

RESOLUTION OF THE
NAABIK'ÍYÁTI' COMMITTEE OF THE
NAVAJO NATION COUNCIL

23RD NAVAJO NATION COUNCIL - FIRST YEAR, 2015

AN ACTION

RELATING TO HEALTH, EDUCATION AND HUMAN SERVICES AND
NAABIK'ÍYÁTI'; SUPPORTING THE NAVAJO BIRTH COHORT STUDY;
RECOMMENDING INCREASED FEDERAL FUNDING IN THE AMOUNT OF \$3.5
MILLION PER YEAR THROUGH FISCAL YEAR 2020 FOR THE PURPOSES OF
CONTINUING THE NAVAJO BIRTH COHORT STUDY ON THE NAVAJO NATION

WHEREAS:

- A. The Health, Education and Human Services Committee of the Navajo Nation Council, among other duties and responsibilities, "review[s] and recommend[s]... [r]esolutions relating to social services, health, environmental health, education, veterans and veterans services, employment and labor." 2 N.N.C. §401(B)(6)(a).
- B. The Naabik'íyáti' Committee of the Navajo Nation Council, among other duties and responsibilities, "coordinate[s] all federal, county and state programs with other standing committees and branches of the Navajo Nation government to provide the most efficient delivery of services to the Navajo Nation. 2 N.N.C. §701(A)(4).
- C. There are more than 1,100 uranium waste sites within the Navajo Nation. *Iina Nizhoni Newsletter, Fall 2014*. These hazardous sites have presented serious public health issues, particularly for those residents near such sites.
- D. The Navajo Birth Cohort Study ("NBCS"), formed in 2010, is a scientific study to investigate whether uranium exposures affect birth outcomes and child development on the Navajo Nation. The study is a partnership of the University of New Mexico Community Environmental Health Program ("UNM", the Southwest Research and Information Center ("SRIC"), the Navajo Nation Department of Health CHR Outreach Program ("NNDOH"), and the Navajo Area Indian Health Service ("NAIHS"). See Exhibit "A," the NBCS organizational chart.

- E. The Navajo Birth Cohort Study is funded by the Centers for Disease Control and Prevention ("CDC"), through the Agency for Toxic Substances and Disease Registry ("ATSDR"), with monies appropriated by the United States Congress. At the beginning of the study, CDC-ATSDR promised \$2 million to the UNM-SRIC team to coordinate the research, and provided separate funding to NNDOH and NAIHS to cover costs associated with their roles in conducting the study. However, funding for the research has never been at the promised level. Most recently, CDC-ATSDR announced it was awarding only \$1 million to UNM for the fourth year of the study beginning September 1, 2015. See, *FY 2015 Solicitation letter FOA-EH TS000135 "Continuing Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation."* Exhibit "B."
- F. The funding allocated to UNM is not sufficient to cover the full costs of conducting the research and will necessitate significant cutbacks in the scope of the study and laying off personnel now employed by the study. In addition, CDC-ATSDR has not begun negotiations with NNDOH to provide continued funding of its responsibilities under the approved research plan, and NNDOH is anticipating having to lay off several employees assigned to the project by December 31, 2015 and again by August 31, 2016. Similarly, NAIHS has indicated that it has received no new funding for its responsibilities under the study plan. At least 10 positions now held by Navajo people, and as many as 15, could be lost in the next year if additional funding is not obtained to support the current NBCS staff and the study's approved research scope.
- G. Additional funding of the Navajo Birth Cohort Study will enable continued recruitment and education of Navajo mothers, dad and babies. The need to expand and increase public health education on the study has become evident within the course of the past two years. The current funding is not sufficient to reach the 1,500 mother-infant enrollment target and not enough to conduct the originally planned studies to adequately understand the health effects of uranium exposure.
- H. Preliminary data from the Navajo Birth Cohort Study have identified uranium in urine from some newborns at concentrations higher than 95% of adults in the United States. See Exhibit "C," a chart indicating uranium levels and distributions among study participants, attached

hereto. These disturbing data underscore the need to continue the study for purposes of fully understanding the risks of uranium exposure on births and development.

