

Aerosols from harmful algal blooms: Exposures and health effects in highly exposed populations

OMB Control No. 0920-1316

Non-substantive change

Supporting Statement Part A –
Justification

Lorraine Backer
Senior Epidemiologist
Division of Environmental Health Science and Practice
Centers for Disease Control and Prevention
Phone: 770-488-3426
Email: lfb9@cdc.gov
Fax: 770-488-3410

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Goals of the study: Human exposures to HAB toxins (harmful algal blooms, or HABS, include marine microalgae; marine macroalgae, such as seaweeds; and cyanobacteria, also called blue-green algae) have been reported to produce a variety of health effects, including respiratory irritation and liver and kidney damage. The goal of this study is to conduct exploratory analyses of the relationships between biomonitoring data, environmental data, and symptom reporting. We expect this research to be hypothesis generating and not necessarily generalizable to participants with similar exposures in the same population or to the public more generally.

Intended use of the resulting data: The data will add to the scant existing scientific literature on the human health impacts of exposure to HAB toxins.

Methods to be used to collect data: The methods used to collect data include telephone screening/baseline surveys to determine eligibility/collect baseline data. Respondents will complete symptom surveys with study staff, who will enter responses directly into the Center for Disease Control and Prevention's (CDC's) REDCap system. Using standard protocols, study staff will collect lung function test data and upload the resulting data into REDCap. Using standard protocols, study respondents will provide nasal swabs to analyze for HAB toxins and urine specimens to analyze for HAB toxins and creatinine. A certified phlebotomist will collect blood samples to analyze for liver enzyme (for liver damage) and creatinine levels (for kidney damage). A contractor will collect ambient and personal air samples to analyze for HAB toxins and gases and vapors emitted by driving

A.1. Circumstances Making the Collection of Information Necessary

This is a new information collection request (ICR) from the National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC). This data collection is authorized by the Public Health Service Act §301 (241) (Attachment 1). NCEH requests 3 years of approval.

Background

Toxins produced by blooms of algae, cyanobacteria, and seaweed (herein called harmful algal blooms or HABS) are among the most potent natural chemicals. Exposure to these toxins can induce a wide variety of reported and documented effects in people and animals. Examples of published studies, including a brief summary of the findings that contribute to our knowledge of the public health impacts of HABS, and any noted study limitations are in Table 1. These studies demonstrate that people and animals are at risk for health effects from exposure to HABS, whether through eating contaminated food, drinking contaminated water, or inhaling contaminated aerosols. Although there is substantial published work describing the public health impacts from these blooms, unanswered questions remain, including quantitative assessments of exposure and characterization of the clinical presentations of illnesses associated with HAB exposures.

HABs and associated environmental impacts (e.g., geographic and temporal extent, composition, toxin production) are difficult, if not impossible to predict and track. Specifically, for the previously approved project, we were not able to align the physical occurrence of a specific type of HAB, a cyanobacterial bloom, of significant magnitude with government approvals and resource commitments. Therefore, we propose a non-substantive change to include aerosols from the next substantial HAB that occurs in Florida whether it comprises cyanobacteria, marine microalgae, or seaweed.

Table 1. Examples of published studies that inform the potential public health impacts of HABS.

Study Citation	Study methods	Summary of Public Health-related findings
Marine HABS		
Backer LC, Fleming LE, Rowan A, Cheng Y-S, Benson J, Pierce RH, Zaias J, Bean J, Bossart GD, Johnson D, Quimbo R, Baden DG. Recreational Exposure to Aerosolized Brevetoxins During Florida Red Tide Events. Harmful Algae. 2003;2:19-28.	Conducted pulmonary function tests (PFT), nasal swabs, and surveys before and after beach visits.	Lower respiratory symptoms (e.g., wheezing) were reported by 8% of unexposed (N=36), 11% of moderately exposed (N=53), and 28% of the highly exposed (N=40) groups. Found inflammatory response in 33% of those experiencing moderate or high exposure. There were no clinically significant changes in PFT

