

A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation

OMB Control No. 0923-0046 (Expiration Date: 02/29/2016)

Extension Request

Supporting Statement Part A –
Justification

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Part A. Justification

- **Goal of the study:** The goal of the study is to better understand the relationship between uranium exposures and birth outcomes and early developmental delays on the Navajo Nation. As supplemental funding has been received, this is an extension request to continue data collection for an additional three years.
- **Intended use of the resulting data:** The data will be used to provide outreach and education on the importance of prenatal care, investigation of environmental prenatal risks, earlier assessment and referral for infants with suspected developmental delays, and a comprehensive assessment of nutrient values and reproductive health outcomes.
- **Methods to be used to collect data:** The methodology is a prospective birth cohort study aimed at enrolling pregnant Navajo women and conducting follow-up assessment of the infants through one year of age. The infants' fathers will also be enrolled.
- **Subpopulation to be studied:** Pregnant Navajo women, fathers, and their infants
- **How data will be analyzed:** A variety of statistical methods will be used in the data analysis, including nonparametric methods, such as LOWESS, and regression models, such as Cox proportional hazards regression, and generalized mixed effect models.

A.1. Circumstances Making the Collection of Information Necessary

This is an Information Collection Request (ICR) for an extension of the previously approved Agency for Toxic Substances and Disease Registry (ATSDR) research study, "A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation" (OMB Control No. 0923-0046; expiration date 02/29/2016). Since supplemental funding is expected to continue until the end of the Fiscal Year (FY) 2017 project period, the program requests Paperwork Reduction Act (PRA) clearance for three years.

Known as the Navajo Birth Cohort Study (NBCS), the purpose of this research study is to better understand the relationship between uranium exposures and birth outcomes and early developmental delays in the Navajo Nation. Since PRA clearance was received in February 2013, over 530 mother-infant pairs and over 160 fathers have been enrolled. An estimated 675 biomonitoring samples have been analyzed for 36 metals/metalloids including uranium, arsenic, lead and mercury. Home environmental assessments (HEAs) consist of gamma radiation surveys, indoor air radon tests, and dust sample analysis of the participant's primary residence during pregnancy, and over 400 HEAs have been completed to date. Study participants receive report back letters on their biomonitoring and HEA results to inform them of uranium and other heavy metals in their bodies and in and around their home environment.

Numerous culturally appropriate study outreach methods have been conducted including Facebook posts, You Tube videos, newsletters, Public Service Announcements, radio ads, chapter meetings, health fairs, conferences, and community awareness walks. It is estimated that these targeted outreach events have reached more than 40,000 people since September 2013. To facilitate appropriate cultural sensitivity and to promote community engagement in the study, over 20 local Navajo professionals have been hired and extensively trained on environmental home assessments, uranium environmental health impacts, and survey administration. In addition, NBCS staff have given 11 study progress presentations to Navajo Nation Human Health Research and Review Board, Navajo Area Indian Health Service clinics, Navajo Uranium Collaboration Initiative, and Navajo Uranium Contamination Stakeholder Workshops. These trainings and presentations may contribute to capacity building and sustainability of future community based participatory comprehensive research studies initiated by Navajo Nation.

In addition to study outreach within Navajo Nation, NBCS staff have presented study progress at over 13 professional meetings and conferences. Two journal publications, with one manuscript currently in-press, have been developed by NBCS staff to date. To ensure NBCS continuity with other uranium mitigation efforts in Navajo Nation, ATSDR and its partners continue to coordinate with Federal 5 Year Plan agencies to address health and environmental impacts of uranium contamination on the Navajo Nation. For example, ATSDR headquarters and Region 9 staff, Navajo Area Indian Health Service, EPA Region 9, and Navajo Department of Health collaborated to train 90 Navajo Community Health Representatives to identify locations of abandoned uranium mines and to educate community members on how to avoid potential uranium exposure.

