

Centers for Disease Control and Prevention

Agency for Toxic Substances and Disease Registry

Biomonitoring Legacy and Emerging Great Lakes Contaminants in Susceptible Great Lakes Populations
CDC-RFA-TS16-1601
Application Due Date: 03/31/2016

Biomonitoring Legacy and Emerging Great Lakes Contaminants in Susceptible Great Lakes Populations

CDC-RFA-TS16-1601

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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-TS16-1601. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Agency for Toxic Substances and Disease Registry (ATSDR)

B. Funding Opportunity Title:

Biomonitoring Legacy and Emerging Great Lakes Contaminants in Susceptible Great Lakes Populations

C. Announcement Type: New - Type 1

This announcement is only for non-research domestic activities supported by ATSDR. If research is proposed, the application will not be considered Research for this purpose is defined at http://www.cdc. gov/od/ science/ integrity/ docs/cdc- policy- distinguishing- public- health- research- nonresearch. pdf.

D. Agency Funding Opportunity Number:

CDC-RFA-TS16-1601

E. Catalog of Federal Domestic Assistance (CFDA) Number:

93.161

F. Dates:

1. Due Date for Letter of Intent (LOI):	**N/A**
2. Due Date for Applications:	**03/31/2016**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.
3. Date for Informational Conference Call:	**03/10/2016**

An informational conference call will be held on Thursday, March 10, 2016, at 2:30PM (Eastern).

Call in number: 1-866-692-3158; Passcode: 81253953

The questions and answers from the call will be published on Grants.gov (as an amendment to this FOA) approximately a week after the call.

G. Executive Summary:

1. Summary Paragraph:

The purposes of this FOA is for the awardee to conduct a biomonitoring program to assess body burden of legacy and emerging contaminants in susceptible Great Lakes populations in areas not monitored under CDC-RFA-TS10-1001 and CDC-RFA-TS13-1302 cooperative agreement programs. Determining which contaminants get into human populations informs public health officials and guides environmental public health action throughout the Great Lakes restoration process.

Awardee will conduct the following activities during the project period: 1) conduct a biomonitoring program to assess exposure to legacy and emerging contaminants in a susceptible population(s) in the Great Lakes basin, particularly in those who are at higher exposure risk, 2) use the results to develop a plan guiding and advancing public health actions and safeguarding people from harmful exposure, 3) conduct multi-level communication and outreaches to high-risk populations, key audiences and stakeholders, and general populations to communicate the risks and benefits of Great Lakes fish consumption, and, to promote healthy fish consumption choices that minimize the risk of contaminant exposure, 4) establish and strengthen collaborations and coordination in biomonitoring activities and projects.

ATSDR anticipates the following outcomes during the project period: 1) improved and expanded knowledge about Great Lakes-specific environmental chemical exposures, 2) increased use of high-quality biomonitoring results as bases for public health actions in the Great Lakes region, 3) increased awareness about chemical exposures and risk and benefit of fish consumption in target population, 4) increased awareness of exposure assessment using biomonitoring to guide public health actions, 5) increased ability at the state and local level to monitor and track Great Lakes-specific exposures, 6) strong collaborations for biomonitoring activities and projects.

The purpose of this amendment is to include Q & A's from the informational conference call on March 10, 2016.

a. Eligible Applicants:	Limited
b. FOA Type:	Cooperative Agreement
c. Approximate Number of Awards:	1
d. Total Project Period Funding:	$1,600,000
e. Average One Year Award Amount:	$800,000

ATSDR anticipates funding one award at up to $895,000 for FY2016 and up to $705,000 for FY2017. The total project period is two years. The total funding level for the project period (FY2016 and FY2017) is approximately $1,600,000. This amount is subject to the availability of funds.

f. Number of Years of Award:	2
g. Estimated Award Date:	07/01/2016
h. Cost Sharing and / or Matching Requirements:	N

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this FOA exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

Over the past century, careless practices have resulted in contamination of the Great Lakes ecosystem with countless chemical products and byproducts of modern life entering into the air, water, land, and biota, and even into people's bodies. People's health in the Great Lakes area can be at risk because the environment/ecosystem is contaminated with these harmful contaminants. It is difficult for public health agencies and others to take effective action unless they know the extent and characteristics of exposure. Biomonitoring is the direct measurement of environmental chemicals, or their products, in people's blood and urine. Biomonitoring measurement represents the amount of chemical that enters the body from all environmental sources, and is the most direct approach on assessing people's exposure.

The purpose of this project is for the awardee to conduct a biomonitoring program to assess body burden of legacy contaminants and chemicals of emerging concern in susceptible Great Lakes populations with potential high exposure to contaminants from Great Lakes fish consumption in areas not monitored previously. This awardee is also required to develop a plan to use the biomonitoring study results to help guide and advance public health actions and safeguard the health of the people in their jurisdiction.

b. Statutory Authorities

This program is authorized by Section 104(i)(15) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act (SARA) [42 U.S.C. 9604(i)15]; additionally, the EPA is authorized to transfer funds to ATSDR for the purpose of undertaking this activity by the Consolidated Appropriations Act, 2014 (P.L. 113-76).

c. Healthy People 2020

This program addresses the "Healthy People 2020" focus area related to Environmental Health; Objective EH-20, "Reduce exposure to selected environmental chemicals in the population, as measured by blood and urine concentrations of the substances or their metabolites." http://www.healthypeople.gov/2020/topics-objectives/topic/environmental-health/objectives

d. Other National Public Health Priorities and Strategies

In 2009, President Obama's Administration announced the Great Lakes Restoration Initiative (GLRI) to protect, restore and maintain the Great Lakes ecosystem. In 2010, GLRI was launched with unprecedented federal agency coordination. A task force of federal agencies developed milestones and outcome measures to make the five-year GLRI Action Plan a national success during FY2010-2014. In 2015, federal agencies developed the GLRI Action Plan II, which summarizes the actions that federal agencies plan to implement during FY15-19 and outlines the next phase of work on Great Lakes environmental problems and associated human health issues (http://greatlakesrestoration.us/actionplan/pdfs/glri-action-plan-2.pdf).

The GLRI Action Plan II identifies objectives, commitments, measures of progress for five focus areas—Toxic Substances and Areas of Concern; Invasive Species; Nonpoint Source Pollution Impacts on Nearshore Health; Habitats and Species; and, Foundations for Future Restoration Actions. Biomonitoring is a valuable tool to assess human exposure to environmental contaminants. Biomonitoring results provide unique exposure information than can guide public health efforts to reduce exposure of human populations to specific chemicals. EPA is funding the ATSDR, in accordance with the Consolidated Appropriations Act, 2014 (P.L. 113-76), to implement the "Biomonitoring Legacy and Emerging Great Lakes Contaminants in Susceptible Great Lakes Populations" program as part of the Focus Area 1, Toxic Substances and Areas of Concern, of the GLRI.

In reference to the Great Lakes Action Plan II, this project directly supports the Focus Area 1 (Toxic Substances and Areas of Concern), Objective 1.2 (Increase knowledge about contaminants in Great Lakes fish and wildlife), Commitment 1.2.1 (Reduce human exposure to contaminants from Great Lakes fish consumption). Activities under this project support Measures of Progress 1.2.1 (Number of people provided information on the risks and benefits of Great Lakes fish consumption by GLRI-funded projects).

e. Relevant Work

This project will provide public health information to supplement the CDC-RFA-TS10-1001 and CDC-RFA-TS13-1302 cooperative agreement programs that were initiated in FY2010 and FY2013, respectively.

As part of CDC-RFA TS10-1001, the ATSDR awarded funds to the Michigan Department of Community Health (MDCH), the Minnesota Department of Health (MDH), and the New York State Department of Health (NYS DOH) to conduct non-research studies of human exposures to select environmental contaminants in order to advance jurisdiction-specific public health actions. This public health effort focuses on vulnerable or susceptible subpopulations with the potential for increased risk of exposure to persistent contaminants common to the Great Lakes watersheds and ecosystems. The health departments in these states targeted four types of susceptible populations in six areas of concerns (AOCs): MDCH – shoreline anglers on the Detroit River AOC; MDH – American Indians near the St. Louis River AOC; and NYS DOH – licensed anglers and immigrants from Burma and their family members living in four Lake Ontario and Lake Erie AOCs. The NYS areas included the Rochester Embayment AOC, the Eighteenmile Creek AOC, and the AOCs along the Niagara and Buffalo Rivers.

