U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Title:	One Health Harmful Algal Bloom System Amendment 1
Project Id:	0900f3eb82498675
Accession #:	NCEZID-DWASHEPI-3/18/22-c20fe
Project Contact:	Amy L Freeland
Organization:	NCEZID/DFWED/WDPB
Status:	**Pending Regulatory Clearance : Amendment**
Intended Use:	**Project Determination**
Estimated Start Date:	06/01/2016
Estimated Completion Date:	06/01/2025
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-1105

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	11/19/24	Peterson_James M. (iyr1) CIO HSC
PRA: **PRA Applies**		11/19/24	Vice_Rudith (nhr9) OMB / PRA
ICRO: **PRA Applies**	OMB Approval date: 11/14/22 OMB Expiration date: 11/30/25	11/20/24	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Priority Justification:	
CDC Priority Area for this Project:	Not selected
Determination Start Date:	11/15/24
Description:	Harmful algal blooms (HABs) are the rapid growth of algae or cyanobacteria (also called blue-green algae) that can cause harm to people, animals, or the local ecology. Toxins from harmful algal blooms (HABs) include some of the most potent natural chemicals; these toxins can contaminate surface water used for recreation and drinking, as well as food sources. HABs pose a threat to both humans and animals. Human and animal illnesses from

environmental exposures to HABs in fresh and marine waters have been documented in the United States. Animal illness may be an indicator of bloom toxicity; thus, it is necessary to provide a One Health approach for reporting HAB-associated illnesses and events. Factors that influence the occurrence of HABs include water temperature and nutrient levels. Warm waters with abundant phosphorus and nitrogen content (e.g., from urban or agricultural run-off) are more likely to form HABs. These conditions promote the growth of phytoplankton or algae that can produce toxins or otherwise cause illness in animals, people, and negatively impact the local ecology (e.g., reduced oxygen and light available for aquatic organisms) and economy (e.g., beach closures, shellfish bed closures). There is evidence that the frequency and severity of HABs might increase as a consequence of climate change. The One Health Harmful Algal Bloom System (OHHABS) was approved (OMB Control No. 0920�1105) and the electronic system launched in June 2016. OHHABS is the national database used for public health surveillance of HAB events and single cases of HAB-associated human or animal illness. A standardized data-collection system for HAB events and HAB-associated illnesses continues to be necessary to quantify and characterize HAB-associated illnesses, refine HAB event and case definitions, and inform One Health prevention efforts. For the first reporting period, years 2016--2018, eighteen states adopted use of the One Health Harmful Algal Bloom System (OHHABS) and entered 421 reports, including information about 389 human illnesses and at least 413 animal illnesses associated with HAB events.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Submitted through IMS Clearance Matrix:	Not selected
Primary Scientific Priority:	Not selected
Secondary Scientific Priority (s):	Not selected
Task Force Responsible:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	OHHABS is a centralized data source for public health surveillance of HAB events and HAB-associated illnesses using a One Health approach that takes into consideration information from the environment, animal cases, and human cases. The purpose of OHHABS is 1) to provide a database for routine data collection at the state and national level to identify and characterize HAB events, HAB-related illnesses, and HAB-related exposures in the United States 2) to better inform and improve our understanding of HAB-related illnesses and exposures through routine surveillance to inform public health policy and illness prevention efforts.
Objective:	A standardized data-collection system for HAB events and HAB-associated illnesses continues to be necessary to quantify and characterize HAB-associated illnesses, refine HAB event and case definitions, and inform One Health prevention efforts. States and territories lacking a database to collect information on HAB events and HAB-related illnesses may use OHHABS as a repository to track and review HAB events and HAB-related illnesses within their state or territory. OHHABS data may help states and territories characterize the baseline frequency of HAB events and HAB-related illnesses. Data from states and territories will be assessed by CDC to determine and characterize HAB events and HAB-related illnesses nationally.
Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project investigate underlying contributors to health inequities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	No
Activities or Tasks:	Secondary Data or Specimen Analysis
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Harmful Algal Bloom ; One Health ; Public Health Surveillance
CDC's Role:	CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens

Method Categories: Secondary Data Analysis; Surveillance Support

Methods: Participating states and territories will be responsible for the collection and interpretation of data elements at the state level and will voluntarily submit them to CDC. HAB event and HAB-related human and animal case definitions, developed by CDC with state and federal partner input, will be available to assist states and territories. States and territories may use these definitions when identifying and reports HAB events or cases reporting to OHHABS. These definitions and the resulting classifications will also be used by CDC to describe events and cases (e.g., in annual reports). To advance public health surveillance, response, and mitigation of HAB impacts, CDC collaborates with state and federal partners. CDC led a state-federal working group during 2014—2016 that informed the development of OHHABS forms and the associated HAB event and case definitions. This group continues to be active but has evolved into a community of practice (https://www.cdc.gov/habs/public-health-capacity.html) that discusses One Health activities related to harmful algal blooms and can inform CDC's understanding of surveillance needs and priorities. To improve the completeness and utility of OHHABS data, CDC will collaborate with federal partners to identify potential data linkages that simplify data collection, analysis, or use. CDC is coordinating with other federal agencies to ensure that there is no duplication of data collection and plans to optimize data use through future data linkages with other federal data systems. Future data linkages may allow other federal agencies to identify HAB events reported in OHHABS to link to their existing systems. For example, if the United States Geology Survey collected toxin levels in their routine water monitoring database, information about when and where the sample was collected might enable a link to a HAB event or HAB-related illnesses reported in OHHABS. Similarly, it might be possible to link data systems to allow states to enter environmental or animal health data more rapidly. Within CDC, case and outbreak surveillance activities might be optimized through measures such as secure linking of OHHABS to the National Outbreak Reporting System (NORS). OHHABS personnel will also coordinate with CDC laboratories to provide laboratory support (e.g., biospecimen testing for presence/absence of toxins, pathology evaluation) to state and territorial partners during case investigations, inclusive of de-identified biospecimens being submitted to and received by the appropriate CDC laboratory and the results reported out to the state/territory according to laboratory protocol. These results might subsequently be reported in OHHABS.

Collection of Info, Data or Biospecimen: OHHABS is a web-based reporting system that is nationally available for state and territorial health departments to voluntarily report information about HAB-associated human and animal cases of illness and HAB events that occur in fresh water, salt water or brackish water. Although other federal agencies (e.g., Environmental Protection Agency, Food and Drug Administration, United States Geological Survey) conduct work related to HABs, no other public health surveillance system exists to collect linked data about HAB events and HAB-associated cases of illness in humans and animals. OHHABS (electronic, year-round collection) includes questions about HAB events and HAB-associated illnesses. Health departments work with their human, animal, and environmental health partners to detect and investigate HAB events and associated illnesses and report them to OHHABS (https://www.cdc.gov/habs/pdf/ohhabs-reporting-flow-diagram-508.pdf). This is a One Health approach that improves surveillance and health outcomes by recognizing that human health is connected to the health of animals and our shared environment. Data obtained describe the location of the HAB event (or location of harvest for foodborne illnesses), general characteristics of the waterbody, and supporting evidence to characterize the bloom (e.g., water appearance, water odor, water quality testing results). Human case data collected are deidentified. They describe the case (age in years, sex), where they were exposed, how they were exposed, symptoms, whether they sought medical care, potential risk factors for a related illness or more severe symptoms, and de-identified results of relevant biospecimen testing. Animal case data are also de-identified. Data collected describe the case (e.g., type of animal), where they were exposed, how they were exposed, signs, health outcomes, veterinary care, potential risk factors for a related illness or more severe signs, and de-identified results of relevant biospecimen testing. Animal cases can be reported in aggregate (e.g., a flock of birds, a school of fish), if necessary. Illness reports are linked to HAB event data by a system-generated numeric identifier. Data elements collected in OHHABS are posted online at https://www.cdc.gov/habs/using-ohhabs.html#forms. OHHABS will not obtain biospecimens directly. De-identified results from biospecimen testing can be reported within human and animal case forms utilizing results from testing at public health, academic, private or other (i.e., non-CDC) federal agency laboratories. Biospecimens tested at CDC would be received by working with state, tribal, territorial, or local health agencies and possibly with other federal agencies; biospecimens submitted to CDC are de-identified prior to being sent to CDC. Results of testing will shared back to the submitting agency, which might then report it in OHHABS. There is currently no electronic linking between CDC laboratory systems and OHHABS. OHHABS can receive de-identified results of biospecimen testing for human and animal cases (e.g., type of toxin tested, concentration, type of test method used). Receipt of biospecimens and management of biospecimen testing data will be overseen by the CDC laboratory staff that conduct such testing and will be in accordance with CDC policies and standards.