Study challenges include loss of participants prior to follow-up assessments, complications in specimen collection among infants, and high turnover rates of laboratory and outreach staff. To address these challenges, best practice meetings, monitoring and evaluation metrics, and technical assistance are regularly established to provide open communication among NBCS partners and stakeholders. Despite these challenges, the NBCS has been able to provide several benefits to study participants and to the Navajo community. Direct participant benefits include: 1) Home and biological assessments to identify any serious contamination, and if identified, the family will be referred to the appropriate agency for further environmental testing and consultation; 2) Information on community-based infant services and programs, including WIC and First Things First; 3) Referrals to Growing In Beauty, the Navajo Nation Early Intervention Program for children with identified developmental delays.

The study will also provide broad public health benefits for Navajo communities through outreach and education on the importance of prenatal care, investigation of environmental prenatal risks, earlier assessment and referral for infants with suspected developmental delays, and a comprehensive assessment of nutrient values and reproductive health outcomes. The information generated by this study may be of value in developing programs and policies to

mitigate environmental uranium exposure and to implement effective public health prevention and intervention strategies.

ATSDR is authorized by Section 301 of Public Health Service Act (42 USC 241) and 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 September 30, 2015 and is further discussed in Section A.8. (See Attachment 2).

A.2. Purpose and Use of the Information Collection

ATSDR and its cooperative agreement partner, University of New Mexico Community Environmental Health Program (UNM-CEHP), oversee the collection of this data by contractor, Navajo Nation Department of Health and interagency agreement partner, Navajo Area Indian Health Service (NAIHS).

The NBCS is the first prospective epidemiologic study of pregnancy and neonatal outcomes in a uranium-exposed population. The primary objective of this study is to evaluate potential exposures to environmental contaminants (i.e., uranium and other heavy metal exposures) among pregnant Navajo women. We will continue to assess their exposure (through biomonitoring, home assessments, and surveys) at key developmental milestones, and then conduct follow-up assessment of children post-birth to investigate any associations with birth defects or developmental delays (Attachment 3). The information generated by this study may be of value in informing programs designed to mitigate environmental uranium exposure. Additionally, the study will provide additional baseline data on exposures, behaviors, and chronic health that may be of value in developing health education and outreach to increase prenatal care utilization.

The study is being conducted in response to Navajo community requests to Congress, which resulted in a 2010-2012 Congressional allocation for ATSDR to conduct this epidemiological study. Supplemental funding has been received since FY 2013 to continue the study. The original funding proposal outlines a power and sample size calculation, and the CDC previously acknowledged that some of the sample size assumptions may not account for the likely variability in exposure and health outcome data or sufficiently power the complex multivariate analyses that may need to be undertaken. Although environmental sampling and the measurement of risk factors associated with these developmental delays is designed to control for as much variance as possible, CDC is committed to acknowledging any potential confounders, limitations and uncertainties that remain at the end of the study for which we have not been able to control.

The extension of supplemental funding will help ATSDR address current challenges encountered related to participant recruitment, loss of participants prior to follow-up assessments, and complications in specimen collection among infants, more time is needed to increase the study sample size. A larger study sample size will help to ensure the study is adequately powered to detect any relevant associations between uranium exposure and adverse birth and pregnancy outcomes.

The results of the study will benefit the Navajo families and contribute to the knowledge base regarding the potential association between exposures to uranium wastes and other environmental contaminants and adverse birth outcomes or developmental delays on the Navajo Reservation.

Furthermore, benefits to participating families will include the potential for early identification of risks or developmental delays. Those with such risks will be referred to support services to ensure early intervention, with the hope of reducing 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 may help in guiding policies that prioritize remedial actions to remove contamination sources from these communities. Remedial actions to remove contamination sources will prioritize whether or not a relationship is found between uranium and study outcomes.

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

Electronic reporting will be used to collect the majority of questionnaire data for this program. It is estimated that 98.5 % of burden hours will be collected by electronic reporting. The eligibility form, which constitutes 63 annual burden hours, will be conducted by paper and pencil form. This study will use the RedCap™ CAPI development tool which is provided through the University of New Mexico Virtual Private Network (VPN). RedCap™ allows for design of a data collection form which can be used to rapidly collect and store questionnaire data in the field. 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 RedCap™. The RedCap™ CAPI will be deployed on laptop computers to collect data.