As part of CDC-RFA TS13-1302, the ATSDR awarded funds to the New York State Department of Health (NYS DOH) to conduct a second biomonitoring program in Syracuse, NY. In this program, NYS DOH targets urban low-income minority anglers and refugees and immigrants from Burma and Bhutan who consume fish from Onondaga Lake and its tributaries (Seneca River, Oswego River AOC) and Lake Ontario.

2. CDC Project Description

a. Approach

Bold indicates project period outcome.

The logic model below describes the program framework for this FOA. Note that the bolded components are those that are expected to be accomplished during the project period.

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-term Outcomes
Biomonitoring • Identify target populations • Develop study protocol, questionnaire, sampling strategy, data collection system, etc. • Designate labs with high quality biomonitoring capabilities • Recruit study participants • Conduct data collection and biological sample collection • Conduct laboratory measurements to determine levels of environmental chemicals in participants • Produce written assessment • Produce data use plan Communication and Outreach • Develop communication and outreach plan • Communicate data & findings to key audiences • Conduct outreach activities on the risk and benefit of fish consumption through multiple channels Collaboration • Engage stakeholders and establish Advisory Committee • Collaborate with state, tribal, local, and other federal partners in biomonitoring activities and projects	**Biomonitoring** • **Accurate assessment of exposure in Great Lakes populations** • **More current data on Great Lakes-specific environmental chemical exposures** • **Strong plan for use of findings** • **Increased use of high-quality biomonitoring results as bases for public health actions** **Communication and Outreach** • **Increased awareness about chemical exposures, and risk and benefit of fish consumption in target population** • **Increased awareness of the value of biomonitoring as a tool for exposure assessment among federal and state governments, policymakers, and stakeholders** • **Improved and expanded knowledge about Great Lakes chemical exposures among the scientific community** **Collaboration** • **Improved ability of Advisory Committee to promote biomonitoring and implement activities** • **Strong collaborations for biomonitoring activities and projects**	• **Findings used by the state and local government to guide public health action to reduce and prevent harmful chemical exposures** • **Increased ability at the state and local level to monitor and track Great Lakes-specific exposures** • Increased awareness of environmental contamination and chemical exposure among the general Great Lakes population • Increased awareness about risk and benefit of fish consumption among the general Great Lakes population	• Changes in behavior among susceptible populations to reduce exposure to harmful Great Lakes contaminants • Reduced exposure to harmful Great Lakes contaminants among susceptible Great Lakes populations • Improved health outcomes in susceptible Great Lakes populations • Improved Great Lakes ecosystem

i. Purpose

The purpose of the current announcement is to evaluate body burden levels of legacy contaminants and chemicals of emerging concern in susceptible Great Lakes populations in an area that was not addressed in the FY2010 CDC-RFA TS10-1001 and FY2013 CDC-RFA TS13-1302 cooperative agreement programs. The susceptible populations include those with potential high exposure to contaminants from Great Lakes fish consumption (e.g. subsistence anglers who tend to be low income minority), and/or those who are susceptible to the potential health effect of such chemical exposure (e.g. children, adolescents and elderly).

ii. Outcomes

During the project period, awardees will achieve the following outcomes:

Short-term outcomes

Biomonitoring

• Accurate assessment of exposure in Great Lakes populations

• More current data on Great Lakes-specific environmental chemical exposures

• Strong plan for use of findings

• Increased use of high-quality biomonitoring results as bases for public health actions

Communication and Outreach

• Increased awareness about chemical exposures, and risk and benefit of fish consumption in target population

• Increased awareness of the value of biomonitoring as a tool for exposure assessment among federal and state governments, policymakers, and stakeholders

• Improved and expanded knowledge about Great Lakes chemical exposures among the scientific community

Collaboration

• Improved ability of Advisory Committee to promote biomonitoring and implement activities

• Strong collaborations for biomonitoring activities and projects

Intermediate outcomes

• Findings used by the state and local government to guide public health action to reduce and prevent harmful chemical exposures

• Increased ability at the state and local level to monitor and track Great Lakes-specific exposures

iii. Strategies and Activities

Awardee will conduct the following activities:

Biomonitoring

1. Identify target populations

• Identify environmental exposure concerns in their jurisdiction presented by Great Lakes pollutants

• Identify past and current activities related to identification, control and prevention of potential adverse human health effects associated with Great Lakes pollutants

• Identify, specify, and describe target population(s) with regard to potential exposure risk, social economic status, geographic location, and other relevant information and justification as deemed necessary.

2. Develop study protocol, questionnaire, sampling strategy, data collection system, etc. in collaboration with ATSDR

• Develop a study protocol that follows CDC guidelines: http://www.cdc.gov/niosh/nas/mining/pdfs/Protocol%20Checklist.pdf.

• Develop a biomonitoring questionnaire interview in collaboration with ATSDR using questionnaire items similar to the FY2010 TS10-1001 and FY2013 TS13-1302 cooperative agreement program.

• Establish a statistically valid sampling strategy in collaborate with ATSDR to ensure that the selection of participants is representative of the targeted, susceptible subpopulation.

• Develop standardized protocols for the collection and analysis of biological specimens, including proficiency-testing, quality assurance, and quality control, established in collaboration with or consistent with the Centers for Disease Control and Prevention's Environmental Health Laboratory.

• Develop an appropriate personal interview component, e.g., computer-assisted personal interview (CAPI), for the questionnaire interview

• Establish quality assurance mechanisms for data collection and management, to provide complete and quality data. Awardees may need to provide certification and accreditation of their data collection system that meets federal Privacy Act standards for protecting the privacy of individuals, including secure electronic storage, to the extent possible, of all collected data.

• Establish a data collection system to collect, synthesize, and manage program data. Develop and maintain the capability to securely export data.

3. Designate labs with high quality biomonitoring capabilities

• Designate a laboratory to be responsible for the processing, analysis and storage of biological specimens.

• The laboratory must provide documentation of Clinical Laboratory Improvement Act of 1988 (CLIA) certification, as well as documentation of the mechanism (e.g., contract) under which they perform clinical measurements (i.e. triglycerides, cholesterol, etc.).

• The laboratory must also provide documentation of participation in an external proficiency testing program(s).

• Describe the laboratory's past and current biomonitoring activities, if any.

4. Recruit study participants

• Follow the established statistically valid sampling strategy, pre-screen the target population regarding established inclusion criteria

• Conduct sampling and recruitment

• Collect biological specimens, conduct clinical screenings and questionnaire interviews

• Train staff, clinic staff and interviewers.

5. Conduct data collection and biological sample collection

• Use the established personal interview component to conduct interview and administer questionnaire.

• Follow the quality assurance mechanisms for data collection and management, to provide complete and quality data.

• Collect, store, and transport biological samples, e.g., blood and urine, from the consenting participants following the standardized protocols for biological specimen collection, storage, and transport.

6. Conduct laboratory measurements to determine levels of environmental chemicals in participants

• Measure the following chemicals in biological samples: PCBs (congeners 28, 52, 101, 105, 118, 138, 153, 180), mercury, lead, mirex, hexachlorobenzene, DDT/DDE, and perfluorinated compounds (perfluorooctanoic acid or PFOA, and, perfluorooctane sulfonate or PFOS).

• Identify additional emerging contaminants that may be included in the study, and provide justification for such selection. Emerging contaminants of concern found in the Great Lakes, including but not limited to, brominated flame retardants (BFRs), polycyclic aromatic hydrocarbons (PAHs), and alkylphenols, are examples of contaminants that may be selected. Because these chemicals of emerging concerns can come from many sources other than consuming fishes from the Great Lakes, appropriate considerations must be taken when designing and conducting the biomonitoring program.

• The designated laboratory or laboratories process and analyze biological specimens for required and optional environmental chemicals or biomarkers, following established analytical, quality assurance, and quality control protocols.

• The laboratory must provide documentation of participation in an external proficiency testing program(s) covering the period of laboratory measurements.

• Provide feedback, e.g., result letters, to participants

7. Produce written assessment

• Analyze data to assess human exposure to environmental chemicals.

• Produce and disseminate a written assessment of the biomonitoring study results. Results should include an assessment of analytes based on percentile levels in study participants relative to NHANES data and other appropriate population-based study results; and, an assessment of the potential influence of exposure parameters collected in the biomonitoring questionnaire interview.

