

Attachment 5

Screening/Baseline Survey

Fleisch-Kincaid Reading Level: 5.9

Aerosols from cyanobacterial blooms: exposures and health effects in highly exposed populations

Eligibility Screening Survey

Hello, I'm _____. I'm working with the Centers for Disease Control and Prevention and the Florida Department of Health. I'd like to know if you are willing to help us with a research study about cyanobacteria, also known as blue-green algae.

You may have heard about cyanobacteria, also called blue-green algae. They are very tiny organisms that grow in water. Some types of cyanobacteria make chemicals, called cyanobacterial toxins. We know these chemicals can cause liver or kidney damage in people when they drink water with a lot of cyanobacterial toxins in it. We don't know what happens if people are exposed to these chemicals in the air.

The purpose of our study is to find out 1). If the toxins made by these blue-green algae get into the air and then into people's bodies and, if so, 2) if exposure to these toxins affects people's health. Similar studies have been done in Florida, Michigan, and California.

We are looking for people who spend at least 2 hours outside each day and who live or work on or near Lake Okeechobee and connecting rivers to be in our study.

CDC estimates the average public reporting burden for this collection of information as 15 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-xxxx).

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.

We are asking you for your verbal consent to answer our screening survey questions. We will ask you for your signed consent before you do any study activities. Do you give us your verbal consent to ask the screening questions?

<IF YES> Thank you for your interest in this study.

<IF NO> Thank you for your interest in this study. But we will not be able to proceed with the screening survey without your consent. Thank you again.

Now, I have a few questions about you:

Age (yrs)	Sex	With which racial group do you most closely identify?	Are you of Hispanic origin?
____ Years <input type="checkbox"/> Don't know <input type="checkbox"/> Refused	<input type="checkbox"/> F <input type="checkbox"/> M <input type="checkbox"/> Other <input type="checkbox"/> Don't know <input type="checkbox"/> Refused	<input type="checkbox"/> 1. American Indian/Alaska Native <input type="checkbox"/> 2. Asian <input type="checkbox"/> 3. Black or African American <input type="checkbox"/> 4. Native Hawaiian/other Pacific Islander <input type="checkbox"/> 5. White <input type="checkbox"/> 6. Don't know <input type="checkbox"/> 7. Refused	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/> Refused

Now, I have a few more questions about whether or not you are eligible for our study.

Are you able to understand English, Spanish, or Haitian Creole?

<IF YES> OK, great.

<IF NO> Thank you for your interest in this study. But we are looking for people who can understand at least one of those languages.

Do you spend at least 2 hours a day outdoors each day for work or other activities?

<IF YES> OK, great.

<IF NO> Thank you for your interest in this study. But we are looking for people who spend at least 2 hours each day outdoors.

Are you able to complete a lung function test? The test involved blowing hard into a tube for as long as you can. We need you to do this at least 3 times each session.

<IF YES> OK, great.

<IF NO> Thank you for your interest in this study. But we are looking for people who are able to do a lung function test.

If you agree to participate, we will ask you to do the following before the bloom season and during the bloom season (approximately March through November):

- Read and sign a consent form
- Make 5 appointments with study staff to do study activities (study days 1, 2, 3, 4, 5). These are not consecutive days, but will be near the time the bloom starts, during the bloom and at the end of the bloom (approximately March through November)
- 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
 - Do the following in the morning and evening:
 - Complete symptom survey
 - Provide urine specimen for cyanobacterial toxin levels
 - Perform lung function test
 - Provide nasal swab for cyanobacterial toxin levels
 - Wear a personal air sampler for the day
 - Record time spent outdoors using our form
 - Allow study staff to put an air sampler for aerosols and an air sampler for gases and vapors (e.g., hydrogen sulfide) near the canal you live on
 - At the end of the day, allow study staff to collect air monitoring equipment
- 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.

We expect these activities to take about 15 hours of your time altogether.

Will you help us with our study?

IF NO:

Okay, well, thank you for your time.

IF YES:

Thank you.

First, I will ask you some questions to see if you qualify to be in our study.

Then I'll ask you to read and sign a consent form and answer a few more questions.

IF PERSON IS INTERESTED IN BEING IN THE STUDY

Okay, just to be sure, you are typically outdoors for at least 2 hours each day, correct?

IF THEY SAY "NO" to any of these questions:

Thanks. But we can only include people who will be outdoors for at least 2 hours each day.

IF THEY SAY "YES" to all three questions:

Thanks. You are eligible to be in our study.

May I please have your name, home address or workplace address, e-mail address, and phone number(s) so we can contact you with study reminders? Once the study is complete and we no longer need to contact you, we will remove your name, address, email address, and phone number(s) from our records and they will not be kept as any part of this research study.