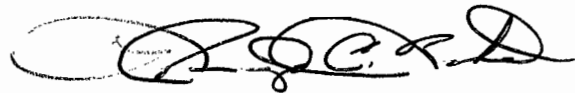
- I. Furthermore, federal budget documentation confirms that the federal Administration's intent is to continued to fund the NBCS (Exhibit "D," pages 7, 13 and 15) and that ATSDR will "evaluate the potential for follow up and continue surveillance of children beyond the research study period" (Exhibit "D," page 15). The possibility of following children beyond the end of the current study necessitates full funding of the study during the five-year study period to achieve the goal of 1,500 mother-infant pairs. ATSDR's budget gives the agency substantial discretion to fully fund the study concomitant with its high priority among specific studies listed in the agency's budget document (Exhibit "D", page 23, "Amount Available for Obligation").
- J. Direct funding will enable the Navajo Nation to improve health care through integration of clinical facilities on Navajo Nation, incorporate environmental exposures into risk assessments, and will improve the Nation's capacity to carry out research on the Navajo Nation through: a) increased training and experience for NNDOH staff through partnership with UNM-SRIC researchers; and b) building an environmental health research focus to ensure comprehensive understanding of impacts of contaminants on human health.

NOW THEREFORE BE IT RESOLVED:

1. The Navajo Nation supports the Navajo Birth Cohort Study on the Navajo Nation. The Navajo Nation urgently requests the Federal Government, including the United States Congress, to increase funding in the amount of \$3.5 million dollars per year through fiscal year 2020 to continue the Navajo Birth Cohort Study.
2. The Navajo Nation recommends that this increased funding be provided directly to the Navajo Nation. Alternatively, the Navajo Nation recommends that the Agency for Toxic Substances and Disease Registry provide funds for the Navajo Birth Cohort Study as follows - \$2 million per year through fiscal year 2020 to the University of New Mexico to conduct and coordinate the research; and \$1.5 million per year through fiscal year 2020 to the Navajo Nation Department of Health to carry out its responsibilities under the Navajo Nation-approved research plan.