• Provide de-identified data of established quality to ATSDR via secure transfer.

8. Produce data use plan

• Develop a plan to use the biomonitoring data to identify, control and prevent potential adverse exposures associated with Great Lakes pollutants, and, to guide public health actions to advance the protection of people in their jurisdiction who are at increased exposure risks to Great Lakes contaminants.

Communication and Outreach

9. Develop communication and outreach plan for the target or at risk populations, key audiences and stakeholder, and general populations.

• Produce study brochures and outreach materials

10. Communicate data & findings to key audiences as outlined in the communication and outreach plan

11. Conduct outreach activities on the risk and benefit of fish consumption during both data collection and result dissemination phases, through multiple channels, including but not limited to website, mail-outs, community meetings, and health fairs.

Collaboration

12. Engage stakeholders and establish advisory committee

• The awardee will establish an advisory committee to assist with consensus building, cooperation, and planning for the state biomonitoring program. Representatives may include intrastate agencies, tribes, universities, and public or nonprofit private agencies, institutions, organizations in their geographic region and others deemed appropriate. (Note: This advisory committee will not be established or utilized by ATSDR or any other component of the federal government.)

• The advisory committee, or a sub-committee if necessary, should also provide guidance on ethical issues that arise from biomonitoring studies such as informed consent in the use of newly collected and archived samples, individual notification of results, interpretation and dissemination of results to the affected subpopulation and plans for action.

13. Collaborate with state, tribal, local, and other federal partners in biomonitoring activities and projects.

Note: In accordance with the Paperwork Reduction Act, ATSDR must obtain approval from the White House Office of Management and Budget (OMB) prior to initiating any program related data collection activities.

1.Collaborations

Applicants are expected to use or develop strategic partnerships that best suit their needs in order to carry out all required activities required. Some state health departments and/or tribal entities may not have all of the technical expertise to conduct a biomonitoring project on this scale. Hence, this cooperative agreement allows for and encourages eligible applicants to partner with other organizations, including universities, non-profit and for-profit organizations, and faith-based organizations, to carry out all planned activities.

Applicants must file the MOU or MOA, as appropriate, name the file "MOUs/MOAs", and upload it as a PDF file at www.grants.gov.

Applicants must file letters of support, as appropriate, name the file "Letters of Support", and upload it as a PDF file at www.grants.gov.

Letters of support need to be provided for collaborations with intrastate agencies, tribes, universities, and public or nonprofit private agencies, institutions, organizations in your geographic region and others deemed appropriate.

a. With other CDC programs and CDC-funded organizations:

Applicants are encouraged to collaborate with states previously or currently funded by ATSDR's Great Lakes Biomonitoring cooperative agreements (New York, Michigan, and Minnesota) to share expertise and learn about program challenges and successes.

Applicants may also consider collaborating with state programs that receive funding through:

• ATSDR's State Cooperative Agreement Program to build capacity to assess and respond to site-specific issues involving human exposure to hazardous substances in communities in the U.S.

• CDC's State-Based Public Health Laboratory Biomonitoring Programs to increase the capability and capacity of state public health laboratories to conduct high-quality biomonitoring science and assess human exposure to environmental chemicals.

• CDC's Environmental Health Tracking Program to develop a state network to track and report environmental hazards and related health problems.

b. With organizations not funded by CDC:

The awardee is required to establish an advisory committee to assist with consensus building, cooperation, collaboration, planning, communication and outreach for the Great Lakes state biomonitoring program. Representatives may include intrastate agencies, tribes, academic institutions, professional organizations, non-profit organizations, advocacy groups, and community groups in their geographic region, and others deemed appropriate.

The advisory committee, or a sub-committee if necessary, should also provide guidance on ethical issues that arise when conducting biomonitoring studies such as informed consent in the use of newly collected and archived samples, individual notification of results, interpretation and dissemination of results to the affected subpopulation and plans for action.

This advisory committee will not be established or utilized by ATSDR or any other component of the federal government.

2. Target Populations

The target populations include those with potential high exposure to contaminants from Great Lakes fish consumption (e.g. subsistence anglers who tend to be low income minority), and/or those who are susceptible to the potential health effect of such chemical exposure (e.g. children, adolescents, women of child-bearing age, and elderly). A subpopulation identified to be at increased risk of exposure to Great Lakes contaminants include racial or ethnic groups with traditional fishing and fish consumption customs, sport anglers and urban poor. Applicants are required to use data, such as social determinant data to identify a subpopulation within their jurisdiction that is at increased risk of exposure to Great Lakes contaminants. The target population must be large enough to recruit a target sample of at least 350 people. The exposure pathway is primarily consumption of locally caught fish, but lifestyles associated with contaminated waters/sediments/soil will also be considered

a. Inclusion

N/A

iv. Funding Strategy (for multi-component FOAs only)

N/A

b. Evaluation and Performance Measurement

1.

i. CDC Evaluation and Performance Measurement Strategy

ATSDR will evaluate program planning, implementation, start-up and progress to assess whether program performance adheres to the guidelines in the FOA plan. Performance measures will be used to guide continuous program improvement and evaluate the success of this FOA to implement a biomonitoring study in a well-defined, at risk target subpopulation of residents in the Great Lakes Basin and assess human exposure to Great Lakes contaminants within their jurisdictions.

The evaluation component will examine whether the program 1) plans the appropriate activities, 2) meets scheduled project milestones and deadlines, and 3) completes the program within the project period. These measures will align closely to the activities and outputs depicted in the logic model and the elaboration of these in the work plan section.

Key evaluation questions and metrics of performance throughout the project period will include:

• Does the awarded program establish effective advisory committees and collaborations?

• Does the awarded program recruit and utilize appropriate staffing?

• Does the awarded program conduct high-quality biomonitoring program?

o Does the awarded program complete all study and laboratory protocols, information collection and community outreach materials for participant recruitment with the first 6 months of receiving the award?

o Are all protocols scientifically sound?

o Does the awarded program develop effective sampling and recruitment strategy?

o Does the awarded program reach the goal of the target sample size of at least 350 participants for biomonitoring?

o Does the designated laboratory have required certifications (e.g. CLIA) and established protocols for the processing, analysis and storage of biological specimens?

• Does the awarded program produce a sound and effective data use plan to guidance public health actions?

• Does the awarded program develop an appropriate communication protocol for the dissemination and use of biomonitoring results?

• Does the awarded program develop an effective multi-channel communication and outreach plan to provide information on the risk and benefit of Great Lakes fish consumption to study participants, key audiences and stakeholders?

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the awardee will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this FOA. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Awardees will be required to submit a more detailed Evaluation and Performance Measurement plan within the first 6 months of award, as described in the Reporting Section of this FOA.

Applicants must provide an overall jurisdiction/community specific evaluation and performance measurement plan that is consistent with the CDC evaluation and performance measurement strategy. The plan must:

• Describe how key program partners will be engaged in the evaluation and performance measurement planning processes

• Describe the type of evaluations to be conducted (i.e. process and/or outcome)

• Describe key evaluation questions to be answered

• Describe other information, as determined by the ATSDR program (e.g., performance measures to be developed by the applicant) that should be included

• Describe potentially available data sources and feasibility of collecting appropriate evaluation and performance data

• Describe how evaluation findings will be used for continuous program and quality improvement

• Describe how evaluation and performance measurement will contribute to development of evidence base, where program strategies are being employed that lack a strong evidence based of effectiveness

c. Organizational Capacity of Awardees to Implement the Approach

Applicants must describe and demonstrate organizational capacity with proposed staffing, organizational structure, staff experience and expertise to carry out all program activities, including scientific and technical aspects, administrative support, project and financial management, collaboration and coordination.

• Provide a staffing plan and an organizational chart, including proposed staffing, with roles clearly stated

• Provide background, experience, and curricula vitae for key staff to indicate ability to carry out the purposes of the program.

• Demonstrate principal investigator and proposed project management's experience, background, and ability to plan, organize, secure and manage resources to successfully accomplish program activities.

• Identify training needs or plan.

• Describes past, current, and proposed activities and collaborations with relevant organizations and agencies on the identification, control and prevention of potential adverse exposures associated with Great Lakes pollutants.

• Describes a current or proposed advisory committee.