		results.
Backer LC, Kirkpatrick B, Fleming LE, Cheng YS, Pierce R, Bean JA, Clark R, Johnson D, Wanner A, Tamer R, Baden D. Occupational Exposure to Aerosolized Brevetoxins during Florida Red Tide Events: Impacts on a Healthy Worker Population. Environmental Health Perspectives. 2005;113-5:644-649.	Longitudinal study of full-time lifeguards on Florida beaches.	Found slight increase in some respiratory symptoms during exposure days.
Kirkpatrick B, Pierce R, Cheng YS, Henry MS, Blum P, Osborn S, Nierenberg K, Pederson BA, Fleming LE, Reich A, Naar J, Kirkpatrick G, Backer LC, Baden D. 2010 Inland transport of aerosolized Florida red tide toxins. Harmful Algae 9:186-189.	Examined air samples collected at various distances from the shore during red tide blooms.	Demonstrated movement of airborne brevetoxins inland for as much as 3 miles.
Kirkpatrick B, Fleming LE, Bean JA, Nierenberg K, Backer LC, Cheng YS, Pierce R, Reich A, Naar J, Wanner A, Abraham WM, Zhou Yue, Hollenbeck J, Baden DG. 2010. Aerosolized Red Tide Toxins (Brevetoxins) and Asthma: Continued health effects after 1 hour beach exposure. 2011. Harmful Algae 10:138-143.	Longitudinal study of respiratory effects from red tides on people with asthma. Collected biomonitoring, health, and environmental data.	Showed lasting effects from inhaled brevetoxins on people with asthma
Cyanobacterial HABs		
Falconer IR, Beresford AM, Runnegar MTC. Evidence of liver damage by toxin from a bloom of the blue-green alga, Microcystis aeruginosa. Med. J. Aust. 1983;1:511-514.	Used hospital records of liver function test results when the water supply was free of blooms and when there was a documented cyanobacterial bloom.	Found higher levels of liver enzymes during a time when the water supply was contaminated with a cyanobacterial bloom
Phillip R. Health risks associated with recreational exposure to blue-green algae (cyanobacteria) when dinghy sailing. Health Hyg. 1992;13:110-114.	Collected health symptom data from people sailing in small boats.	Reported health symptoms for dinghy sailors similar whether or not they were exposed to cyanobacterial blooms.
Carmichael WW, Falconer IR. Diseases related to freshwater bluegreen algal toxins, and control measures. In: Falconer, I.R. (Ed.), Algal Toxins in Seafood and Drinking Water.	Summarized health effects from exposure to cyanobacterial toxins	Summary of possible health effects.

Academic Press, London, 1993. pp. 187-209.		
Gilroy DJ, Kauffman KW, Hall, RA, Huang X, Chu FS. Assessing potential health risks from microcystin toxins in blue-green algae dietary supplements. <i>Environ. Health Perspect.</i> 2000;5:435-439.	Examined blue-green dietary supplements from a bloom contaminated with <i>Microcystis</i> species.	Found that blue-green dietary supplements were contaminated with microcystins when the harvest was contaminated with <i>Microcystis</i> species.
De Magalhaes VF, Soares RM, Azevedo SMFO. Microcystin contamination in fish from the Jacareqagua Lagoon (Rio de Janeiro, Brazil): ecological implication and human health risk. <i>Toxicon</i> 2001;29:1077-1085.	Examined fish harvested during cyanobacterial blooms.	Fish harvested from lakes with ongoing cyanobacterial blooms were contaminated with microcystins.
Carmichael, WW, Azevedo MFO, An JS, Molica RJR, Jochmisen EM, Lau S, Rinehart KL, Shaw GR, Egelsham GK. Human fatalities from cyanobacteria: chemical and biological evidence for cyanotoxins. <i>Environ. Health Perspect.</i> 2001;109, 663-668.	Outbreak investigation of people with fatal liver disease following dialysis in clinics in Brazil.	Dialysis water was contaminated with microcystins.
Stewart I, Webb PM, Schluter J, Fleming LE, Burns JW Jr, Ganta M, Backer LC, Shaw GR. Acute effects of recreational exposure to freshwater cyanobacteria-a prospective epidemiologic study. pp. 473-474. In: Steidinger KA, Landsberg JH, Tomas CR, and GA Vargo (Eds.). 2004. <i>Harmful Algae 2002</i> . Florida Fish and Wildlife Conservation Commission, Florida Institute of Oceanography, and Intergovernmental Oceanographic Commission of UNESCO.	Epidemiology study including symptom surveys and environmental data collection.	Symptom reporting was low; however, cyanobacterial toxins were generally present at low levels, if at all.
Xie L, Xie P, Guo L, Li L, Miyabara, Y, Park H-D. Organ distribution and bioaccumulation of microcystins in freshwater fish at different trophic levels from the eutrophic Lake Chaohu, China. <i>Environ. Toxicol</i> 2005;20:293-300.	Examined the distribution of microcystins in fish and mussel tissue.	Found detectable levels of microcystins in bile and bloom of wild fish.
Kann J. Microcystin Bioaccumulation in Klamath River Fish and Freshwater Mussel Tissue: Preliminary 2007 Results. Technical Memorandum. Aquatic Ecosystem Sciences, LLC, Ashland, Oregon. 2008. 48 pp.	Examined distribution of microcystins in fish and mussels	Found microcystin bioaccumulation in fish and mussel tissues during blooms.
Backer LC, McNeel SV, Barber T, Kirkpatrick B, Williams C, Irvin M, Zhou Y, Johnson TB, Nierenberg K, Aubel M, LePrell R, Chapman	Observational study that collected symptom data, nasal	Low microcystin concentrations were found in water samples and personal