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

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.

Previously, 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 IC is duplicated for the: 1) proposed population of interest; 2) specific area of concern; and 3) proposed chemical contaminants. Consultations with Navajo Nation Department 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.

The circumstances of this research study are unique in that 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

The questions have been held to the absolute minimum required for the intended use of the data. 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, respondents will respond to information collection during pregnancy, as well as, post-pregnancy. When studying developmental endpoints it is necessary to collect data during multiple critical developmental time periods. Please see Attachment 4 (Study Information and Participant Timeline) 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. A 60-day Federal Register Notice was published on September 30, 2015 in Volume 80 No. 189, pages 58733-4 (Attachment 2). CDC/ATSDR received one public comment in support of continued information collection (Attachment 2a). An agency response was not requested. ATSDR is committed to continuing and successfully completing the Navajo Birth Cohort Study (NBCS).
- B. In September 2009, ATSDR representatives met with several Navajo agency and department representatives (NNDOH, NNEPA), NAIHS, Environmental Protection Agency (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 House Committee on Oversight and Government Reform in consultation with the EPA, Bureau of Indian Affairs (BIA), Nuclear Regulatory Commission (NRC), NAIHS, and the Department of Energy (DOE). 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.

Table 4: 2010-2015 ATSDR Consultations

Name	Title	Affiliation	Phone	Email
<i>OUTSIDE CONSULTANTS</i>				
Douglas Peter, MD	Chief Medical Officer	Navajo Area Indian Health Service	(928) 871-5811	Douglas.Peter@ihs.gov
Stephen Ettisy	Director	Navajo Nation Environmental Protection Agency	(928) 871-7692	stephenbetsitty@navajo.org
Madan Poudel, PhD	Director	Navajo Nation Department of Health	(928) 871-6350	M.Poudel@nndoh.org
Mae-Gilene Begay, MSW	Director	Navajo Community Health Representatives Program	(928) 871- 6785	mg.begay@nndoh.org
Chris Shuey, MPH	Director	Southwest Research and Information Center	505-262-1862	sric.chris@earthlink.net
<i>ACADEMIC INSTITUTIONS</i>				
Johnnye Lewis, PhD	Director,	University of New Mexico	(505)991-3489	jlewis@cybermesa.com

	Community Environment al Health Program			
Adrienne Ettinger, PhD	Assistant Professor, Center for Perinatal, Pediatric & Environment al Epidemiology	Yale University	(203) 785-6232	adrienne.ettinger@yale.edu
David Begay, PhD	Professor	DiNEH College	(928) 607-0365	dbegay@gmail.com
CDC NCEH LABORATORIES				
Kathleen Caldwell, PhD	Branch Chief	Inorganic, Radiation, and Toxicology Analytical Branch	(770) 488-7990	klc7@cdc.gov

A full detailed list of individuals consulted is in Attachment 5. Please see Attachment 6 for Community Outreach Chronology and Attachment 7 for ATSDR Timeline of Engagement.

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

The incentive plan was previously approved by OMB and Navajo Nation Human Research Review Board. Implementation of this incentive plan has been successful; therefore, no changes have been made to the incentive plan. The approved incentive plan involves the following tokens of appreciation:

- \$10 gift card + skin care products valued at \$15 donated by a company in partnership with Navajo Nation. These items are given to moms and dads during their initial home visit after Eligibility Forms (Attachment 8a) and Enrollment Surveys (Attachment 8b and 8i) and prenatal labs are completed and a home-visit is scheduled.
- \$75 gift card after completion of Ages and Stages Questionnaires (ASQs) (Attachment 8c); Mullen Scales of Early Learning (MSEL) (Attachment 8d); 2 month Postpartum Surveys (Attachment 8e), and the 6, 9, and 12 month Postpartum Surveys (Attachment 8f). This card will be presented as final gift when the second punch card is completed at one-year.
- \$35 gift card + bag with in-kind donations of baby care products and a compact disc (CD) recording of Navajo language stories for baby. These gifts are presented when the first punch card is completed for the Food Frequency/WIC Form (Attachment 8g), Home Environmental Assessment (Attachment 8h), mom's delivery blood and urine samples, cord blood, and baby urine.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This ICR was initially reviewed by the NCEH/ATSDR Privacy Officer who determined that the Privacy Act does apply. There will be no changes to the system. Data is primarily collected by the ATSDR contractor Navajo Nation Department 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, and to schedule and follow-up prenatal and home visits. 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."

The following information in identifiable form (IIF) categories apply to this information collection: name, date of birth, mailing address, employment status, biological specimens, and medical information and notes. The eligibility form and enrollment surveys (Attachment 8a, 8b, 8i) have questions that involve IIF including name, mailing address, phone number, employment status and date of birth. The medical record abstraction form (Attachment 9) includes questions about participants' medical information and notes. There are six participating clinics. We assume one Cohort Clinical Liaison (CCL) per clinic is assigned to do the record abstractions; therefore, medical record abstractions do not incur burden and do not appear in the burden table estimates. All IIF information is stored using the CDC-approved Redcap™ Virtual Private Network (VPN). Biological specimens are critical for evaluating uranium and other contaminant levels. Information and /or specimens collected as part of the study are labeled with an assigned study ID number.

Access to information will be tiered to the roles and responsibilities of members of the research staff. Data will be collected using Research Electronic Data Capture (RedCap™). The NCEH/ATSDR Information Systems Security Officer (ISSO) has approved a Data Privacy & Security Plan to ensure measures are in place to protect participant data while using RedCap™ software. The system's Security Plan defines the process for handling security incidents. The system's team and the Office of the Chief Information Security Officer (OCISO) share the responsibilities for event monitoring and incident response. The team will direct reports of suspicious security or adverse privacy-related events to the NCEH/ATSDR ISSO, CDC helpdesk, or to the CDC Incident Response team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

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). 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.

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/>. See Attachment 10 for further discussion of data privacy and security measures.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The study protocol and data collection instruments have been reviewed and approved annually by Navajo Nation Human Research Review Board (NNR #11.332) and UNM Health Sciences Center Human Research Review Committee (Study ID #11-330). NBCS research team also presents to Navajo Nation Human Research Review Board quarterly and during the annual Navajo Nation Human Research Review Board Review Conference. CDC's Human Research Protection Office reviewed and approved the request to continue reliance on a non-CDC IRB (protocol #6149) in accordance with 45 CFR 46.114. 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. Please see Attachment 11 for all IRB approval forms and Attachment 12 for consent and HIPAA forms.

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. 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. Please see Attachment 13 for survey question sources and additional exposure assessment information.

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 susceptibility.

There will be two consent forms, one for the father and one for the mother of the unborn child (Attachment 12). 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 14). 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 (Attachment 12).

Finally, the study partners include several Navajo language and culture experts who will ensure that all questions are asked in a manner that is culturally appropriate, and that staff conveys professional and cultural sensitivity to increase the confidence in safeguarding and professional management of information. Navajo is a descriptive language and traditionally not a written language – very few Navajos actually read Navajo although many are fluent speakers. Therefore, the Navajo team members have worked for several months to establish consistency in translation of materials introducing the study and the consent and HIPAA forms. The actual participants in the study are all likely to speak English, and therefore, we anticipate the actual survey administration will be in English. However, when clarification is requested, the team will have the background provided through these working session to convey concepts in Navajo in a consistent manner. This method has been used by this team in field surveys before. The project staff are also involved in ongoing, multidisciplinary training programs 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.

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 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 estimated sample size is 1,500 mother-infant pairs over the three extended years of the study. The total estimated annual burden hours equals 4,455.