CERTIFICATION

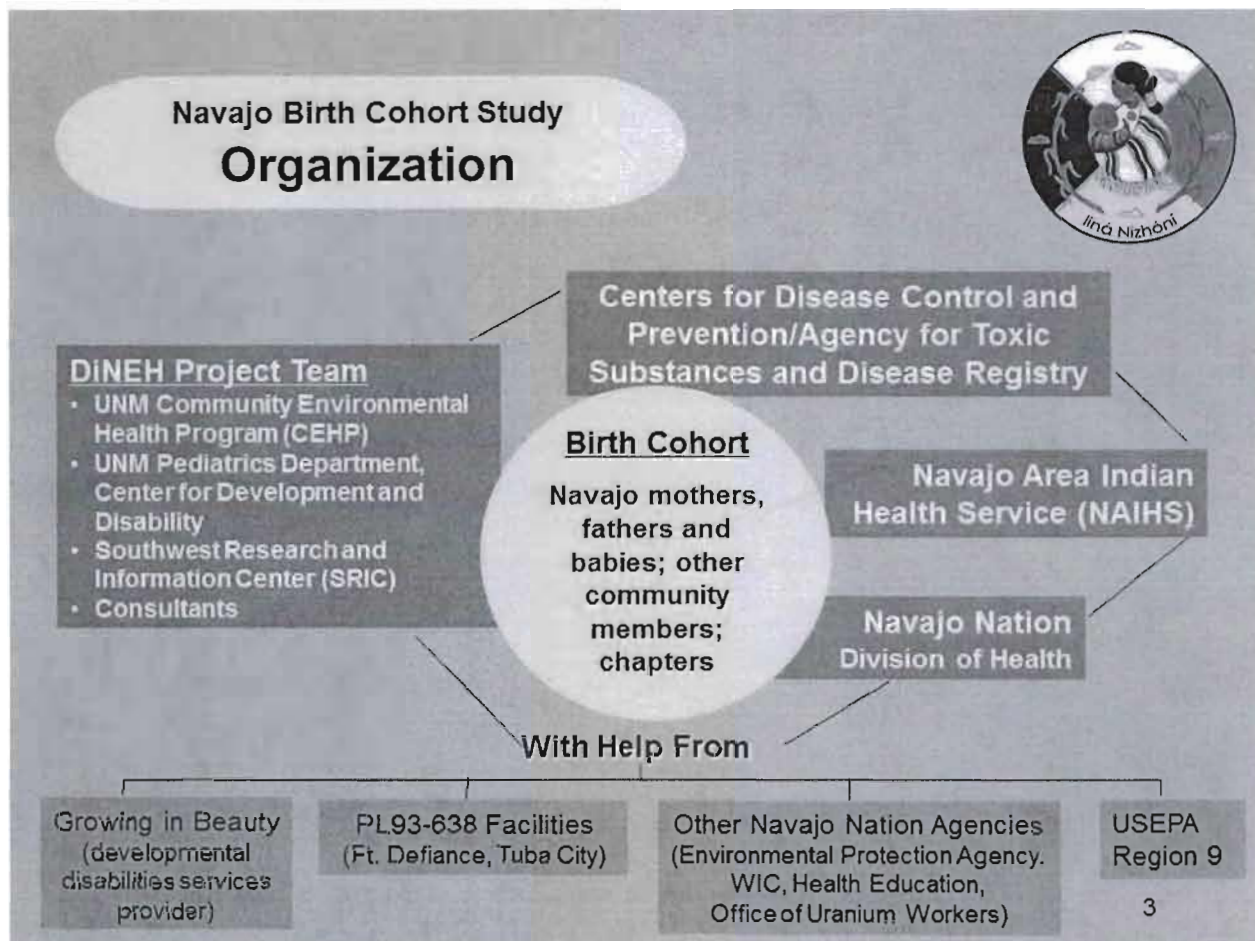
I hereby certify that the foregoing resolution was duly considered by the Naabik'íyáti' Committee of the 23rd Navajo Nation Council at a duly called meeting in Window Rock, Navajo Nation (Arizona), at which a quorum was present and that the same was passed by a vote of 12 in favor and 0 opposed, this 17th day of August, 2015.

A handwritten signature in black ink, appearing to read "LoRenzo C. Bates", written over a faint circular stamp.

LoRenzo C. Bates, Chairperson
Naabik'íyáti' Committee

Motion : Honorable Jonathan Perry
Second : Honorable Dwight Witherspoon

NAVAJO BIRTH COHORT STUDY ORGANIZATIONAL CHART





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

03/12/2015

Johnnye L. Lewis
University of New Mexico
College of Pharmacy
1 University of Mexico
MSC09 5360
Albuquerque, NM 87131



Reference:

Award: TS000135
FOA: TS13-001 - Continuing Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation (U01)

Dear Grantee:

This letter solicits your non-competing continuation application for the budget year **09/01/2015** through **08/31/2016**. Please prepare your budget at no more than **\$1,000,000** (direct and indirect costs). This amount is an estimate; it is subject to change based on final budget determination. Your application budget should be based on this amount, including the effect of any estimated un-obligated balance of funds.

The continuation application must be submitted on Public Health Service (PHS) Non-competing Grant Progress Report, PHS Form 2590. The form may be downloaded from <http://grants1.nih.gov/grants/funding/2590/2590.htm#forms>.

Please follow the instructions provided in the attached guidance document to prepare your continuation application. The original application plus two copies must arrive at CDC no later than **05/05/2015**. A late or incomplete application may result in an enforcement action such as a delay in processing the award and/or reduction in the upcoming year funds. CDC will only accept requests for an extension to the deadline after adequate justification has been provided and approved by the Grants Management Officer. Send the completed application to the following address:

Centers for Disease Control and Prevention
Procurement and Grants Office
Acquisition and Assistance Branch IV
ATTN: Terrian J. Dixon
2920 Brandywine Road, MS E-01
Atlanta, GA 30341-4146

If additional information is required in regards to budget preparation, please contact Terrian J. Dixon at 770.488.2774. For programmatic information, please contact Sue Neurath at 770.488.3368.