<p>A, Foss A, Corum S, Hill VR, Kieszak SM, Cheng Y-S. Recreational Exposure to Microcystins During Algal Blooms in Two California Lakes. <i>Toxicon</i> 2010, 55:909-921.</p>	<p>swabs from people recreating on a lake with a bloom and those recreating on a lake without a bloom. Collected environmental data.</p>	<p>air samples from people using the blooming lake, but not from people using the non-blooming lake. Detected low levels of microcystins on nasal swabs in people using the blooming lake.</p>
<p>Stewart I, Carmichael 22, Backer LC, Fleming LE, Shaw GR. Recreational Exposure to Cyanobacteria. In: Nriagu JO (ed) <i>Encyclopedia of Environmental Health</i>. Elsevier, The Netherlands, 2011:776-788</p>	<p>Overview of public health impacts from environmental exposures to cyanobacteria in recreational waters.</p>	<p>Report includes reference to CDC's surveillance activities.</p>
<p>Hilborn ED, Roberts VA, Backer L, DeConno E, Egan JS, Hyde JB, Nicholas DC, Weigert EJ, Billing LM, DiOrio Mary, Morh, MK, Hardy J, Wade TJ, Yoder JS, Hlavsa MC. Algal bloom-associated disease outbreaks among users of freshwater lakes—United States, 2009-2010. <i>MMWR</i>, 2014,63(1):11-15.</p>	<p>Reported results from the One Health Harmful Algal Bloom System from 2009-2010</p>	<p>States reported 11 freshwater HAB-associated illness outbreaks, including 61 illnesses and two hospitalizations.</p>
<p>Backer LC, Manassaram-Baptiste D, LePrell R, Bolton B. 2015. Cyanobacteria and Algae Booms and Public Health: Data from the Harmful Algal Bloom-related Illness Surveillance System (HABISS). <i>Toxins</i>, 7, 1048-1064. doi:10.3390/toxins7041048</p>	<p>Summarized data collected via the Harmful Algal Bloom-related Illness Surveillance System (HABISS)</p>	<p>11 states contributed reports for 4534 bloom events, including 458 cases of suspected and confirmed human illnesses and 175 animal morbidity and mortality events from 2007-2011.</p>
<p>Lavery A, Backer LC, Daniel J. Evaluation of electronic claims data for monitoring exposure to harmful algal blooms in the United States. <i>Journal of Environmental Health</i>. 2021;83(9):8-14.</p>	<p>Examined the utility of using EHR in combination with bloom data to assess a possibly association.</p>	<p>Although HAB-related diagnostic codes were used infrequently, they were most often recorded during bloom seasons in warmer months.</p>
<p>Seaweed HABs</p>		
<p>Resiere D, Mehdaoui H, Florentin J, Gueye P, Lebrun T, Bateau A et al. Sargassum seaweed health menace in the Caribbean: clinical characteristics of a population exposed to hydrogen sulfide during the 2018 massive stranding. <i>Clinical Toxicology</i>. 2020;59(3):215-223. https://doi.org/10.1080/15563650.2020.1789162</p>	<p>Data analysis using 154 patient records, H2S concentration estimates based on measurements temporal and geographic distribution of</p>	<p>Public health impacts from sargassum strandings likely associated with by-product gases released as the bloom material rots on the beaches.</p>

	<p>sargassum seaweed stranding in Martinique. The toxicologic syndrome associated with sargassum seaweed exposure (hospital visits) is close to the toxidrome associated with H2 exposure (0-10 ppm). Included neurologic, digestive, and respiratory symptoms.</p>	
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CDC will use the same forms, biospecimen collection protocols, and other documents previously approved by CDC’s IRB and OMB. Any documents that specify cyanobacterial blooms (e.g., in the name of the document) will be modified to reflect our new definition of potential exposure that includes aerosols from HABs, that is, blooms of marine microalgae and macroalgae (e.g., seaweed), as well as cyanobacteria.

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention, requests a three-year Paperwork Reduction Act (PRA) clearance for a new information collection request titled “Aerosols from harmful algal blooms: exposures and health effects.” NCEH is generally authorized to conduct research under the Public Health Service Act, Section 301, “Research and investigation,” (42 U.S.C. 241) (Attachment 1).

We will conduct a cohort study of 200 people highly exposed to HABs in Florida. We define “highly exposed” as those exposed because of their occupation (e.g., lock gate keepers, fishing guides) and those exposed because they live on a canal or river and spend at least two hours outside on most days.