The minimum organizational capacity needed to execute the FOA program successfully includes a principal investigator, project coordinator, laboratory manager and staff, computer programmer/data manager, statistical adviser, epidemiologist, data analyst, trained interviewers, phlebotomists and financial administrative support.

d. Work Plan

Applicants must construct a logical and stepwise work plan including a detailed plan that covers the first year of the project period and a high level plan for the second year. The work plan must integrate and delineate specifically how the awardee plans to carry out strategies and activities, evaluation and performance measurement, timeline and milestones, to achieve the project period outcomes. The work plan is a guide to the awardee in implementing their work, assists the Project Officer in monitoring awardee activities, and reflects activities supported by the annual budget. The work plan should also demonstrate how the outcomes, strategies, activities, timelines, and staffing/collaborations work together.

The work plan should address the following:

• Activities and timelines to support achievement of FOA outcomes

• Specific public health needs the program will address

• Staffing and collaboration to support implementation of the award

• Staff training

• Activities to establish and maintain an advisory committee

• Communication plans for reporting results to participants and stakeholders

• Evaluation and assessment processes to ensure successful implementation

Under the Paperwork Reduction Act, ATSDR must obtain approval from the OMB before data collection can begin. ATSDR must submit an information collection request (ICR) package that includes all the data collection instruments along with justifications for the data collection. The OMB process includes a 60-day and a 30-day comment period via notices published in the Federal Register. The OMB clearance process may take 9 months or more to complete.

A sample work plan format is presented below. In this format, the table would be completed for each project period outcome. If a particular activity leads to multiple outcomes, it should be described under each outcome measure.

Project Period Outcome: [from Outcomes section and/or logic model]	**Outcome Measure:** [from Evaluation and Performance Measurement section]		
Strategies/Activities	**Process Measure:** [from Evaluation and Performance Measurement section]	**Responsible Position/Party**	**Completion Date**
1.			
2.			
3.			

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and awardees, site visits, and awardee reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking awardee progress in achieving the desired outcomes.
- Ensuring the adequacy of awardee systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that awardees are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with awardees on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Other activities deemed necessary to monitor the award, if applicable.
These activities may include monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk grantees.

ATSDR will use ongoing communication with awardees. Conference calls will occur monthly between ATSDR and the awardee at a mutually agree upon day and time. The awardee will be asked to provide a written program update monthly to ATSDR in a mutually agreed upon format. ATSDR will conduct yearly site visits to monitor adherence to established study protocols and progress toward outcomes.

f. CDC Program Support to Awardees (THIS SECTION APPLIES ONLY TO COOPERATIVE AGREEMENTS)

In addition to site visits and regular performance and financial monitoring during the project period, ATSDR will have provide the following supports.

• Provide technical assistance in the development and final selection of standard questionnaire elements to be used by the awardee.

• Provide technical assistance in the development of a statistically valid sampling strategy.

• Provide ongoing consultation and technical assistance to ensure effective planning and management as well as scientific and programmatic elements are consistent with the FY2010 CDC-RFA-TS10-1001 and FY2013 CDC-RFA-TS13-1302 cooperative agreement programs.

• Collaborate in establishing or endorsing program requirements for completeness, timeliness and accuracy of data.

• Provide technical assistance in selecting or establishing standardized protocols for the collection and laboratory analysis of biological samples, including proficiency-testing and quality assurance, in collaboration with or consistent with the Centers for Disease Control and Prevention's Environmental Health Laboratory.

• Under the Paperwork Reduction Act, ATSDR must obtain approval from the OMB before data collection can begin.

B. Award Information

1. Funding Instrument Type: Cooperative Agreement

CDC's substantial involvement in this program appears in the CDC Program Support to Awardees Section.

2. Award Mechanism: U61, Preventive

3. Fiscal Year: 2016

Estimated Total Funding: $895,000

4. Approximate Total Fiscal Year Funding: $895,000

This amount is subject to the availability of funds.

5. Approximate Project Period Funding: $1,600,000

6. Total Project Period Length: 2 year(s)

7. Expected Number of Awards: 1

8. Approximate Average Award: $800,000 Per Budget Period

ATSDR anticipates funding one award at up to $895,000 for FY2016 and up to $705,000 for FY2017. The total project period is two years. The total funding level for the project period (FY2016 and FY2017) is approximately $1,600,000. This amount is subject to the availability of funds.

This amount is subject to the availability of funds.

9. Award Ceiling: $895,000 Per Budget Period

10. Award Floor: $500,000 Per Budget Period

11. Estimated Award Date: 07/01/2016

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the awardee (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total project period comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

12. Budget Period Length: 12 month(s)

13. Direct Assistance

Direct Assistance (DA) is not available through this FOA.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
Native American tribal governments (Federally recognized)
Native American tribal organizations (other than Federally recognized tribal governments)
Others (see text field entitled "Additional Information on Eligibility" for clarification)

Additional Eligibility Category:

Government Organizations:

State (includes the District of Columbia)
Local governments or their bona fide agents
American Indian or Alaska Native tribal governments (federally recognized or state-recognized)

Non-government Organizations:

American Indian or Alaska native tribally designated organizations

2. Additional Information on Eligibility

Eligible primary applicants for this FOA are limited to state, local and tribal governments in eight states (Illinois, Indiana, New York, Ohio, Pennsylvania, Michigan, Minnesota, and Wisconsin) and their Bona Fide Agents. Health departments in state, local and tribal governments in these eight states are uniquely qualified to work toward the purpose of the FOA: conducting an applied public health project to assess chemical exposure in Great Lakes populations and to advance public health actions to protect people in the Great Lakes basin.

This new project is a continuation of two previous ATSDR-funded projects. In 2010, ATSDR announced CDC-RFA-TS10-1001 and funded three state health departments in New York, Minnesota, and Michigan to conduct biomonitoring of susceptible populations in the Great Lakes states. In 2013, ATSDR announced CDC-RFA-TS13-1302 and funded New York to conduct an additional study in a new area of concern that was not studies in the 2010 program. The same eligibility criteria for this FOA have been previously requested and approved for CDC-RFA-TS10-1001 and CDC-RFA-TS13-1302.

If an application is non-responsive to the special eligibility requirements listed in this section, it will not receive further review.

The award ceiling for this FOA is $895,000. CDC will consider any application requesting an award higher than this amount as non- responsive and it will receive no further review. If a pre-application is required, then specify here and include it in the special eligibility requirements section. (http:// www.hhs.gov/ asfr/ ogapa/ aboutog/ hhsgps107.pdf)

3. Justification for Less than Maximum Competition

Eligible primary applicants for this FOA are limited to state, local and tribal governments in eight states (Illinois, Indiana, New York, Ohio, Pennsylvania, Michigan, Minnesota, and Wisconsin), and their Bona Fide Agents. Health departments in state, local and tribal governments in these eight states are uniquely qualified to work toward the purpose of the FOA: conducting an applied public health project to assess chemical exposure in Great Lakes populations and to advance public health actions to protect people in the Great Lakes basin. Annex 2 of the Great Lakes Water Quality Agreement (1987) requires the eight Great Lakes state governments to develop and implement Lakeside Management Plans for the lake waters and Remedial Action Plans for areas of concerns. State and local health departments and tribal entities are responsible for protecting the public health within their jurisdiction, and have jurisdiction over the public health issues encountered in their geographic area. Therefore, state, local, and tribal health departments in the eight Great Lakes states are the only entities that can collect information to make data-driven decisions on how to protection people's health in the Great Lakes basin. Some state health departments and/or tribal entities may not have all of the technical expertise to conduct a biomonitoring project on this scale. Hence, this cooperative agreement allows for and encourages eligible applicants to partner with other organizations, including universities, non-profit and for-profit organizations, and faith-based organizations, to carry out all planned activities. Governmental, territorial, and tribal entities outside of the Great Lakes region are not eligible to conduct this work, because they do not have purview to make decisions regarding impacted Great Lakes populations that are not within their jurisdiction. No business, university, or organization would be able to lead collaborative efforts to conduct such an applied public health program and develop/advance public health actions to protect population at large in the Great Lakes basin.

This new project is a continuation of two previous ATSDR-funded projects. In 2010, ATSDR announced CDC-RFA-TS10-1001 and funded three state health departments in New York, Minnesota, and Michigan to conduct biomonitoring of susceptible populations in the Great Lakes states. In 2013, ATSDR announced CDC-RFA-TS13-1302 and funded New York to conduct an additional study in a new area of concern that was not studies in the 2010 program. The same eligibility criteria for this FOA have been previously requested and approved for CDC-RFA-TS10-1001 and CDC-RFA-TS13-1302.

