

Study ID

Date _____

Attachment 6

Consent Form

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Fleisch-Kincaid Reading Level: 9.3

Note: We will enroll those likely to be highly exposed to cyanobacterial aerosols because of the work they do or where they live. The population is educated and will be able to understand the text.

Cyanobacterial Harmful Algal Blooms (CyanoHABs) Study

CDC protocol # 7242: Aerosols from cyanobacterial blooms: Exposures and health effects in highly exposed populations

Consent Form

Introduction

The Centers for Disease Control and Prevention (CDC) invites you to be in a research study. Please ask questions if there is anything you do not understand.

Please be assured that CDC will take COVID-19 prevention measures at every step of our work in your community. The study will be conducted following all state, local, and CDC guidelines in place at the time the study is conducted. CDC team members will be monitored twice daily for fever and any COVID-19-related symptoms. Any team members with fever or COVID-19-related symptoms will not be allowed to collect data until they have quarantined for the recommended period, if appropriate, and have tested negative for COVID-19. There will be times when study staff will visit your home to collect information (study forms, urine specimens, personal air samples). If there is any face-to-face contact with study staff at that time, study team members will wear surgical masks and gloves and study participants will wear a face covering or mask. If you do not have a mask, one will be provided to you. If you are unable to wear a mask for medical reasons, you can let us know.

What is the purpose of this study?

The purpose of this study is to understand if people who live near or need to work near harmful cyanobacteria (also called blue-green algae) blooms (CyanoHABs) are exposed to the toxins these blooms produce and if these exposures cause health symptoms.

How long will you need me?

We will need you for about 15 hours total during the period from March to November, depending on when the bloom forms.

What do you want me to do if I decide to be in this study?

- Read and sign a consent form

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- Make 5 appointments with study staff to do study activities (study days 1, 2, 3, 4, and 5)
NOTE: study days will not be consecutive but will occur across bloom season—one day at the beginning of the bloom, 3 during the bloom, and one at the end of the bloom.
- On study days 1, 3, and 5:
 - Provide a blood specimen for liver enzyme levels and creatinine levels in the morning
 - Receive training on how to collect a urine sample (one time only)
 - Do the following in the morning and evening:
 - Complete symptom survey
 - Provide urine specimen for cyanobacterial toxin and creatinine levels
 - Perform lung function test
 - Provide nasal swab for cyanobacterial toxin levels
 - Wear a personal air sampler during the day
 - Record time spent outdoors
 - Allow study staff to put air samplers (one for aerosols, one for gases and vapors (e.g., hydrogen sulfide) near your home or worksite
 - At the end of the day, allow study staff to collect air monitoring equipment
 - Provide a fish if you fish on the study day
- On study days 2 and 4:
 - Do all study activities you do on study days 1, 3, and 5, except that you will not need to give us a blood sample.
- Allow us to store your biological specimens for future research related to environmental toxins.

Are there risks to me if I decide to be in this study?

The risks from being in this study are minimal. There are no health risks expected from providing a nasal swab or urine sample. There is a slight risk of fainting when you provide a blood sample or when you do the lung function test. There is a very small risk that your results or answers to the survey might not be kept confidential; however, we will have precautions in place to ensure to the best of our ability that this does not happen.

Are there any benefits from being in this study?

Your benefits from being in this study include learning about health symptoms that may be from your exposures to cyanobacteria and their toxins. Results from our study will help others who may need to respond to CyanoHABS to learn how people can become exposed and what their symptoms might be when they are exposed.

How many people will be in this study?

We plan to recruit 200 people to be in this study.

Are there any incentives for being in this study?

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We will give you incentives for being in the study. We give you a gift card for \$15 for each time you provide a urine specimen and nasal swab, and do the lung function test, \$25 for each time you provide a blood specimen, and \$5 for each time you complete the symptom survey or record the amount of time you spent outdoors. If you do all study activities, we will give you a total of \$300 in gift cards.

Are there any additional costs to me for being in this study?

There should be no additional costs for you being in this study.

Will the information I give you be kept private?

This research is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Who should I call if I have questions about this study or think I may have gotten sick or been harmed by the study?

If you have questions or concerns about this study, you may call one of the following people:

- Lorraine Backer, principal investigator, CDC: 770-488-3426
- XXXX, local project lead, XXX: XXX-XXX-XXXX

Who should I call if I have questions about my rights as a research volunteer?

If you have questions about your rights for being in this study, please contact the CDC/ATSDR (Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry) Acting Deputy Associate Director for Science at 1-800-584-8841. Leave a message with your name and phone number. Please refer to this protocol, Aerosols from cyanobacterial bloom exposures and health effects in highly exposed populations. Someone will call you back.

Do I have to be in this study?

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Being in this study is voluntary. You can refuse to be in the study or drop out at any time without losing any benefits you normally have.

Can my participation in this study be ended?

We do not anticipate that your participation will be ended. However, if you do not complete study activities, your participation may be ended.

Can I get my results?

We will give you the clinical results from the study, which include lung function test results and levels of liver enzymes and creatinine in your blood.

We will analyze your urine and nasal swabs for the cyanobacterial toxins microcystins and nodularins and maybe for others (e.g., we may analyze your urine for another toxin if it is found in air samples). We will not give you the results of the analysis of cyanobacterial toxins in your urine or on your nasal swabs because there are no standards and we cannot be certain what the results mean.

What will you do with my information and blood and urine specimens?

Your specimens and information will be collected and assigned a study identification number. During the study, CDC will have a key to that study identification number so we can contact you during the study. When the study is completed, we will destroy the key. Your de-identified information (e.g., survey results and biological specimens) will be saved for future CDC-sponsored studies on environmental toxins. For example, when we get additional resources, we will analyze these specimens for other cyanobacterial toxins. Your blood and urine specimens will not be used for commercial profit.

Will my blood and urine specimens be used for gene sequencing studies?

Your blood and urine specimens will not be used for gene sequencing studies.

Signature

I have been told about the study. I have been allowed to ask questions and have had all my questions answered. I would like to be in this study. By signing this form, I agree to be in the study.

Name of participant	Signature of participant	Date
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Permission to contact you for future studies

Will you allow our staff to contact you for future studies? If you agree, you will allow our

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staff to contact you by mail or telephone to ask if you would like to be in a future study. These studies will about human exposure to toxins in the environment. Study staff will be from the Centers for Disease Control and Prevention (CDC) or a contractor working with CDC.

Please initial one

___ I AGREE to be contacted to be asked if I can be in future research studies.

___ I DO NOT WANT to be contacted to be asked if I can be in future research studies.