Study participant inclusion criteria are as follows: the individual must be at least 18 years old; understand English, Spanish, or Haitian Creole; spend at least 2 hours a day outside each day; be able to do a lung function test; and be willing to do all study activities listed in the screening/baseline survey. Study participant exclusion criteria are as follows: the individual is less than 18 years old, cannot understand English, Spanish, or Haitian Creole; does not spend at

least 2 hours a day outside each day; is unable to do a lung function test; and is unwilling to do all study activities listed in the screening/baseline survey.

Bloom composition and concentrations of toxins can vary over time during a bloom (Paerl and Otten, 2013) and CDC is interested in not only exposure, but also how exposure varies as the blooms develop, mature, and die off. Also, we cannot predict where a bloom may occur in a given timeframe. Thus, we will work closely with the Florida Department of Environmental Protection to identify when a bloom develops (either via limited routine monitoring or by visual indications followed by water testing for HABs organisms and toxins). Once a bloom is verified, we will initiate the study (i.e., recruit and enroll respondents in collaboration with the Florida Department of Health) in the area affected by the bloom. Study staff will collect data from respondents in the morning and evening on 5 study days (day 1 during the beginning of a bloom, days 2-4 in the middle of the bloom, and day 5 toward the end of the bloom) between March and November.

The 60-day Federal Register Notice was published on September 17, 2019; and is further discussed in Section A8 (Attachment 2).

A.2. Purpose and Use of the Information Collection

Environmental public health stakeholders, including public health officials, the medical community, local elected officials, and the public pose many questions about the associations between exposure to HABs and the associated toxins and health outcomes. There is scant available literature aside from the papers by Backer et al. (2008, 2010) that specifically try to explore these associations.

The purpose of this information collection is to conduct research on exposures and health effects from aerosols generated during HABs. Human exposures to HAB toxins have been reported to produce a variety of health effects, including respiratory irritation and liver and kidney damage. The results from this research will enhance the body of knowledge about how exposure to HABs may affect public health.

We expect this research to be hypothesis generating and not necessarily generalizable to participants with similar exposures in the same population or to the public more generally. The results from the proposed data collection help address some of the scientific questions associated with HABS, including the following:

- Can HAB toxins be found in urine and on nasal swabs in people exposed to HABS?
- Can we identify markers of kidney and liver damage in people exposed to HABS?
- Can we explore reporting of acute symptoms and determine whether we can generate hypotheses about the relationship between those symptoms and exposure, including related to changes over the bloom season.

- Are environmental levels of HABs predictive of what we can find in people?

Sample size calculation of N=150 was based on the one available study on changes in liver enzyme values following exposure to microcystins in drinking water (see Supporting Statement B). For the other endpoints, (e.g., respiratory, gastrointestinal symptoms) we will report descriptive statistics because data are not available for power calculations.

If NCEH does not collect the information described for this study, gaps in knowledge about using biomonitoring to exposure exposures to aerosols contaminated with HAB toxins and the potential health effects will remain.

The information collected will be broadly applicable to other geographic regions experiencing HABs in waters widely used by the public. The organisms comprising HABs tend to be from a widely known groups of organisms and, while the organisms comprising a specific bloom will vary, they are likely to contain organisms like the ones we will identify in this study.

Purpose of collecting samples and specimens

Environmental samples, particularly the air samples, will be used to verify human exposures to aerosols contaminated with HAB toxins that are generated during HABs. The toxins have no odor or taste, thus environmental sample collection and analysis is needed to demonstrate exposure.

We will collect fish from respondents who fish during their study day(s). This will allow quantitative analysis of the fish for HAB toxins. This information will be valuable in assessing potential human exposures from seafood.

Human biomonitoring using nasal swabs, lung function tests, urine, and blood is needed to assess the amount of HAB toxins are in the bodies of people who are exposed to the aerosols generated during HABs. The biomonitoring results will help us understand what doses of the HAB toxins are relevant to human health endpoints such as respiratory irritation or liver damage. The results from biomonitoring data collected in the morning are expected to be different from those collected during the evening after respondents have been outside and exposed to aerosols from the HABs. By collecting biomonitoring data during different stages of a HAB, we will be able to assess trends in the values of biomonitoring data across the bloom season.

How data will be analyzed

Results from symptom surveys, blood and urine specimens, nasal swabs, lung function test results, and water, air, and fish samples will be analyzed using univariate methods to

summarize the data. CDC staff will compare the following information to determine if there are changes or correlations: 1) individual's morning results with evening results, and 2) biomonitoring results with HAB toxin levels in air, water, and fish. CDC staff will assess environmental and biomonitoring over time.