If this limited eligibility justification is not approved, applicants who are not responsible for, or authorized to, implement public health actions in the Great Lakes area would be able to apply for this cooperative agreement. If selected for award, an applicant like this would not be able to fully carry out the full range of project activities on collecting information and making data-driven decisions to protect people's health in the Great Lakes basin. If this FOA is not approved, the health departments in the Great Lakes state and tribal governments would not have such a funding opportunity specifically aimed to collect valuable data on body burden contaminants in susceptible Great Lakes populations, use the data to develop and implement public health actions and safeguard the health of the people in the Great Lakes basin.

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement: No

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this FOA exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Required Registrations

Additional materials that may be helpful to applicants: http://www.cdc.gov/od/pgo/funding/docs/Financial ReferenceGuide.pdf.

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.
a. Data Universal Numbering System: All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.
The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http:// fedgov.dnb. com/webform/ displayHomePage.do. The DUNS number will be provided at no charge.
If funds are awarded to an applicant organization that includes sub-awardees, those sub-awardees must provide their DUNS numbers before accepting any funds.
b. System for Award Management (SAM): The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as an awardee. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at ***www.SAM.gov***.
c. Grants.gov: The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Get Registered" option at www.grants.gov.
All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	Data Universal Number System (DUNS)	1. Click on http:// fedgov.dnb.com/ webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http:// fedgov.dnb. com/ webform) or call 1-866-705-5711
2	System for Award Management (SAM) formerly Central Contractor Registration (CRR)	1. Retrieve organizations DUNS number 2. Go to www.sam.gov and designate an E-Biz POC (note CCR username will not not work in SAM and you will need to have an active SAM account before you can register on	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/fsd -gov/home.do Calls: 866-606-8220

		grants.gov)		
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	Register early! Log into grants.gov and check AOR status until it shows you have been approved

2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this funding opportunity at www.grants.gov. If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC OGS staff at 770-488-2700 or e-mail OGS ogstims@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY 1-888-232-6348.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the FOA, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.

a. Letter of Intent Deadline (must be emailed or postmarked by)

N/A

b. Application Deadline

Due Date for Applications: **03/31/2016**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.

Date for Informational Conference Call: 03/10/2016

An informational conference call will be held on Thursday, March 10, 2016, at 2:30PM (Eastern).

Call in number: 1-866-692-3158; Passcode: 81253953

The questions and answers from the call will be published on Grants.gov (as an amendment to this FOA) approximately a week after the call.

5. CDC Assurances and Certifications

All applicants are required to sign and submit "Assurances and Certifications" documents indicated at http://wwwn.cdc.gov/ grantassurances/ (S(mj444mxct51lnrv1hljjjmaa)) /Homepage.aspx.
Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications with each application submission, name the file "Assurances and Certifications" and upload it as a PDF file with atwww.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http://wwwn.cdc.gov/ grantassurances/ (S(mj444mxct51lnrv1hljjjmaa))/ Homepage.aspx

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

LOI is not requested or required as part of the application for this FOA.

8. Table of Contents

(No page limit and not included in Project Narrative limit): The applicant must provide, as a separate attachment, the "Table of Contents" for the entire submission package.
Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" atwww.grants.gov.

9. Project Abstract Summary

(Maximum 1 page)
A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box atwww.grants.gov.

10. Project Narrative

(Maximum of 20 pages, single spaced, Calibri 12 point, 1-inch margins, number all pages. Content beyond 20 pages will not be considered. The 20 page limit includes the work plan. For a multi-component FOA, maximum page limit is 25.)

The Project Narrative must include all of the bolded headings shown in this section. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire project period as identified in the CDC Project Description section. Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at www.grants.gov.

a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the problem as described in the CDC Background section.

ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the project period. Outcomes are the results that the program intends to achieve. All outcomes must indicate the intended direction of change (e.g., increase, decrease, maintain). (See the logic model in the Approach section of the CDC Project Description.)

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the project period outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan, how these strategies will be evaluated over the course of the project period. (See CDC Project Description: Strategies and Activities section.)

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC.

Applicants must file the MOU or MOA, as appropriate, name the file "MOUs/MOAs", and upload it as a PDF file at www.grants.gov.

Applicants must file letters of support, as appropriate, name the file "Letters of Support", and upload it as a PDF file at www.grants.gov.

Letters of support need to be provided for collaborations with intrastate agencies, tribes, universities, and public or nonprofit private agencies, institutions, organizations in your geographic region and others deemed appropriate.

2. Target Populations

Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. Refer back to the Target Population section in the CDC Project Description.

a. **Inclusion**: N/A

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the awardee will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this FOA. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. See Section E (pages 4 and 5) at http://www. hhs.gov/ asfr/ogapa/ aboutog/ogpoe/ gpd2-02.pdf. For further information about CDC's requirements under PRA see http://www.hhs.gov/ ocio/policy/collection/.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Awardees will be required to submit a more detailed Evaluation and Performance Measurement plan within the first 6 months of award, as described in the Reporting Section of this FOA.

Awardees will be required to submit a more detailed evaluation and performance measurement plan within the first 6 months of the project, as outlined in the reporting section of the FOA.

Awardees will be required to submit a more detailed evaluation and performance measurement plan within the first 6 months of the project, as outlined in the reporting section of the FOA.

d. Organizational Capacity of Applicants to Implement the Approach

Applicant must address the organizational capacity requirements as described in the CDC Project Description.

Applicants must name this file "CVs/Resumes" or "Organizational Charts" and upload it at www.grants.gov.

11. Work Plan

Included in the Project Narrative Page limits:

Multiple components: maximum of 15 pages for the base and up to 4 additional pages per component)
Single component: maximum of 20 pages)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the awardee plans to carry out achieving the project period outcomes, strategies and activities, evaluation and performance measurement.

12. Budget Narrative

Applicants must submit an itemized budget narrative, which may be scored as part of the Organizational Capacity of Awardees to Implement the Approach. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

Indirect costs will not be reimbursed under grants to foreign organizations, international organizations, and foreign components of grants to domestic organizations (does not affect indirect cost reimbursement to the domestic entity for domestic activities).
For guidance on completing a detailed budget, see Budget Preparation Guidelines at:http:// www.cdc.gov /grants /interested in applying /application resources.html . If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this FOA to meet national standards or seek health department accreditation through the Public Health Accreditation Board (seehttp://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the FOA. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.
Applicants must name this file "Budget Narrative" and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Grantees under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it atwww.grants.gov.

Applicants must provide an overall budget for the project period and an individual budget for each year as a separate attachment at www.grants.gov.

13. Tobacco and Nutrition Policies

Awardees are encouraged to implement tobacco and nutrition policies.

Unless otherwise explicitly permitted under the terms of a specific CDC award, no funds associated with this FOA may be used to implement the optional policies, and no applicants will be evaluated or scored on whether they choose to implement these optional policies.

CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following optional recommended evidence-based tobacco and nutrition policies within their own organizations. The tobacco policies build upon the current federal commitment to reduce exposure to secondhand smoke, specifically Pro-Children Act of 2001, 20 U.S.C. Sections 7181-7184, that prohibits smoking in certain facilities that receive federal funds in which education, library, day care, health care,or early childhood development services are provided to children.
Tobacco Policies:

1. Tobacco-free indoors: Use of any tobacco products (including smokeless tobacco) or electronic cigarettes is not allowed in any indoor facilities under the control of the awardee.
2. Tobacco-free indoors and in adjacent outdoor areas: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the awardee.
3. Tobacco-free campus: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities or anywhere on grounds or in outdoor space under the control of the awardee.

Nutrition Policies:

1. Healthy food-service guidelines must, at a minimum, align with HHS and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations. These guidelines apply to cafeterias, snack bars, and vending machines in any facility under the control of the awardee and in accordance with contractual obligations for these services (seehttp:// www.gsa.gov/ graphics/ pbs/ Guidelines_for__Federal__Concessions_and_Vending__Operations.pdf).
2. Resources that provide guidance for healthy eating and tobacco-free workplaces are:

http://www.cdc.gov/ nccdphp/dnpao/hwi/ toolkits/ tobacco/index.htm
http://www. thecommunityguide.org/ tobacco/index.html
http:// www.cdc.gov /obesity /strategies /food-serv-guide.html

14. Health Insurance Marketplaces

A healthier country is one in which Americans are able to access the care they need to prevent the onset of disease and manage disease when it is present. The Affordable Care Act, the health care law of 2010, creates new Health Insurance Marketplaces, also known as Exchanges, to offer millions of Americans affordable health insurance coverage. In addition, the law helps make prevention affordable and accessible for Americans by requiring health plans to cover certain recommended preventive services without cost sharing. Outreach efforts will help families and communities understand these new options and provide eligible individuals the assistance they need to secure and retain coverage as smoothly as possible. For more information on the Marketplaces and the health care law, visitwww.HealthCare.gov.

