

Attachment 6: Instructions: How to collect a urine specimen

Aerosols from harmful algal blooms (HABs): exposures and health effects in highly exposed population

Instructions: How to collect a urine specimen

1. Get a sterile urine cup from study staff.
2. Confirm that the label has your correct study ID, time, date, and whether the sample is collected before or after your trip.
3. Wash hands with soap and water.
4. Fill sterile cup with urine.
5. Secure lid.
6. Wash hands with soap and water.
7. Place urine specimen in the provided specimen bag.
8. Hand the bag with the urine specimen cup to study staff.

Attachment 7 Instructions: How to collect a water sample

Aerosols from harmful algal blooms (HABs): exposures and health effects in highly exposed population

Instructions: How to collect a water sample

TBD based on discussions with Florida Department of Environmental Protection

Attachment 8 Privacy Assessment

TBD pending review by Brian Nicholson

TBD pending review by Brian Nicholson

Attachment 9 Data Flow Figure from the Manual of Procedures

Attachment 10 Data Management Plan

Sample shipping –
see DMP

NCEH/ATSDR Data Management Plan Template for CDC Datasets

Purpose: This template helps CDC¹ dataset custodians and extramural researchers develop data management plans (DMPs). The template is intended for use with any type of CDC and CDC-funded public health datasets, including non-research (public health practice) data received from state health departments (such as surveillance and program data); non-research (public health practice) data collected by CDC (such as surveillance and emergency investigation data); and research data collected or received by CDC or CDC grantees.

Background: DMPs should comply with the CDC/ATSDR Policy on Releasing and Sharing Data (<http://isp-v-maso-apps.cdc.gov/Policy/Doc/policy385.pdf>) in addition to any policies from the relevant CIO, division, and branch. In addition, DMPs for research involving human subjects should adhere to procedures approved by relevant Institutional Review Boards, if applicable.

Data collected and received by CDC are federal records and are subject to federal laws and rules, as described in Attachment B of the CDC-ATSDR Data Release Guidelines and Procedures for Re-release of State-Provided Data.

Plans for datasets provided by states should also be consistent with the CDC-ATSDR Data Release Guidelines and Procedures for Re-release of State-Provided Data (available at <http://www.cste2.org/webpdfs/drgwgreport.pdf>).

When to use this document: First, complete the NCEH/ATSDR Data Management Plan Determination form. If a DMP is needed, use this template to develop such a plan for each data collection activity. Complete the DMP during the project planning phase; the plan will represent a mutual understanding between CDC and the data source institution(s), if any.

Data categories: Covered by policy: green shading (D1–D3); covered by policy but release/sharing limited: yellow shading (D4–D7); not covered by policy: red shading (D8–D10).

D1 = data collected or generated by CDC	D6 = data deemed not shareable due to inadequate return on investment
D2 = data collected or generated by other agencies or organizations funded or co-funded by CDC	D7 = data deemed not shareable for other reasons
D3 = data reported to CDC by another entity that become part of a CDC data collection system	D8 = data collected or generated by other organizations that are shared with CDC and without CDC funding

¹ References to CDC also include the Agency for Toxic Substances and Disease Registry (ATSDR) throughout this document.

D4 = data protected from disclosure by applicable laws or regulations	D9 = data provided to CDC by license or other agreements (MOU, IAA, DTA or MTA) that state restrictions on use or sharing of data
D5 = data deemed not sharable due to a potential dual-use research of concern	D10 = data provided to CDC by another federal agency under restricted terms of use and sharing of the data

NCEH/ATSDR Data Management Plan Template for CDC Datasets

Purpose: This template helps CDC² dataset custodians and extramural researchers develop data management plans (DMPs). The template is intended for use with any type of CDC and CDC-funded public health datasets, including non-research (public health practice) data received from state health departments (such as surveillance and program data); non-research (public health practice) data collected by CDC (such as surveillance and emergency investigation data); and research data collected or received by CDC or CDC grantees.

Background: DMPs should comply with the CDC/ATSDR Policy on Releasing and Sharing Data (<http://isp-v-maso-apps.cdc.gov/Policy/Doc/policy385.pdf>) in addition to any policies from the relevant CIO, division, and branch. In addition, DMPs for research involving human subjects should adhere to procedures approved by relevant Institutional Review Boards, if applicable.

Data collected and received by CDC are federal records and are subject to federal laws and rules, as described in Attachment B of the CDC-ATSDR Data Release Guidelines and Procedures for Re-release of State-Provided Data.