For short-term effects (e.g., self-reported symptoms), study respondents can serve as their own controls. For the cumulative effect on pulmonary function tests, we will use a comparison group from NHANES for the most appropriate demographics, season, and geographic area (e.g., southeastern U.S. or Florida).

For long-term effects (e.g., changes in liver enzyme concentrations), study respondents will experience cumulative exposures over the study period. There is some evidence of seasonal variation in liver enzyme concentrations from a study in Japan (Miyake et al., 2009). The authors used approximately 1,270,000 test results collected over seven years from one hospital and reproduced with an additional 215,000 test results collected over 2 years from another hospital. The serum levels of liver enzymes tended to increase in the winter. For example, serum levels of AST and ALT increased about 6% in men and about 5% in women in tests done in winter when compared with results from tests done in summer. For our study, respondents will serve as their controls (i.e., beginning of bloom compared with late in the bloom). We will use NHANES liver enzyme data stratified by the season of sample collection and clinical values for creatinine as additional comparison values.

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

To reduce the burden on study respondents, CDC will use electronic data entry for 77% (188 of 244 burden hours) of the burden hours. Specifically, the screening/baseline/baseline survey (Excel), and CDC staff will collect survey responses directly into the CDC's instance of the survey platform REDCap. Data entry for the remaining 23% of the burden will be paper and pencil collection. To enhance the ease of data recording, the survey will include automatic skip patterns. Study staff will simultaneously collect survey data on a paper form which will be compared with the data in REDCap to ensure accuracy and then destroyed. CDC will also embed appropriate ranges for questions with numerical answers to limit data entry or transcription errors.

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

CDC consulted with our federal partners at the U.S. Geological Survey and the U.S. Environmental Protection Agency and the information collections proposed for this study are not being done elsewhere. CDC is not aware of any other studies utilizing this protocol.

CDC conducted literature and World Wide Web searches and did not identify studies collecting the information proposed here.

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

This data collection will not involve small businesses.

A.6. Consequences of Collecting the Information Less Frequently

The respondents will do the study activities for this information collection on 5 study days (some responses will occur twice in each study day). The first study day will be during the period just after the bloom is identified and the other 4 will occur during mid-bloom and after the bloom has ended. The study days will occur over a period of months (e.g., March through November) and will hereafter be noted as study days 1, 2, 3, 4, and 5.

CDC is requesting multiple responses for a number of reasons. We cannot predict when the HAB will form, nor can we predict when a HAB might produce toxins; thus, we will collect data over the bloom season. The blooms typically comprise different organisms over time, and we would like to assess exposure to the blooms as they evolve. Finally, we would like to know if the toxins or effects of the toxin accumulate or worsen over time as a person is exposed. The consequences of collecting the data less frequently include that we would not be able to assess exposures as they change over time nor will we be able to look at how health effects change during the duration and evolution of the bloom.

There are no technical or legal obstacles to reducing burden.

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

The following special circumstance(s) apply to this information collection. We are requiring the following: Respondents will report information to the agency more often than quarterly.

CDC is requesting multiple responses for a number of reasons. We cannot predict exactly how a HAB will develop or die off. Thus, we will collect data over the bloom season. The blooms typically comprise different organisms and produce different toxins over time, and we would

like to assess exposure to the blooms as they evolve. Finally, we would like to know if the toxins or effects of the toxin accumulate or worsen over time as a person is exposed.

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

- A. A 60-day Federal Register Notice was published in the *Federal Register* on September 17, 2019, vol. 84, No. 180, pp. 48929-48931 (Attachment 2). CDC/ATSDR received a total of 162 public comments, including 3 substantive comments. The comments and the CDC/ATSDR response is provided. Based on the comments received, CDC made a number of changes to the protocol (Attachment 2a).
- B. The following people outside and inside the agency were consulted to obtain their views on the availability of data, frequency of collection, the clarity of instructions, and on the data elements to be reported.

Table A.8.1 External and internal consultations for this data collection.

Name	Title	Affiliation	Phone	Email
Consultations outside the agency				
Lesley D’Anglada, DrPH, MEH	Senior microbiologist	Office of Science and Technology, U.S. EPA	202-566-1125	danglada.lesley@epa.gov
Keith Loftin, PhD	Water quality specialist	U.S. Geological Survey (USGS), Kansas Water Science Center	785-832-3543	kloftin@usgs.gov
Greg Boyer, PhD	Professor	SUNY College of Environmental Science and Forestry	315-470-6825	gboyer@esf.edu
Barry Rosen, PhD	Biologist	USGS, Florida	407-738-0669	brosen@usgs.gov
Andrew Reich	Marine Toxin Specialist	Florida Department of Health	813-307-8015 x 5961	Andy.reich@flhealth.gov
Alice M. Shumate, PhD, MPH LCDR	Co-Director, Center for Maritime Safety and Health Studies	Respiratory Health Division at NIOSH	Phone: 509-354-8018	wii5@cdc.gov
Kathleen Clark PhD MS RRT CPFT	Research Epidemiologist	CDC/NIOSH/RHD/Surveillance Branch	(304) 285-5764	lln9@cdc.gov