15. Intergovernmental Review

Executive Order 12372 does not apply to this program.

16. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations (CFR) section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

16a. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Grantees will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide grantees and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 2 CFR 200 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

16b. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.
The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

16c. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.
B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) ("United States foreign assistance funds"). Outlined below are the specifics of this requirement:
1) Annual Report: The grantee must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the grantee did not pay any taxes during the reporting period.]
2) Quarterly Report: The grantee must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.
3) Terms: For purposes of this clause: "Commodity" means any material, article, supplies, goods, or equipment; "Foreign government" includes any foreign government entity; "Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.
4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.
5) Contents of Reports: The reports must contain: a. grantee name; b. contact name with phone, fax, and e-mail; c. agreement number(s) if reporting by agreement(s); d. reporting period; e. amount of foreign taxes assessed by each foreign government; f. amount of any foreign taxes reimbursed by each foreign government; g. amount of foreign taxes unreimbursed by each foreign government.
6) Subagreements. The grantee must include this reporting requirement in all applicable subgrants and other subagreements.

17. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Awardees may not use funds for research.
- Awardees may not use funds for clinical care except as allowed by law.
- Awardees may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, awardees may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the awardee.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
  - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
  - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See Additional Requirement (AR) 12 for detailed guidance on this prohibition and additional guidance on lobbying for CDC awardees.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

Research for this purpose is defined at http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

18. Other Submission Requirements

a. Electronic Submission: Applications must be submitted electronically at www.grants.gov. The application package can be downloaded at www.grants.gov. Applicants can complete the application package off-line and submit the application by uploading it at www.grants.gov. All application attachments must be submitted using a PDF file format. Directions for creating PDF files can be found at www.grants.gov. File formats other than PDF may not be readable by OGS Technical Information Management Section (TIMS) staff.

Applications must be submitted electronically by using the forms and instructions posted for this funding opportunity at www.grants.gov.

If Internet access is not available or if the forms cannot be accessed online, applicants may contact the OGS TIMS staff at 770- 488-2700 or by e-mail at pgotim@cdc.gov, Monday through Friday, 7:30 a.m.–4:30 p.m., except federal holidays. Electronic applications will be considered successful if they are available to OGS TIMS staff for processing from www.grants.gov on the deadline date.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the FOA. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Grants.gov Online User Guide.
http://www.grants.gov/help/html/help/index.htm?callingApp=custom#t=Get_Started%2FGet_Started.htm

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@www.grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.
e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@www.grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis.
An applicant's request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered.
   If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases.

a. Phase I Review

All applications will be reviewed initially for completeness by CDC PGO staff and will be reviewed jointly for eligibility by the CDC ATSDR and PGO. Incomplete applications and applications that do not meet the eligibility criteria will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility or published submission requirements.

b. Phase II Review
A review panel will evaluate complete, eligible applications in accordance with the criteria below.
i. Approach ii. Evaluation and Performance Measurement iii. Applicant's Organizational Capacity to Implement the Approach

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

Approach	Maximum Points: 50

a. Identify target populations (12 pts)

The extent to which the applicant describes:

• environmental exposure concerns in their jurisdiction presented by Great Lakes pollutants (2 pts)

• past and current activities related to identification, control and prevention of potential adverse human health effects associated with Great Lakes pollutants (2 pts)

• target population(s) with regard to potential exposure risk, social economic status, geographic location, and other relevant information and justification as deemed necessary (4 pts)

• past and current studies of the target populations in the state related to Great Lakes pollutants (2 pts)

• a sound justification for a biomonitoring program as related to the "Purpose" section of this announcement (2 pts)

b. Biomonitoring implementation plan, capability, and timeline (25 pts)

The extent to which the applicant describes:

• a list of environmental chemicals to be measured in the program, along with justifications as deemed necessary (3 pts)

• development of the study protocol, questionnaire, sampling strategy, data collection system, etc. in collaboration with ATSDR (2 pts)

• designated laboratory's biomonitoring capabilities, past and current biomonitoring activities, CLIA certification, and participation in an external proficiency testing program(s) (5 pts)

• a work plan that elaborates on each of the awardee strategies and activities that are realistic, achievable and appropriate to accomplish the outcomes listed in the Project Description and logic model (10 pts)

• a projected timetable that displays appropriate and realistic dates for the accomplishment of specific biomonitoring project activities (5 pts)

c. Written assessment and data utilization plan (5 pts)

The extent to which the applicant describes:

• data analysis plan to assess human exposure to environmental chemicals in the target population (1 pt)

• a plan to produce and disseminate a written assessment of the biomonitoring study results (1 pt)

• a relevant and realistic plan to use the biomonitoring data to identify, control and prevent potential adverse exposures associated with Great Lakes pollutants (3 pts)

d. Communication and outreach (8 pts)

The extent to which the applicant describes:

• a communication and outreach plan to communicate the biomonitoring study findings to the target or at risk populations, key audiences and stakeholder, and general populations (4 pts)

• planned outreach activities on the risk and benefit of fish consumption during both data collection and result dissemination phases, through multiple channels, including but not limited to website, mail-outs, community meetings, and health fairs. (4 pts)

Evaluation and Performance Measurement	Maximum Points: 25

The extent to which the applicant describes:
• an evaluation and performance measurement plan based on the logic model and the CDC evaluation and performance measurement strategy (5 pts)

• an evaluation and performance measurement plan that address key evaluation questions and metrics of performance throughout the project period (5 pts)

• a reasonable plan to evaluate progress in attaining program goals (5 pts)

• a plan to continuously measure and improve performance for the proposed timeline (5 pts)

• how performance measurement and evaluation findings will be reported, and used to demonstrate the outcomes of the FOA and for continuous program quality improvement. (5 pts)

Applicants Organizational Capacity to Implement the Approach	Maximum Points: 25

The extent to which the applicant describes and demonstrates organizational capacity with proposed staffing, organizational structure, staff experience and expertise to carry out all program activities, including scientific and technical aspects, administrative support, project and financial management, collaboration and coordination.

The extent to which the applicant:

• provides a staffing plan and an organizational chart, including proposed staffing, with roles clearly stated (4 pts)

• provides experience, background, and curricula vitae for key staff to indicate ability to carry out the technical and scientific aspects of the program (3 pts)

• demonstrates the principal investigator's and proposed project manager's experience and background to indicate ability to plan, organize, secure and manage resources to successfully accomplish program activities (3 pts)

• describes a project management structure, administrative and financial support that will be sufficient to achieve the project outcomes (3 pts)

• identifies training needs or plan (2 pts)

• describes a current or proposed advisory committee (3 pts)

• describes past, current, and proposed activities and collaborations with relevant organizations and agencies within the state and with other states or national,

international organizations related to identification, control and prevention of potential adverse exposures associated with Great Lakes pollutants (3 pts)

• provides letters of support, MOU, or MOA from relevant organizations and agencies (4 pts).

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

c. Phase III Review

All scored applications will be arranged in rank order. In addition, the following factors may affect the funding decision. CDC will justify any decision to fund out of rank order based upon the following:

Preference may be given to applications targeting subpopulations which have evidence of higher exposure risk and/or potential human health effects. Evaluation of exposure risk is based on evidence of exposure to required and optional analytes listed in the awardee activities of this FOA. Exposure may be through recreational water use, air, soil, and food consumption in the subpopulations(s) targeted as part of the proposed project plan, with particular emphasis on existing evidence for human health effects from exposure through food, especially consumption of Great Lakes fish.

Preference may be given to applications to ensure that different geographic areas or specific subpopulations are represented. The intent of the Biomonitoring of Great Lakes Populations program is to fund programs in as many of the eight Great Lakes states and regions as possible. Funding out of rank order may be necessary to exclude multiple proposals that target subpopulations in the same geographic area.