Table 1: Estimate of Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Response (Hours)	Total Burden (Hours)
Mothers	Eligibility Form	750	1	5/60	63
	Mother Enrollment Survey	550	1	2	1,100
	Ages and Stages Questionnaire (2, 6, 9, 12 months)	500	4	15/60	500
	Mullen Scales of Early Learning	500	1	20/60	167
	Postpartum Survey (2 months)	500	1	1	500
	Postpartum Survey (6, 9, 12 months)	500	3	15/60	375
	Food Frequency Questionnaire/ WIC Intake Form	500	1	45/60	375
	Home Environmental Assessment	550	1	1	550
Fathers	Father Enrollment Survey	550	1	90/60	825
Total					4,455

B. Burden costs are included in Table 2. The study participants will be members of the general public in the Navajo Nation (e.g., mothers and fathers). According to recent 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>) and 2010 Demographic Analysis of the Navajo Nation (<http://www.azcia.gov/Documents/Links/DemoProfiles/Navajo%20Nation.pdf>).

Table 2: Estimate of Annualized Burden Costs

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Total Burden Cost(s)
Mothers	3,630	\$10.15	\$36,844.50
Fathers	825	\$10.15	\$ 8,373.75
Total			\$45,218.25

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

There are no capital or maintenance costs incurred by respondents. 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 \$16 million. This estimated is based on \$2 million Congressional allocation received for FY 2010-2012 project study period (\$6 million) and the program projected allocations for FY 2013-2018 (\$10 million).

Therefore, the estimated average annualized cost of the program is \$2 million.

- NNDOSH Sole Source Contract: ~ \$325,000 a year
- UNM Research Cooperative Agreement: ~\$1,200,000 a year
- Navajo Area IHS Interagency Agreement: \$375,000 a year
- ATSDR Personnel and Travel Costs: \$100,000

A.15. Explanation for Program Changes or Adjustments

This is an extension request and the burden has not changed from the burden shown in the current inventory.

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

A variety of statistical methods will be used in the data analysis, including nonparametric methods, such as LOWESS, regression models, such as Cox proportional hazards regression, and generalized mixed effect models (See Supporting Statement Part B). Three years are requested for continued data/information collection activities. Project Time Schedule is listed below.

Table A.16.1 Project Time Schedule	
Activity	Time Schedule
Continue to raise awareness of the study through outreach and education	0-24 months after OMB approval
Continue study recruitment	0-24 months after OMB approval
Continue data collection, cleaning, merging and analysis	5-36 months after OMB approval
Continue data analysis and 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	24-36 months after OMB approval

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

The display of the OMB expiration date is not inappropriate.

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

There are no exceptions to the certification.

List of Attachments

Attachment 1: Authorizing Legislation

Attachment 2: 60-day Federal Register Notice

2a: Public Comments

Attachment 3: Developmental Assessment Manual and Feedback Form

Attachment 4: Study Information and Participant Timeline

Attachment 5: Individuals Consulted

Attachment 6: Community Outreach Chronology

Attachment 7: Timeline of Engagement

Attachment 8: Data Collection Instruments

8a: Eligibility Form

8b: Mother Enrollment Survey

8c: Ages and Stages Questionnaire

8d: Mullen Scales of Early Learning

8e: Postpartum Survey (2 months)

8f: Postpartum Survey (6, 9, 12 months)

8g: Food Frequency Questionnaire/WIC Intake Form

8h: Home Environmental Assessment

8i. Father Enrollment Survey

Attachment 9: Medical Record Abstraction Table & Form

Attachment 10: Data Security & Privacy Protocols

Attachment 11: IRB Approval

Attachment 12: Consent and HIPAA Forms

Attachment 13: Survey Question Sources

Attachment 14: Recruitment Poster, Brochure, and Template Examples

Attachment 15: Biomonitoring Table & Analyte Justification

Attachment 16: Biomonitoring Standard Operating Procedures

Attachment 17: Biomonitoring and Home Environmental Assessment Participant Report Letter