Consultations inside the agency				
Stephanie Kieszak, MA, MPH	Statistician	National Center for Environmental Health (NCEH)	770-488-3407	skieszak@cdc.gov
Dana Flanders	Statistician	Emory University/NCEH	404-727-8716	flanders@sph.emory.edu
David Olson	Statistician	NCEH	770-488-3724	dolson@cdc.gov
Elizabeth Hamlin	Research Chemist	Division of Laboratory Sciences, NCEH	770-488-7082	ehamlin@cdc.gov
Kanta Sircar	Epidemiologist	NCEH	770-488-3384	ksircar@cdc.gov

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

Below is an explanation of study activities that were used to justify the incentives for respondents.

Based on study activities and previously approved OMB data collections, we will provide study participant incentives as shown in Table 3 below. The incentives will be in the form of gift cards given to respondents as they complete the study activities.

To guide decisions about incentives, we used previous OMB-approved incentives listed here.

Table A.9.1. Study participant incentives.

Study Activity	Number of times study participant does the activity	Incentive for each time study participant does the activity	Total incentive for activity
Complete survey	10 (twice on all study days)	\$10 each study day after completing both surveys	\$50
Provide blood specimen for liver enzyme levels and creatinine	3 (on study days 1, 3, and 5)	\$75 after the third blood draw	\$75
Complete record of time spent outdoors	5	\$5	\$25
Provide urine and nasal swab for HAB toxins, do lung function test	10 (twice on all study days)	\$30 on each study day after providing both urine specimens	\$150
Provide fish	1 time during study	0	0
TOTAL			\$300

If all parts of the study are completed, respondents will receive a total of \$300 in gift cards. Respondents will be asked to sign a receipt in a standard receipt book to indicate that they acknowledge receiving the gift card each time they receive one.

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

A.10.1. Privacy Impact Assessment

This project was reviewed by the NCEH Information Security Systems Office for applicability of the Privacy Act by the CDC Chief Privacy Officer. The Privacy Act does apply. The applicable System of Records Notice is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems.

The following PII will be collected CDC will use this information to maintain communications with respondents and to send respondents their results letters.

Name

Home Address (if study days will be at their home)

Workplace Address (if study days will be at their workplace)
E-mail
Telephone number(s)
Date of birth
Biologic specimens

The study staff will make every effort to keep the data secure by a variety of methods. Data are entered into a password-protected database. A unique Study ID is assigned as a key identifier for all study forms. The environmental and biological samples and measurements are only identified by study ID. Data collectors maintain their paper files in locked cabinets and their electronic files are stored on secured servers with password protection. Encrypted data files are sent electronically to investigators at CDC. Data are stored on highly-secured CDC servers in Atlanta, GA. The servers are housed in a secure computer room complete with climate control, emergency power, and an uninterruptible power supply (UPS). Daily back-ups and integrated security are implemented through the CDC computer services infrastructure. All data access is password-protected, and all network communications use encryption. All servers and PCs that are part of the CDC infrastructure are protected by both host-based firewalls and software in order to prevent the undetected installation of "spyware." At CDC, only our investigators are given access to read the encrypted data files.

Data are treated in a secure manner and are not disclosed, unless otherwise compelled by law.

Information about the data to be collected is below and summarized in Table A.10.1.

Environmental samples for each study day for each participant

- Air sampler on shore for aerosol particle size distribution and HAB toxin concentrations
- Air sampler on-shore for gases and vapors emitted as HABs die off
- Personal air samplers for HAB toxin concentrations

Human biomonitoring specimens

- All study days (morning and evening)
 - Urine specimen for HAB toxin levels
 - Lung function test
 - Nasal swab for HAB toxin levels
 - Survey responses for activities and symptoms
- Study days 1, 3, and 5
 - Blood specimen for liver enzyme levels and creatinine levels

Fish biomonitoring

- Fish tested by EPA for HAB toxin levels

Other information

- Record of time spent outdoors

Table A.10.1. Summary of information & materials to be collected and who will collect them. There will be 5 study days, one at the beginning of the bloom, 3 during the bloom, and one near the end of the bloom. For study days 1, 3, and 5, we will collect blood in addition to the survey responses, biospecimens, and environmental samples (see also SSB, Table B.2.1 and Consent form [Attachment 6]).