2. Announcement and Anticipated Award Dates

Awards will be announced electronically or by mail. Anticipated date of award is July 1, 2016.

F. Award Administration Information

1. Award Notices

Awardees will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the awardee and CDC. The NOA will be signed by an authorized GMO and emailed to the Awardee Business Officer listed in application and the Program Director. Any applicant awarded funds in response to this FOA will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.
Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt or by U.S. mail.

2. Administrative and National Policy Requirements

Awardees must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available at http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-17.

The HHS Grants Policy Statement is available at http:// www.hhs.gov /asfr /ogapa /aboutog /hhsgps107.pdf.

The following Administrative Requirements (AR) apply to this project: Generally applicable ARs:

- AR-9: Paperwork Reduction Act http://www.hhs.gov/ocio/policy/collection/infocollectfaq.html
- AR-10: Smoke-Free Workplace
- AR-11: Healthy People 2020
- AR-12: Lobbying Restrictions
- AR-14: Accounting System Requirements
- AR-21: Small, Minority, And Women-owned Business
- AR-24: Health Insurance Portability and Accountability Act
- AR-25: Release and Sharing of Data
- AR-26: National Historic Preservation Act of 1966
- AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving,” October 1, 2009
- AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- AR-33: Plain Writing Act of 2010
- AR-34: Patient Protection and Affordable Care Act (e.g., a tobacco-free campus policy and a lactation policy consistent with S4207)

ARs applicable to awards by ATSDR:

- AR-19: Third Party Agreements – ATSDR

ARs applicable to awards related to conferences:

- AR-27: Conference Disclaimer and Use of Logos

Organization-specific ARs:

- AR-8: Public Health System Reporting (community-based, nongovernment organizations)

For more information on the CFR visit http://www.ecfr.gov/cgi-bin/ECFR?page=browse.

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that awardees encounter throughout the project period. Also, reporting is a requirement for awardees who want to apply for yearly continuation of funding. Reporting helps CDC and awardees because it:

- Helps target support to awardees;
- Provides CDC with periodic data to monitor awardee progress toward meeting the FOA outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the project period and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the FOA.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the "Agency Contacts" section of the FOA copying the CDC Project Officer.

Report	When?	Required?
Awardee Evaluation and Performance Measurement Plan	6 months into award	Yes
Annual Performance Report (APR)	No later than120 days before end of budget period. Serves as yearly continuation application.	Yes
Data on Performance Measures	CDC program determines. Only if program wants more frequent performance measure reporting than annually in APR.	No
Federal Financial Reporting Forms	90 days after end of calendar quarter in which budget period ends	Yes
Final Performance and Financial Report	90 days after end of project period.	Yes

a. Awardee Evaluation and Performance Measurement Plan (required)
With support from CDC, awardees must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; awardees must submit the plan 6 months into the award.

This plan should provide additional detail on the following:

- The frequency that evaluation and performance data are to be collected.
- How data will be reported.
- How evaluation findings will be used for continuous quality and program improvement.
- How evaluation and performance measurement will yield findings to demonstrate the value of the FOA (e.g., improved public health outcomes, effectiveness of FOA, cost-effectiveness or cost benefit).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

b. Annual Performance Report (APR) (required)
The awardee must submit the APR via www.grants.gov 120 days before the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but weblinks are allowed.
This report must include the following:

- **Performance Measures:** Awardees must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Awardees must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Awardees must update work plan each budget period to reflect any changes in project period outcomes, activities, timeline, etc.
- **Successes**
  - Awardees must report progress on completing activities and progress towards achieving the project period outcomes described in the logic model and work plan.
  - Awardees must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
  - Awardees must describe success stories.
- **Challenges**
  - Awardees must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the project period outcomes.
  - Awardees must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Awardees**
  - Awardees must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving project period outcomes.
- **Administrative Reporting** (No page limit)
  - SF-424A Budget Information-Non-Construction Programs.
  - Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
  - Indirect Cost Rate Agreement.

For year 2 and beyond of the award awardees may request that as much as 75% of their estimated unobligated funds be carried over into the next budget period.

The carryover request must:
- Express a bona fide need for permission to use an unobligated balance;
- Include a signed, dated, and accurate Federal Financial Report (FFR) for the budget period from which funds will be transferred (as much as 75% of unobligated balances);
- and Include a list of proposed activities, an itemized budget, and a narrative justification for those activities.

The awardee must submit the Annual Performance Report via www.grants.gov 120 days before the end of the budget period.

c. Performance Measure Reporting (optional)
CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for awardees at the beginning of the award period.

A required data field for the Performance Measure Report is the estimated number of people provided information on the risks and benefits of Great Lakes fish consumption through various communication and outreach channels.

d. Federal Financial Reporting (FFR) (required)
The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the calendar quarter in which the budget period ends. The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, awardees are required to submit a letter of explanation to PGO and include the date by which the Grants Officer will receive information.

e. Final Performance and Financial Report (required)
This report is due 90 days after the end of the project period. CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire project period and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Awardees must report final performance data for all process and outcome performance measures.
- Evaluation Results – Awardees must report final evaluation results for the project period for any evaluations conducted.
- Impact/Results/Success Stories – Awardees must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

Awardees must email the report to the CDC PO and the GMS listed in the "Agency Contacts" section of the FOA.

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)
Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web sitehttp://www.USASpending.gov.
Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over $25,000.
For the full text of the requirements under the FFATA and HHS guidelines, go to:

- https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf,
- https://www. fsrs.gov/documents /ffata_legislation_ 110_252.pdf
- http://www.hhs.gov /asfr/ogapa/aboutog /Grants%20Management %20Information/ ffata_guidelines.html.

G. Agency Contacts

CDC encourages inquiries concerning this FOA.

Program Office Contact
For programmatic technical assistance, contact:

Zheng Li, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE, MS-F57
Atlanta, GA 30341
Telephone: (770) 488-7940
Email: ZJLi@cdc.gov

Grants Management Office Information
For **financial, awards management, or budget assistance,** contact:

Jon Messick, Grants Management Specialist
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS E-01
Atlanta, GA 30341
Telephone: (770) 488-1005
Email: JMessick@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.
Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

For all other **submission** questions, contact:
Technical Information Management Section
Department of Health and Human Services
CDC Office of Financial Resources
Office of Grants Services
2920 Brandywine Road, MS E-14
Atlanta, GA 30341
Telephone: 770-488-2700
E-mail: ogstims@cdc.gov

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348.

H. Other Information

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- CDC Assurances and Certifications
- Table of Contents for Entire Submission

Optional attachments, as determined by CDC programs:

- Resumes / CVs
- Letters of Support
- Organization Charts
- Non-profit organization IRS status forms, if applicable
- Indirect Cost Rate, if applicable
- Memorandum of Agreement (MOA)
- Memorandum of Understanding (MOU)
- Bona Fide Agent status documentation, if applicable

References can be uploaded as an optional attachment in the "Other" category.

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 74 and Part 92 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the FOA; awardees must comply with the ARs listed in the FOA. To view brief descriptions of relevant provisions, see http://www.cdc.gov/grants/additional requirements/index.html. Note that 2 CFR 200 will supersede the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the project period.Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

Catalog of Federal Domestic Assistance (CFDA): A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

CFDA Number: A unique number assigned to each program and FOA throughout its lifecycle that enables data and funding tracking and transparency.

CDC Assurances and Certifications: Standard government-wide grant application forms.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established project period (i.e., extends the “life” of the award).

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the awardees. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the awardee.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA.http:// www.cdc.gov /grants /additionalrequirements /index.html.

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at http://fedgov.dnb.com/ webform/displayHomePage.do.

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The FOA evaluation plan is used to describe how the awardee and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Healthy People 2020: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list:http://www.whitehouse.gov/omb/ grants_spoc/.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The results of program operations or activites; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Plain Writing Act of 2010: Requires federal agencies to communicate with the public in plain language to make information more accessible and understandable by intended users, especially people with limited health literacy skills or limited English proficiency. The Plain Writing Act is available at www.plainlanguage.gov.

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Program Official: Person responsible for developing the FOA; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Project Period Outcome: An outcome that will occur by the end of the FOA's funding period.

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditationhttp://www.phaboard.org.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of project period outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

QUESTIONS AND ANSWERS FROM 12/1/2015 CONFERENCE CALL

Please note that the information below does not represent an actual transcript of the conversation. The information has been edited for both accuracy and clarity.