Sincerely yours,

Terrian J. Dixon
Grants Management Specialist
Procurement and Grants Office
Centers for Disease Control and Prevention

NON-COMPETING CONTINUATION GUIDANCE – RESEARCH

FOA Number, FOA Title: TS13-001 – Continuing Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation – Research (U01)

The application should consist of:

- **Cover Letter signed by the Principal Investigator/Program Director and an official in the business office**
- **PHS 2590 Forms**
 - **Form Page 1, Face Page**
 - **Form Page 2, Detailed Budget for the Next Budget Period**
 - **Form Page 3, Budget Justification**
 - **Form Page 4, Biographical Sketch**
 - **Form Page 5, Progress Report Summary**
 - **Form Page 6, Checklist**
 - **Form Page 7, Key Personnel**
 - **Continuation Page (optional)**
 - **Planned Enrollment**
 - **Enrollment Report**
- **Indirect Cost Rate Agreement**
- **Human Subjects Testing IRB Approval**

General Application Tips:

- Include the original plus two copies of application and appendices.
- Include the complete grant/notice of award number on each page of the application.
- Number all pages.
- Do not exceed 15 pages (including appendices, excluding budget and support)
- Do not staple or bind.
- Use a 12 point font.
- Where the instructions on the forms conflict with these instructions, follow these.



SPECIFIC COMPONENTS OF THE APPLICATION ARE PROVIDED BELOW:

COVER LETTER:

- The cover letter must include the grant number and the amount of funds being requested.
- Include signatures of *both* the Project Director/Principal Investigator and an official in the Business Office authorized to sign for the organization.
- Current contact information of *both* the Project Director/Principal Investigator and the Business Official to include:
 - Address
 - E-mail address
 - Telephone number
 - Facsimile number

PHS Form 2590: You can download the forms from:

<http://www.grants.nih.gov/grants/funding/2590/2590.htm>

- Face Page (mandatory)
 - Fill out all blocks carefully and completely.
 - Ensure that the form is signed by the parties with the appropriate authority.
 - The face page must include:
 - Signatures
 - Dates
 - IRB approvals
 - Accurate contact information.
- Detailed Budget (mandatory)
 - This is a top level summary of proposed direct costs by cost categories.
- Budget Justification (mandatory)
 - Provide detailed explanations, justifications, and itemization of proposed direct cost categories.
 - Use continuation pages – as needed.
 - Enter the following information about the current budget year and financial progress on the "Budget Justification" page:
 - On the top half of the page, explain any significant budgetary issues or concerns. Disregard the instructions in the block as they do not apply to this type of award.
 - On the bottom half of the page provide an estimate of the overall expenses and obligations for the current budget period (12-months of effort), as follows:

Funding for current budget period: \$ _____

Estimate of current obligations: \$ _____

Estimate of un-obligated at this point in time: \$ _____

Estimate of un-obligated at the end of the budget period*: \$ _____

****Note: Any reported estimated unobligated balance may be used to fund new award. If you report any estimated unobligated dollars, please be sure to include an interim FSR indicating estimated unobligated dollars for the 12-month budget year.***
 - It is **essential** that you provide detailed support and justification for the funds you are requesting.
 - The support and justification should be to the level of detail and the general form prescribed in the Budget Guidelines. These can be found at:

<http://www.cdc.gov/od/pgo/funding/budgetguide.htm>

- Biographical Sketch (optional)
 - Include this information if there have been any changes in key personnel.
 - Include this information if biographical information on key personnel has changed.
- Checklist (mandatory)
 - Note that Facilities and Administrative (F&A) costs are synonymous with Indirect Costs for the purposes of this application.
 - Be certain to clearly describe the method that you used to calculate indirect costs. Make sure that the method is consistent with your Indirect Cost Rate Agreement.
 - In the section of the form entitled "Explanations", be sure to describe how you calculated the base amount upon which the indirect cost rate was applied.
 - The Budget Guidelines provide more direction on this cost element.
- Personnel (optional)
 - If there were any changes in personnel, this section of the application should be completed.
- Continuation Page (optional)
 - Use as needed.
- Summary of Trainees (optional)
- Planned Enrollment
- Enrollment Report
- Progress Report Summary (mandatory)
 - Use continuation pages as needed.