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When to use this document: First, complete the NCEH/ATSDR Data Management Plan Determination form. If a DMP is needed, use this template to develop such a plan for each data collection activity. Complete the DMP during the project planning phase; the plan will represent a mutual understanding between CDC and the data source institution(s), if any.

Data categories: Covered by policy: green shading (D1–D3); covered by policy but release/sharing limited: yellow shading (D4–D7); not covered by policy: red shading (D8–D10).

D1 = data collected or generated by CDC	D6 = data deemed not shareable due to inadequate return on investment
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D2 = data collected or generated by other agencies or organizations funded or co-funded by CDC	D7 = data deemed not shareable for other reasons
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NCEH/ATSDR Data Management Plan Form

This plan describes the anticipated use and release by CDC of the dataset named below. All CDC DMPs are required to be in compliance with the CDC/ATSDR Policy on Releasing and Sharing data, available at <http://isp-v-maso-apps.cdc.gov/Policy/Doc/policy385.pdf>. This plan is modifiable and does not represent a legal contract between CDC and any other entity. The elements included do not necessarily constitute an exhaustive list of all possible elements for a DMP, so users should add elements as needed.

The DMP is submitted through eClearance for review and approval. Use “TBD” if you cannot determine some of this information at the time of submission. Elements with an asterisk (*) are required data fields for metadata.

Table 1 - Core DMP Elements *(should be filled out when project approval is sought)*

MRID <i>(NCEH/ATSDR metadata repository identifier - for NCEH/ATSDR OD use only.)</i> P1903-0006
*Title <i>(Human-readable name of the project. Title should be in plain English and include sufficient detail to facilitate search and discovery.)</i> Aerosols from cyanobacterial blooms: exposures and health effects in a highly exposed population

***Description**

(Human-readable description with sufficient detail to enable a user to quickly understand whether the project or dataset is of interest. A short, clear description is ideal.)

Goal of the study: To assess exposures and health symptoms in people whose occupations result in exposure to cyanobacterial harmful algal blooms (CyanoHABs).

Intended use of the resulting data: The data will inform the Florida state health departments about the effects CyanoHABs have on the coastal population and whether there is a need for public health intervention activities to reduce exposures, and will support local public health action to reduce exposures to CyanoHABs. In addition, the data will be available for the U.S. EPA when they update the current guidance for microcystins and cylindrospermopsin in drinking and recreational waters.

Methods to be used to collect data: The methods used to collect data include telephone interviews to determine eligibility and periodic questionnaires completed on-line 24 times (before and after each of 12 trips on their vessels). Nasal swabs, air, and water samples will be collected and analyzed by a contractor with specific expertise in cyanobacterial toxins. Blood samples will be collected by a certified phlebotomist and analyzed by a clinical laboratory for liver enzyme levels and kidney function using standard methods. Pulmonary function tests will be done by study staff trained in spirometry. Urine specimens will be collected from study participants after each trip and analyzed for cyanotoxins.

***Last DMP Update**

(Most recent date on which the DMP was changed, updated, or modified.)
7-9-2019

***Contact Name and Email**

CDC PI or POC Name (last, first): Backer, Lorraine
CDC PI or POC e-mail address: lfb9@cdc.gov
CDC PI or POC phone number: 770-488-3426

Organization

(Use CIO/Division/Branch as locator of where the project is conducted or supported; or use the awardee institution for an extramural project.)
NCEH/DEHSP/EMRCB

***Unique Identifier and catalog/database name**

(A unique identifier for the project as maintained within an Agency catalog or database. For intramural submissions, protocol/S3P number can be used. For extramural submissions, grant/cooperative agreement/ contract number can be used to map to related documents.)
NA

***Data Access Level(s) – CHECK ALL APPLY**

(The degree to which the data collected as part of this project could be made publicly available, regardless of whether it has been made available. Projects can have multiple datasets or different data elements within a single dataset that are approved for different levels of public access.)

PUBLIC Release

- ☐ Public release – Full dataset

*(Dataset can be made available without restrictions; data steward no longer controls data. **This should be the default selection for all datasets unless justified otherwise.**)*

Note that the data will comprise the water analysis values only. There will be no data on the study participants per se.

- ☒ Public release – Aggregate data

(Underlying dataset cannot be released or shared, but aggregate/summary data can be made available to public access without restriction)

Justification (required if selected):

Aggregate data will be provided in a peer-reviewed publication which will be made available via NIHMS.