Information & materials to be collected	Collected by	Number of times information and materials collected per participant N = 200 respondents	Data to be collected
Telephone Screening/Baseline Survey	Study staff (CDC staff and contractors)	1	Whether or not an interested person meets study inclusion criteria and baseline data
Symptoms Survey	Study staff	10 (morning and evening of each study day)	Health symptoms, other relevant exposures, etc.
Dock air samples	Study staff	5 (one for each of 5 study days)	Gases and vapors emitted as blooms die off and HAB toxin levels
Personal air samples	Study staff	5 (one for each study day)	HAB toxin levels
Water samples	Study staff	5 (one for each study day)	HAB organism taxonomy and HAB toxin levels
Nasal swabs	Study staff	10 (morning and evening of each study day)	HAB toxin levels
Lung function test	Study staff	10 (morning and evening of each study day)	Lung function parameters
Blood samples	Registered phlebotomist	3 (on study days 1, 3, and 5)	Liver enzyme levels, creatinine levels
Urine samples	Study participants	10 (morning and evening of each study day)	HAB toxin levels
Fish	Study staff (who will forward to EPA)	≤5 (maximum of one for each study day when respondent is fishing)	HAB toxin levels in fish

Record of time spent outdoors	Study participants	5 (one on each study day)	Hours spent outdoors
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We will post study Flyers (Attachment 4 – Flyer) throughout the community experiencing a HAB to recruit potential respondents. The study Screening/Baseline Survey is Attachment 5, the Consent Form is Attachment 6, and the Symptom Survey is Attachment 7. Instructions for providing a blood specimen; for providing urine, nasal swabs, and lung function tests; and to be outfitted with a personal air sampler are in Attachments 8, 9, and 10, respectively. The Record of Time Spent Outdoors and Information about collecting a fish are in Attachments 11 and 12, respectively.

For the Screening/Baseline Survey, there are up to 33 questions, depending on the skip pattern applied. For the Symptom Survey, there are 51 questions pre- and 49 questions at the end of the study day (see Table A.10.3).

Table A.10.2. Overview of questions types in the Screening/Baseline Survey.

Question Type	# of Questions Used
Name, home address (if relevant), workplace address (if relevant), email, phone numbers (to maintain contact during study, to allow us to go to their home or workplace, and provide individual results and final paper to respondents)	3
Demographics (age, sex, race—needed to interpret creatinine levels and lung function tests)	2
Occupation (to verify exposure potential)	1
Question about being outdoors for at least 2 hours per day	1
Question about ability to do a lung function test	1
Questions about other sources of exposure to HAB toxins (to use in assessing effects from exposure to Florida HABs.	2
Diagnosis with asthma and/or COPD (Questions were used in previously OMB-approved national studies such as Behavioral Risk Factor Surveillance System [BRFSS])	1-11*
Diagnosis with other chronic conditions that may impact clinical test results (Based on the literature and professional judgement)	3
Alcohol use (recommended to help distinguish non-alcoholic liver injury associated with exposure to microcystins)	1-2
Smoking (recommended to help interpret lung function test results)	1-3
Use of blue-green algae supplements (to help evaluate exposures)	1
Water consumption (recommended to help interpret creatinine values)	1

Height and weight (needed to interpret lung function tests)	2
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* Total number of questions depends on responses.

Table A.10.3. Overview of question types in the survey.

Question Type	# of Questions Used
Morning	
Questions about current respiratory and gastrointestinal illness	2
Symptoms possibly associated with exposure to HABs	43
Information about pet health	6
Evening	
Water quality	5
Symptoms of others	1
Symptoms possibly associated with exposure to HABs	43
Information about the species of fish and where it was caught	2

For the survey, most questions are yes/no responses or multiple choice, except the three questions about pulmonary function testing results asked in the morning and evening.

We will provide study respondents with the results from their clinical assays (Attachment 13 – Results Letter).

Information about protection of privacy (i.e., the Privacy Impact Assessment) is in Attachment 14 – Privacy Impact Assessment.

Study documents will be maintained according to Records Control Schedule CDC RG-0442, Scientific and Research Project Records, Minor Research Records Authorized Disposition: Maintain at least six years, but no longer than ten years after retirement of the system depending on the program needs for scientific, legal or business reference, then delete/destroy.

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

This study was reviewed by the NCEH/ATSDR human subjects advisor and determined to be non-exempt human subjects' research under 45 CFR 46. The CDC IRB approval memo is found in Attachment 15 – IRB Approval Memo.

CDC will not collect sensitive information from study respondents. CDC will collect age, race, and ethnicity data (see Attachment 5 – Screening/Baseline Survey) because it is needed to compare clinical test results with laboratory and other standards (e.g., lung function tests).