Progress Report Summary Should Include the Following Four Sections:

1. Milestone Summary

This section should reflect the status of each milestone outlined in the investigator's work plan in the progress report section of the application. Milestones that are deficient or deferred must be fully explained with the appropriate corrective action described including specific dates of completion.

2. Progress Summary:

- a. A progress report - a detailed summary from project start-up through current budget year;
- b. Major findings/accomplishments;
- c. Significance of those findings/accomplishments (a description of how the findings impact or contribute to the public health goal of preventing or reducing injury severity, disability or death);
- d. Proposed objectives and activities for the upcoming budget year; and
- e. Publications (recipients should include abstracts, publications/manuscripts/reports/etc. and presentations completed and those submitted for presentation/publication; including presentations at meetings and other significant efforts to disseminate research results).

3. Project Milestones for the Next Budget Year

The third section should include the project milestones for the upcoming budget year that begins (start of new budget period) and ends 12 months later. The work plan format should follow instructions provided in the announcement. The milestones should be time specific and reflect critical tasks that are good indicators of progress.

Include comments pertaining to any budgetary issues that might hamper the success or completion of the research project as originally proposed and approved.

4. Programmatic Changes

The fourth section should address any programmatic changes and the reason for changes. Describe progress made and how you have adjusted. Include milestones in any new activity.

INDIRECT COST RATE AGREEMENT:

- The DHHS Agreement is synonymous with Indirect Cost Rate Agreement for the purposes of this application.
- If indirect costs are proposed that is based on a provisional rate that will be in effect at the time of the start of the budget period, then the Rate Agreement must be less than 12 months old at the time the application was submitted.
- If indirect costs are proposed based on a predetermined rate, it must be in effect at the time of the start of the budget period.
- If you do not have a current Indirect Cost Rate Agreement, you can charge indirect costs as direct only when it is an approved practice, adequately supported and justified, and are proposed under an approved cost allocation plan. Please see the Budget Guidelines (<http://www.cdc.gov/od/pgo/funding/budgetguide.htm>) for additional information.
- You may get additional information on Indirect Cost Rate Agreements and Cost Allocation plans from the HHS Division of Cost Allocation: <http://rates.psc.gov/>

HUMAN SUBJECTS IRB APPROVAL:

- Please include copies of current IRBs for all test sites. If IRBs are not current at the time of award, please identify the specific cost categories and amounts that relate to research involving human subjects.
 - If there were human subject restrictions placed on the current year award that have not been lifted, please identify in this section the specific cost categories and amounts that are linked to research activities involving Humans Subjects.
-