- ☐ Public release - Release by ad-hoc request

(Metadata will be released and the dataset is available by ad-hoc request; data requests CANNOT be denied; no data use agreement or restrictions; data steward no longer controls data.)

Justification (required if selected):

RESTRICTED Release

- ☐ Restricted use data sharing

(Dataset is available to particular parties under certain use restrictions or use agreement; data not always under CDC custody. The use restriction/agreement (or template) needs to be attached.

Justification (required if selected):

- ☐ Restricted access data sharing

(Dataset is only available in an RDC; data need to remain under CDC custody.)

Justification (required if selected):

No Data Release/Sharing

- ☐ No release or data sharing

Justification (required if selected):

Access Rights/Restrictions <i>(Include information regarding access or restrictions based on privacy, security, or other policies of the owner of the data. Include an explanation for the selected “Public Access Level” above.)</i> Aggregated data will be made available to the public through a peer-reviewed publication.
License/Other Agreements <i>(The license or non-license [i.e., public domain] status with which the dataset will be published. See Open Licenses for more information. May include DTA, MTA, IAA, MOU or other agreements concerning data use and access.)</i> NA
*Publisher/Owner <i>(The publishing entity and optionally their parent organization(s). This could be the “owner” of the data.)</i> CDC
Access URL(s), If Known <i>(URL providing indirect access to the DMP, dataset, data dictionary [variable names and valid values], data collection instrument and other relevant information, including the research protocol if possible.)</i> TBD
Download URL(s), If Known <i>(URL providing direct access to a downloadable file of the dataset, summary data, or data tables.)</i> TBD
*Spatial <i>(The range of spatial applicability of a dataset. Could include a geographic region or a named place [city, county, state, region, country].)</i> The study will be done on Lake Okeechobee and nearby rivers.

Temporal(The range of temporal applicability of project)*

Start date of data collection (month/year): 2019

End date of data collection (month/year): 2021

Table 2 – Additional DMP Elements *(should be filled out where possible when project approval is sought; however, many fields can only be filled out later when publication/report is cleared)****Tags/Keywords***(Keywords to help users discover the dataset.)*

NA

***Intramural or Extramural Project**☒ Intramural (funding for DLS)☒ Extramural (grant, cooperative agreement, contract, IAA, CDC Foundation, other)

Specify mechanism: IAA with USGS, in-kind with US EPA, contract TBD

Project Type – CHECK ALL APPLY*(Multiple selections may apply.)*☒ Research☐ Emergency☐ Non-research☐ Exposure investigation☐ Surveillance☐ Ongoing collection☐ Evaluation☐ Other**Dates**

Estimated date of data release/sharing (month/year): TBD

Preservation expiration date (year that the dataset will be available until): TBD

Data Category*(For explanation of D1 to D10 codes, see Table on page 1)*☐ D1☐ D2☐ D3☐ D4☐ D5☐ D6☒ D7☐ D8☐ D9☐ D10

Justification: (provide detailed information about the data category selected above. If D6 is selected, provide quantitative estimates of costs in releasing data and expected volume of use. If D7 is selected, specify the reason that prevents the owner from releasing/sharing the data.)

Population Represented*(e.g., “residents of x,” “inpatients at x,” “users of product x”)*

Staff of Florida Department of Environmental Protection who work on and around Lake Okeechobee.

Data Collection Protocol

(Brief description with reference to document or website that provides detailed information.)

The methods used to collect data include telephone interviews to determine eligibility and periodic questionnaires completed on-line 24 times (before and after each of 12 trips on their vessels). Nasal swabs, air, and water samples will be collected and analyzed by a contractor with specific expertise in cyanobacterial toxins. Blood samples will be collected by a certified phlebotomist and analyzed by a clinical laboratory for liver enzyme levels and kidney function using standard methods. Pulmonary function tests will be done by study staff trained to use spirometry equipment. Urine specimens will be collected from study participants before and after each trip and analyzed for cyanotoxins.

Data Management Protocol

(Brief description with reference to physical location(s) or system(s) where data will be housed (e.g., CDC shared network drive, data host system name, SQL database, etc.) and to data formats. Include the locations of dataset both before data release and after data release.)

We plan to use RedCap, a CDC-approved data collection platform, for all data collection.

Data Quality Protocol (to address issues of confidentiality protection and statistical stability)

(Brief description with reference to document or website that provides detailed information. Describe methods for data validation and error resolution, removal or shielding of any proprietary information, removal or shielding of sensitive information [i.e., data with dual use applicability], removal or shielding of any individually identifying information including indirect identification.)