1. Does the study area have to be in the portion of the state that has a watershed that drains into the Great Lakes or just be in a Great Lake state?

Response: Please see the FOA, sub-section "Target Populations", for the specification on the target populations: "The target populations include those with potential high exposure to contaminants from Great Lakes fish consumption (e.g. subsistence anglers who tend to be low-income minority), and/or those who are susceptible to the potential health effect of such chemical exposure (e.g. children, adolescents, women of child-bearing age, and elderly). A subpopulation identified to be at increased risk of exposure to Great Lakes contaminants include racial or ethnic groups with traditional fishing and fish consumption customs, sport anglers and urban poor. Applicants are required to use data, such as social determinant data to identify a subpopulation within their jurisdiction that is at increased risk of exposure to Great Lakes contaminants. The target population must be large enough to recruit a target sample of at least 350 people. The exposure pathway is primarily consumption of locally caught fish, but lifestyles associated with contaminated waters/sediments/soil will also be considered."

As indicated in the "Target Populations" sub-section, the study area will need to be near a contaminated water shed connected to the Great Lakes.

2. Does the program need to be tied into Areas of Concerns or AOCs?

Response: As indicated in the "Target Populations" sub-section, the study areas will need to be near a contaminated water shed connected to the Great Lakes, but do not need to be in/near an Area of Concern or AOC.

3. Would it be possible to bio-monitor two to three susceptible populations with this grant funding?

Response: The FOA allows for multiple target populations; however, at least one target population must fulfill the required minimum samples size (350 participants). In the previous cooperative agreement programs, some grantees included two target populations, one being the main target population with the required number of participants, and another population with a smaller sample size.

4. Is ATSDR more interested in a general population approach where the at-risk population is those who reside in the AOC area? Or, do you want applicants to specifically target those who eat fish caught from an AOC water body or a Great Lake and are a vulnerable population such as women of child bearing age, or low income, etc.?

Response: As indicated in sub-section "Target Populations", the program is intended to target populations who eat fish caught from contaminated water body connected to Great Lakes, and/or those who are susceptible to the potential health effect of such exposure. The study areas do not need to be in/near an Area of Concern (AOC).

5. Is ATSDR interested in, or OK, with site specific sampling in addition to human biomonitoring? For example, could we propose to conduct dust sampling in a small subset of houses that back up to AOC water bodies to assess if that is also a route of exposure to contaminants?

Response: Please see the FOA, sub-section "Strategies and Activities", for all activities pertaining to this FOA. Additional site-specific sampling beyond

biomonitoring, such as dust sampling, is outside of the scope of this FOA and would not be supported by the funding from this program. In addition, please note that this FOA is for a non-research cooperative agreement, and a web link for the definition of research vs. non-research is given in the FOA, under the sub-section "Funding Restrictions".

6. Under "Funding Restrictions", it is stated that "Awardees may not use funds for research". Can you elaborate on the non-research requirement? Can the program be tied to other existing research activities?

Response: CDC/ATSDR has specific definitions on "research" and "non-research", as given on the website http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf (the web link is also given under "Funding Restriction" in the FOA). This FOA is to fund a new non-research cooperative agreement program, and it cannot be tied to other existing research activities.

7. Regarding eligible applicants, can an academic university partner with a county health department to apply for this FOA?

Response: As stated in the FOA, "Eligible primary applicants for this FOA are limited to state, local and tribal governments in eight states (Illinois, Indiana, New York, Ohio, Pennsylvania, Michigan, Minnesota, and Wisconsin) and their Bona Fide Agents." Therefore, a county health department/government in one of the eight Great Lakes states is eligible to apply for the FOA as a primary applicant. An academic university is not eligible to be a primary applicant but could partner with an eligible applicant. This cooperative agreement encourages eligible applicants to partner with other organizations, including universities, non-profit and for-profit organizations, and faith-based organizations, to carry out all planned activities.

8. The state public health laboratory in our state has limited lab capacity and cannot carry out all analyses on required analytes. Can we get assistance from other laboratories, such as CDC's Environmental Health Laboratory?

Response: It is the applicant's responsibility to designate a lab(s) to do the analytical work in the proposal. If your state lab does not have the capability, please identify a lab(s) with the necessary capability in the proposal, and include letters of support, as appropriate, as part of the application package. Previous program awardees have partnered with other state labs, private labs, and the CDC Environmental Health Laboratory. If the grantee requests technical assistance from the CDC Environmental Health Laboratory with the analysis of any of the analytes specified in the FOA, we will help coordinate discussions between the grantee and the CDC Environmental Health Lab post-award. The grantee will need to budget and pay for any expenses incurred for the cost of analysis including sample shipment.

9. Can a commercial laboratory with biomonitoring capability apply for this FOA?

Response: A commercial laboratory is not eligible to apply for this FOA. A commercial laboratory can serve as a partner to an eligible primary applicant.

10. Is it permissible to partner with a health department in another Great Lakes state?

Response: Yes. In the previous cooperative agreement programs, some awardees (state health departments) have partnered with collaborators outside of their state.

11. If we would use the OMB-approved questionnaires, would the program still need to go through OMB-approval?

Response: This is a new cooperative agreement program. OMB-approval will need to be obtained prior to any program-related data collection activities, regardless of whether the questionnaires were previously approved by OMB.

12. Can we have a copy of OMB-approved questionnaires from previous cooperative agreement programs?

Response: Please visit the OMB website for the complete OMB-approved packages, including questionnaires, for the previous cooperative agreement programs.

• CDC-RFA-TS10-1001, Biomonitoring of Great Lakes Populations Program, http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0923-0044

• CDC-RFA-TS13-1302, Biomonitoring of Great Lakes Populations Program II, http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201411-0923-001

13. Is CLIA required for all laboratory analysis?

Response: CLIA-certification is required for the designated laboratory(s) that will measure the required analytes, but not required for the lab(s) that will measure additional analytes that grantees propose. In addition, the designated lab(s) need to participate in an external proficiency testing program(s) for the required analytes.

QUESTIONS AND ANSWERS FROM 3/10/2016 CONFERENCE CALL

Please note that the information below does not represent an actual transcript of the conversation. The information has been edited for both accuracy and clarity.

1. Why was the FOA re-opened and how was the application due date determined?

RESPONSE: The FOA was first published in Oct 2015. The FOA was open for more than three months, and the application due date was Feb 1, 2016. Among the applications that we received, none passed Phase I Review by the Office of Grants Services (OGS) and technical review by the program. Therefore, under the OGS's guidance, the FOA was re-opened on Feb 26, 2016, and the application deadline for the re-opened FOA was set for March 31, 2016.

2. What are the budget requirements?

RESPONSE: As stated in the FOA, the award ceiling is $895K per budget period and CDC will consider any application requesting an award higher than this requirement as non-responsive and the application will not receive further review.

Please also consider the additional award information in the FOA as guidance when developing the budget for your application, "ATSDR anticipates funding one award at up to $895,000 for FY2016 and up to $705,000 for FY2017. The total project period is two years. The total funding level for the project period (FY2016 and FY2017) is approximately $1,600,000." (page 16 of 30)

3. What are the requirements on the study area?

RESPONSE: As stated in the FOA, the study area for this program must be near a contaminated watershed that is connected to the Great Lakes, and, has not been studied in previous TS10-1001 and TS13-1302 programs. The Relevant Work section lists the specific geographic areas that were studied in previous programs. Proposing a study in a geographic area that was already included in previous programs will be deemed non-responsive to a key technical requirement during its objective/technical review. Additionally, the study area needs to have documented contaminations, but does not need to be a Great Lakes Area of Concerns (AOC).

4. Where can the applicant include a list of references with their proposal? Can this be submitted as an Optional Attachment?

RESPONSE: A list of references does not have to be included in the Project Narrative and may instead be uploaded as an Optional Attachment in the "Other" category.

5. Can funding that was unused in the first budget period be carried over into the second year?

RESPONSE: As long as there is available funding and the awardee provides legitimate justification, unobligated funds from the first budget period can be carried over to the second year. Please see "Annual Performance Report (APR)" Section (Page 25 of 30) for information on carry-over request.

6. How was the time period determined between the application due date and the award date?

RESPONSE: The application due date for this FOA is March 31, 2016. The anticipated award date is July 1, 2016. The actual award date will depend on the application review and selection process, and the award administration process. The actual award date could be earlier or later than the anticipated award date.