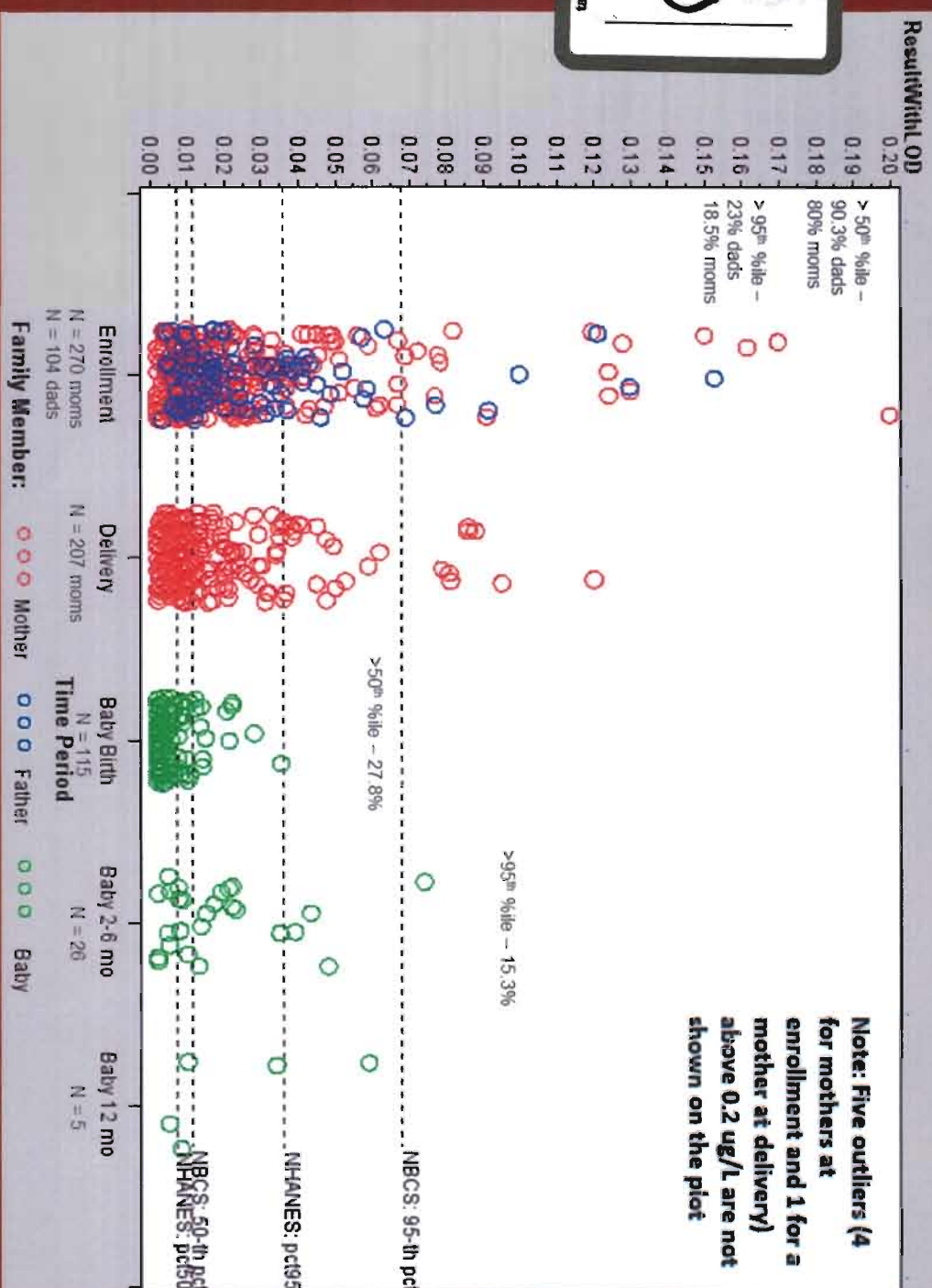
Uranium

distributions consistent across all service units

- Now have sufficient data to begin examining relationships between moms, dads, babies, babies over time, and relationships to exposure sources
- Cannot directly address placental transfer, U in urine at birth a concern
- Concern that babies exposures increase & at levels 3x greater than expected for adults (NHANES)

NBCS Levels of UUR (Uranium - Urine), ug/L (LOD included)

Reference Lines (ug/L): NHANES (pct50 = 0.007, pct95 = 0.036), NBCS (pct50 = 0.011, pct95 = 0.068), LOD = 0.002 ug/L

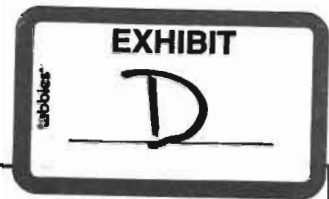


EXHIBIT



asymptot

All percentile comparisons are to NHANES 2010-2011 adults – no infant comparisons found.



DEPARTMENT of HEALTH and HUMAN SERVICES

**Fiscal Year
2016**

**Agency for Toxic Substances
and Disease Registry**

*Justification of
Estimates for
Appropriation Committees*

MESSAGE FROM THE ADMINISTRATOR

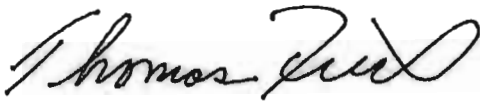
We are pleased to present FY 2016 Congressional Justification for the Agency for Toxic Substance and Disease Registry (ATSDR). The budget request provides funding for ATSDR's congressionally mandated programs and activities.

ATSDR's unique focus is on the impact of hazardous substances on human health. Our scientific and programmatic experts ensure Americans have a safe and healthy environment in which to work, play, and live. We use sound science and ethical principles to meet real public needs.