Expected Use of Findings/Results and their impact: Data collected through OHHABS will be compiled and analyzed on an annual or biennial basis. Summary reports will be distributed within the public health community and to state and federal partners. For example, CDC has released a MMWR report summarizing 2016-2018 data (Roberts et al, 2020) as well as an annual summary for 2019 data available online (https://www.cdc.gov/habs/data/2019-ohhabs-data-summary.html). Data might also be disseminated in response to data requests, in which case, CDC will use data request and release protocols in accordance with Division and agency guidance related to best practices and to balance disclosure of information with risks inherent to collecting case-level data. CDC will use the information provided by states and territories in OHHABS to identify and address knowledge gaps. This may include improving existing HAB event and case definitions. OHHABS data will also help characterize temporal and spatial trends of HAB-related illnesses and health risks from HAB events, which can be used to improve public health prevention and response in the United States. CDC will routinely assess the quality of, tabulate, analyze, and publish OHHABS data in surveillance reports. The Great Lakes Restoration Initiative (GLRI), which supported early development of OHHABS, might request and use OHHABS data to inform and evaluate its work to restore and protect the Great Lakes ecosystem.

Could Individuals potentially be identified based on Information Collected? No

Funding

 Funding yet to be added .....

HSC Review

Regulation and Policy

Do you anticipate this project will require review by a CDC IRB or HRPO? No

Estimated number of study participants

Population - Children   Protocol Page #:

Population - Minors   Protocol Page #:

Population - Prisoners   Protocol Page #:

Population - Pregnant Women   Protocol Page #:

Population - Emancipated Minors   Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPAA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Will you be working with an outside Organization or Institution? No

 Institutions yet to be added .....

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	CITI Good Laboratory Practice Exp. Date	Staff Role	Email	Phone	Organization
Robyn Espinosa	06/27/2026		11/15/2025			Program Lead	pnk2@cdc.gov	770-488-6975	Domestic WASH Epi Team

Data

DMP

Proposed Data Collection Start Date:

Proposed Data Collection End Date:

Proposed Public Access Level:

Public Access Justification:

How Access Will Be Provided for Data:

**Plans for Archival and Long Term
Preservation:**

Spatiality

Spatiality (Geographic Locations) yet to be added .....

Dataset

Dataset Title	Dataset Description	Data Publisher/Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	11/20/2024	NOA 0920-1105 (2022)	Notice of Action	NOA 0920-1105_2022.pdf
Current	Freeland_Amy L. (igc3) Project Contact	11/15/2024	NOA 0920-1105 (2019)	Notice of Action	NOA 0920-1105_2019.pdf
Current	Freeland_Amy L. (igc3) Project Contact	11/15/2024	Proposed human form	Data Collection Form, 0.1260 Request to End Review of Human Research Studies	Human Form_OMB 2024.pdf
Current	Freeland_Amy L. (igc3) Project Contact	11/15/2024	Proposed Environmental form	Data Collection Form, 0.1260 Request to End Review of Human Research Studies	Environmental Form_OMB 2024.pdf
Current	Freeland_Amy L. (igc3) Project Contact	11/15/2024	Proposed animal form	Data Collection Form, 0.1260 Request to End Review of Human Research Studies	Animal Form_OMB 2024.pdf
Current	Freeland_Amy L. (igc3) Project Contact	11/15/2024	This is the OHHABS data dictionary that describes the data fields collected in OHHABS.	Other-OHHABS Data Dictionary	ohhabs_datadictionary.xlsx
Current	Freeland_Amy L. (igc3) Project Contact	11/15/2024	This document is the project determination request template that was completed and used to enter this project in STARS. This document contains additional details that might be helpful if there are questions about the project.	Other-Project Determination Request Template	OHHABS NCEZID Project Determination Request 18Mar2022.docx
Current	Freeland_Amy L. (igc3) Project Contact	11/15/2024	N/A	HS Research Determination Memo	032922VR-NR-signed.pdf
Current	Freeland_Amy L. (igc3) Project Contact	11/15/2024	Current non-research determination pre-STARS submission	HS Research Determination Memo, 0.1260 Request to End Review of Human Research Studies	Att. D - Non-research determination.pdf
	Zirger_Jeffrey (wtj5) ICRO Reviewer	03/30/2022	NOA 0920-1105 (2019)	Notice of Action	NOA 0920-1105_2019.pdf
	Peterson_James M. (iyr1) CIO HSC	03/29/2022	N/A	HS Research Determination Memo	032922VR-NR-signed.pdf
	Roberts_Virginia (evl1) Project Contact	03/18/2022	This is the OHHABS data dictionary that describes the data fields collected in OHHABS.	Other-OHHABS Data Dictionary	ohhabs_datadictionary.xlsx
	Roberts_Virginia (evl1) Project Contact	03/18/2022	This document is the project determination request template that was completed and used to enter this project in STARS. This document contains additional details that might be helpful if there are questions about the project.	Other-Project Determination Request Template	OHHABS NCEZID Project Determination Request 18Mar2022.docx