During the consent process, CDC-trained interviewers explain to the residents that participation in the study is voluntary and they may withdraw from the study at any time without negative consequences. The interviewers also explain the intended uses of the data, with whom information will be shared, and the legal authority for the data collection (i.e., through the Public Health Service Act). The interviewers will also ask if respondents are willing to be contacted for possible participation in future studies.

A.12. Estimates of Annualized Burden Hours and Costs

The estimate of the burden of the information collection on respondents is displayed in Table A.12.1. The burden estimates for providing biomonitoring data were derived from CDC staff's experience in previous studies. Estimates for the time needed to complete the Screening/Baseline Survey and Symptom Survey are based on pilot testing with 7 volunteers.

Table A.12.1 Estimates of annualized burden hours.

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Interested community members	Screening/Baseline Survey	84	1	15/60	21
Eligible study respondents	Symptom Survey	67	10	15/60	167
Eligible study respondents	Record of Time Spent Outdoors	67	5	10/60	56
Eligible respondents	Provide Blood Specimen	67	3	15/60	51
Eligible respondents	Provide Specimens	67	10	1	670

	(urine, nasal swabs, lung function test)				
Eligible respondents	Be Outfitted with Personal Air sampler	67	5	45/60	252
Eligible respondents	Provide Fish (if respondent went fishing and caught fish)	67	5	10/60	56
Total					1,273

Annualized cost to respondents for the burden hours for the collection of information is \$31,050.00 and is provided in Table A.12.2. The mean hourly wage rate was obtained from the [Department of Labor National Occupational Employment and Wage Estimates United States](https://www.bls.gov/oes/current/oes_nat.htm#45-0000) website (U.S. Department of Labor, Bureau of Labor Statistics, May 2018 National Occupational Employment and Wage Estimates, United States (https://www.bls.gov/oes/current/oes_nat.htm#45-0000)). We used \$24.42, the wage for first line supervisors of farming, fishing, and forestry workers as those workers are likely respondents.

Table A.12.2. Estimated Annualized Burden Costs

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Interested community members	Screening / Baseline Survey	84	1	15/60	21	\$24.42	\$513
Eligible respondents	Symptom Survey and	67	10	15/60	167	\$24.42	\$4079
Eligible respondents	Record of Time Spent	67	5	10/60	56	\$24.42	\$1368

	Outdoors						
Eligible respondents	Provide Blood Specimen	67	3	15/60	51	\$24.42	\$1228
Eligible respondents	Provide Specimens (urine, nasal swabs, lung function test)	67	10	60/60	670	\$24.42	\$16362
Eligible respondents	Be Outfitted with Personal Air sampler	67	5	45/60	252	\$24.42	\$6136
Eligible respondents	Provide Fish (if respondent went fishing)	67	5	10/60	56	\$24.42	\$1364
Total							\$31050

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

There are no additional costs to respondents.

A.14. Annualized Cost to the Federal Government

The estimated annualized cost to the Federal Government over the three years of this OMB approval is detailed in Table A.13.1. The calculations are based on hours and estimates of the costs of sample collection, shipping and analysis from laboratory quotes.

Table A.14.1. Annualized cost to the federal government.

Item	Total cost over three years	Annualized cost
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Contract		
Personnel (including fringe) (680 hours)	\$79,701.80	\$26567.27
Travel	\$33,600	\$11,200
Consultant	\$44,000	\$14,666.67
Incentives	\$30,750	\$10,250
Equipment, sample collection, shipping, and analyses	\$234,900	\$78,300
Contract Subtotal	\$422,951.80	\$140,983.94
Personnel		
PI (GS 15) 20% time (including fringe)	\$120,960	\$40,320
Study manager (GS 13) 50% of time (including fringe)	\$180,000	\$60,000
Travel	\$33,600	\$11,200
TOTAL	\$757,511.80	252,503.94

A.15. Explanation for Program Changes or Adjustments

This is a new information collection.

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

The plans for tabulation and publication and project time schedule are detailed in Table A.16.1. Note that the time schedule for the activities are dependent on the development of a HAB in Florida and the schedule may shift.

Table A.16.1 Project Time Schedule

Activity	Time Schedule
Respondent recruitment	1—2 months after OMB approval
Baseline information/data collection	2—3 months after OMB approval
Information/Data collection	3—8 months after OMB approval
Complete field work	8—20 months after OMB approval*
Validation	10—22 months after OMB approval*
Analyses	12—30 months after OMB approval*
Publication	30 months after OMB approval*

* Timeline will be adjusted based on development of HAB bloom

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

The display of the OMB expiration date is appropriate.

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

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