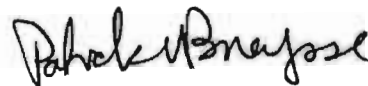
Performance improvement is a critical aspect of our work. We evaluate our progress in reducing exposures at the most hazardous sites and closely track programmatic activities. As such, we believe that performance data in ATSDR's FY 2016 Congressional Justification are accurate, complete, and reliable.

We are confident this Congressional Justification will support ATSDR's essential work.

Sincerely,



Thomas R. Frieden, MD, MPH
Director, Centers for Disease Control
and Prevention
Administrator, Agency for Toxic
Substances and Disease Registry



Patrick Breyse, PhD
Director, Agency for Toxic Substances and
Disease Registry

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

(dollars in millions)	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Budget Authority	\$74.691	\$74.691	\$74.691	\$0.000
ACA (mandatory) ¹	N/A	\$18.540	N/A	N/A
FTEs	279	279	279	0

¹The Patient Protection and Affordable Care Act (P.L. 111-148) appropriated \$23,000,000 for the period of FY 2010–2014, and \$20,000,000 for each five-year period thereafter, in no-year funding for the early detection of certain medical conditions related to environmental health hazards.

Summary

The Agency for Toxic Substances and Disease Registry (ATSDR) promotes healthy and safe environments and prevents harmful exposures through responsive public health actions. ATSDR's FY 2016 request of **\$74,691,000** in budget authority is level with the FY 2015 Enacted level to maintain ATSDR's scientific and programmatic capabilities to safeguard human health. The request includes resources to continue epidemiological studies of health conditions caused by non-occupational exposures to uranium released from mining and milling operating at the Navajo Nation.

Performance Highlights

- Investigated the potential health risks of more than a million people in 600 communities in the United States who were potentially exposed to harmful substances. The investigations resulted in federal, state, and local actions that protected the health of more than 125,000 people who were being exposed to harmful substances.
- Ensured that 85 percent of ATSDR's recommendations were adopted by regulatory agencies, industries, and other partners to prevent and stop hazardous exposures. For example, when an exterminator exposed hundreds of people from Rutland, Vermont to the dangerous pesticide chlorpyrifos, ATSDR took immediate action. ATSDR regional field staff partnered with the state health department to go door-to-door to talk to the more than 400 residents about the health effects of chlorpyrifos. ATSDR also referred concerned residents to environmental health specialists for clinical consultations and provided recommendations to EPA and the state health department about when cleanup and other health protective actions should be taken.
- Funded 25 states to assess environmental hazards and educate people on environmental health risks. For example, through a cooperative agreement with ATSDR, the New Hampshire Department of Environmental Services (DES) detected high levels of 1,4-dioxane, a toxic substance, in 40 private wells around Atkinson, New Hampshire. ATSDR and DES helped the local residents understand the health risks of this carcinogen. In response to DES and ATSDR findings, the residences with affected wells have been connected to public water supply. In addition, ATSDR and DES provided special support to a resident battling leukemia, working quickly to remove any exposures that could complicate his recovery.

In FY 2016, ATSDR will continue the Navajo Birth Cohort Study with its collaborators—the Navajo Nation Department of Health, University of New Mexico, and Indian Health Service—to investigate possible neonatal health effects caused by uranium exposure from past mining and milling operations on the Navajo Nation. The study will continue to recruit pregnant mothers from the designated service units, evaluate their exposure (and the exposure to their unborn child), and then follow the children post-birth to identify any adverse birth outcomes and/or developmental delays. Individual study results will be disseminated to the participants. Summary study results will be presented to the Navajo Nation and published in peer-reviewed scientific literature.

Conducting Environmental Surveillance

ATSDR designs and conducts surveillance and registry programs to help evaluate the adverse health effects on persons exposed to hazardous substances. Existing surveillance activities include examining the public health consequences (e.g., morbidity and mortality) from acute chemical spills and releases that occur around the country each year through the National Toxic Substance Incidents Program (NTSIP). Findings from NTSIP data safeguard the public, first responders, and employees in the private sector. ATSDR also conducts or collaborates on health registries to follow the health and well-being of people exposed or potentially exposed to harmful substances.