PII will be collected to allow us to communicate with study participants. Within RedCap, each study participant will be assigned a study ID number, and those numbers will be used to link environmental data and test results to study participants. No PII will be shared with the public when results are published.

Data Retention/Disposal Plan

(State when and how the dataset will be archived or destroyed [in accordance with CDC/ATSDR Records Control Schedule: <http://isp-v-maso-apps/RecSched/images/RCS.pdf>].)

PII and links to PII will be destroyed when the manuscript describing the study is published.

Data Analysis Plan

(Brief description of planned use of the data. Can include reference to document [e.g., information collection request, research protocol, or other] that provides more detailed information.)

Results from symptom surveys, blood and urine specimens, nasal swabs, and water and air samples will be analyzed using univariate methods to summarize the data. We will also compare individual's pre-exposure results with post-exposure results as we did in earlier studies examining recreational exposures to microcystins (one common CyanoHAB toxin). Finally, we will compare biomonitoring results with air and water concentrations to determine if there are correlations.

Publication Plan

(Brief description of planned CDC-authored and CDC-coauthored publications, including topic, type of publication, and estimated timeline.)

We anticipate a manuscript describing study results.

Data Release Documentation

(List documents provided to users, e.g., variable definitions, codebook, metadata file, guidance on data use.)

Aggregate data will be released via a peer-reviewed publication.

Data Release Format

(Recommend to use non-proprietary format when possible, such as CSV, JSON, etc. Also specify data dictionary file format.)

Aggregate data will be released via a peer-reviewed publication.

Data Release Notification

(State how potential users will be informed of dataset availability.)

Aggregate data will be released via a peer-reviewed publication.

Date Form Completed: 3-20-19

By: Lorraine Backer, Environmental Epidemiologist
Name, Title

Date Form Last Revised: 3-27-2019

By: Lorraine Backer, Environmental Epidemiologist

Name, Title

Date Form Last Revised: 7-9-2019

By: Lorraine Backer, Environmental Epidemiologist

Name, Title

Attachment 11 Participant Results Letter

Address

Florida Department of Health



**National Center for Environmental Health
Centers for Disease Control and Prevention**

**4770 Buford Highway
Chamblee, GA 30341**

XX, 2018

**Aerosols from cyanobacterial blooms: exposures and health effects in highly exposed populations
Results from blood and urine specimens and pulmonary function tests**

Dear <study participant>,

We would like to thank you again for being in our research study of aerosols from cyanobacterial blooms. The purpose of this study is to understand if people who need to work near harmful cyanobacterial blooms (CyanoHABs) are exposed to the toxins these blooms produce and if these exposures cause health symptoms.

When you signed the consent form you said that you wanted to know the results of the analysis of your biological specimens, including blood and urine, and your pulmonary function test results.

Your results for the amount of creatinine in your urine and the liver enzymes in your blood are provided in the table below. For comparison, we provide the standard clinical (or normal) range for these parameters. You can compare your results to see whether they are in the normal range. We have also provided your pulmonary function test results and the predicted clinical range, which is based in part on your age and sex.

If you have any questions about your results, you may contact <State investigation leader> for <affiliation, state> at <phone number>. .

Sincerely,

<State investigation leader>

<Title>

<Affiliation>

The results from the analysis of your blood specimens and from the pulmonary function tests are below.

Test	Appointments		
	1 <Date>	2 <Date>	3 <Date>
B specimen test results			
Creatinine (mg/dL). Clinical ranges are approximately 0.6 to 1.2 milligrams (mg) per deciliter (dL) in adult males and 0.5 to 1.1 milligrams per deciliter in adult females.			
Aspartate aminotransferase (AST). Clinical range is 8-48 units/L of blood			
Alanine aminotransferase (ALT). Clinical range is 7-55 units/L of blood			
Alkaline phosphatase (ALP). Clinical range is 45 – 115 units/L of blood			
Gamma-glutamyl transpeptidase (GGT). Clinical range is 0 – 30 units/L of blood.			
Pulmonary Function Tests: Predicted values are based on age and sex (Scanlon et al, 1999).			
Forced vital capacity (FVC) in L			
Forced expiratory volume in the first second you exhale (FEV ₁) in L/sec.			
Forced expiratory volume in			

the first second over forced vital capacity (FEV ₁ /FVC) in %			
Forced expiratory flow from 25% to 75% of vital capacity (FEF _{25%-75%}) in L/sec			
Peak expiratory flow rate (PEF) in L/sec.			