)
Mothers	2771	$10.15	$28125.65
Fathers	825	$10.15	$ 8373.75

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital or maintenance costs incurred by respondents other than travel to their designated prenatal visits. There are no costs or burden to respondents for recordkeeping.

A.14. Annualized Cost to the Federal Government

The total estimated cost to the government is $6 million, based on $2 million Congressional allocation projected for the 3 year project study period. The estimated average annualized cost of the program is ~ $2 million.

NNDOH Sole source contract: ~$250,000 a year

UNM Research Coop: ~$1 million a year

Navajo Area IHS interagency agreement: $375,000 a year

ATSDR personnel and travel total costs: $168,102

A.15. Explanation for Program Changes or Adjustments

This is a new study data collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

A.16-1 Project Time Schedule	
Activity	Time Schedule
Raise awareness of the study through outreach and education	1-2 months after OMB approval
Conduct study recruitment	2-12 months after OMB approval
Data collection, cleaning, merging and analysis	5-36 months after OMB approval
Report preliminary study findings to Navajo community and at scientific meetings	12-36 months after OMB approval
Prepare reports and publications as analyses are completed	18 months after OMB approval

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

Exemption from displaying the expiration date for the OMB approval of forms is not being requested.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.