Ongoing health registries created or managed by ATSDR:

- Katrina and Rita Exposures (KARE) Registry¹⁰ – A survey of people who lived or stayed in trailers furnished by the Federal Emergency Management Agency (FEMA) after Hurricanes Katrina and Rita.
- National Amyotrophic Lateral Sclerosis (ALS) Registry¹¹ – A congressionally mandated registry for persons in the United States with ALS. It is the only population-based registry in the United States that collects information to help scientists learn more about who gets ALS and its causes.
- Tremolite Asbestos Registry¹² – A listing of individuals with an asbestos-related disease or those at high risk of developing asbestos-related disease because of exposure to asbestos.
- Rapid Response Registry¹³ – Helps local, state, and federal agencies rapidly establish registries of persons who are exposed or potentially exposed to chemicals or other harmful agents during catastrophic events.
- World Trade Center Registry¹⁴ – A comprehensive and confidential health survey of those most directly exposed to the events of September 11, 2001.

State and Local Grants

State Cooperative Agreements

ATSDR's state cooperative agreement program¹⁵ funds health departments to investigate and respond to harmful exposures in communities and teach the public about exposure prevention. Direct funding to states increases local knowledge and improves efficiency as state-based public health officials are able to travel to sites more quickly and respond to local issues with greater specificity. ATSDR awarded three-year cooperative agreements to 25 states in FY 2014. Funding decisions were based on a state's projected burden of harmful environmental exposures, technical capacity to conduct investigations, and ability to educate the public. ATSDR will award the third year of funding in FY 2016.

¹⁰ <https://kareregistry.org/>

¹¹ <https://wwwn.cdc.gov/ALS/Default.aspx>

¹² http://www.atsdr.cdc.gov/asbestos/sites/libby_montana/

¹³ <http://www.atsdr.cdc.gov/rapidresponse/>

¹⁴ <http://www.nyc.gov/html/doh/wtc/html/registry/registry.shtml>

¹⁵ <http://www.atsdr.cdc.gov/states/>

Navajo Nation

ATSDR funds a birth cohort study at the Navajo Nation¹⁸ to evaluate the potential association between uranium and other heavy metal exposure and reproductive birth outcomes. The study results will help mitigate and prevent uranium exposure and increase prenatal care utilization. Moving forward through FY 2016, the program will continue to recruit Navajo mothers to participate, assess uranium exposure at key developmental milestones, and follow children to evaluate any associations with birth defects or developmental delays. With guidance and input from the Navajo Nation, ATSDR will disseminate the results of the study when completed and will evaluate the potential for follow-up and continued surveillance of children beyond the research study period.

¹⁸ http://www.atsdr.cdc.gov/sites/navajo_birth_cohort_study/

AMOUNTS AVAILABLE FOR OBLIGATION¹

(dollars in millions)	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget
Discretionary Appropriation:			
FY 2013 Enacted Amount	\$74,691,000	\$74,691,000	\$74,691,000
OMB 0.2% Rescission	\$0	\$0	\$0
Sequestration	\$0	\$0	\$0
Subtotal, adjusted Discretionary Appropriation	74,691,000	74,691,000	74,691,000
Mandatory and Other Appropriations:			
Transfers from Other Accounts	\$0	\$0	\$0
Mandatory Appropriation ²	\$0	\$18,540,000	\$0
Subtotal, adjusted Mandatory Appropriation	\$0	\$18,540,000	\$0
Recovery of prior year Obligations	\$0	\$0	\$0
Unobligated balance start of year	\$14,412,090	\$11,736,268	\$9,060,446
Unobligated balance expiring	\$0	\$0	\$0
Unobligated balance end of year	(\$11,741,000)	(\$9,060,446)	(\$6,384,624)
Total Obligations	77,362,090	95,906,822	77,366,822

¹ Excludes the following amounts for reimbursements: FY 2014: \$12.8M; and FY 2014: \$12.8M; FY 2015: \$12.8M.

² FY 2015 amount includes mandatory sequestration reduction.