Name:

First Name _____

Last Name _____

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

Street _____

City _____

State _____

Zip code _____

Workplace Address (if study days will be at their workplace):

Street _____

City _____

State _____

Zip code _____

E-mail: _____

Telephone number(s) where we can most easily reach you:

Phone number _____

Phone number _____

Baseline Survey for those interested and eligible to be respondents

NOTE

- The questions about exposure to cyanobacteria and algae-containing supplements are based in the need to assess sources of exposure to cyanobacterial toxins
- The questions about asthma, COPD, emphysema, chronic bronchitis, and the household and living environment are from the previously OMB-approved Behavioral Risk Factor Surveillance Survey (BRFSS) Asthma Call-back Survey –2007 Adult Questionnaire and the Baseline Questionnaire for the Green Housing Study (question 16a).
- The questions about liver disease, bowel disease, and alcohol consumption are based on published findings of the possible affects from exposure to cyanobacterial toxins.
- The questions about smoking, height, and weight are needed to interpret the lung function tests.

Now, I have a few more questions about you and your lifestyle that can help us interpret the information we collect from you.

What do you do that may have exposed you to cyanobacteria during your activities?

- Collect water samples
- Collect cyanobacteria samples
- Other

Specify: _____

- Don't know
- Refused

1. Do you use a dietary supplement made from blue-green algae, such as Super Blue-Green?

No	
Yes	2
Don't know	8
Refused	9

1a. How often do you take the supplement?

Daily	1
More than once a week	2
More than once a month	3
Occasionally	4
Don't know	8
Refused	9

1b. How much of the supplement do you take?

	AMT.	UNITS (PILL, TSP., ETC.)
Don't know	8	
Refused	9	

2. Do you take any other dietary supplements, such as herbs or teas or vitamins?

No	1
Yes	2
Don't know	8
Refused	9

2a. Can you tell me what supplements you take?

3. Have you ever been told by a doctor or other health professional that you have asthma?

No	
Yes	2
Don't know	8
Refused	9

3a. How old were you when you were first told by a doctor or other health professional that you had asthma?

___ (Enter age in years)

Under one year old	
Don't know	8
Refused	9

3b. Do you still have asthma?

No	
Yes	2
Don't know	8
Refused	9

3c. How long has it been since you last talked to a doctor or other health professional about your asthma? This could have been in your doctor's office, the hospital, an emergency room or urgent care center.

Never	1
Within the past year	2
1 year to less than 3 years ago	3
3 years ago to 5 years ago	4

More than 5 years ago	5
Don't know	8
Refused	9

3d. Do you have symptoms all the time? "All the time" means symptoms that continue throughout the day. It does not mean symptoms for a little while each day.

No	1
Yes	2
Don't know	8
Refused	9

3e. How long has it been since you last had any symptoms of asthma?

___ Years	Months	Weeks	Days	(circle time unit)
Don't know				8
Refused				9

3f. During the past 30 days, on how many days did you have any symptoms of asthma?

___ Days	
No symptoms in the past 30 days	1
Every day	2
Don't know	8
Refused	9

READ: Asthma attacks, sometimes called episodes, refer to periods of worsening asthma symptoms that make you limit your activity more than you usually do, or make you seek medical care.

3g. During the past 12 months, have you had an episode of asthma or an asthma attack?

No	1
Yes	2
Don't know	8
Refused	9

4. Have you ever been told by a doctor or health professional that you have chronic obstructive pulmonary disease also known as COPD?

No	1
Yes	2
Don't know	8

Refused 9

5. Have you ever been told by a doctor or health professional that you have emphysema?

No 1
Yes 2
Don't know 8
Refused 9

6. Have you ever been told by a doctor or health professional that you have chronic bronchitis?

No 1
Yes 2
Don't know 8
Refused 9

7. Have you ever been told by a doctor or health professional that you have any other lung diseases?

No 1
Yes 2
Don't know 8
Refused 9

8. Has a doctor, nurse, or other health professional ever told you that you had any of the following chronic liver diseases?

<input type="checkbox"/> Alcoholic liver disease	Yes	No	Don't know	Refused
<input type="checkbox"/> Non-alcoholic fatty liver disease	Yes	No	Don't know	Refused
<input type="checkbox"/> Cirrhosis	Yes	No	Don't know	Refused
<input type="checkbox"/> Viral hepatitis (B or C)	Yes	No	Don't know	Refused
<input type="checkbox"/> Autoimmune hepatitis	Yes	No	Don't know	Refused
<input type="checkbox"/> Liver cancer	Yes	No	Don't know	Refused

9. Has a doctor, nurse, or other health professional ever told you that you had any of the following bowel diseases?

<input type="checkbox"/> Irritable Bowel Syndrome	Yes	No	Don't know	Refused
<input type="checkbox"/> Ulcerative colitis	Yes	No	Don't know	Refused
<input type="checkbox"/> Crohn's Disease	Yes	No	Don't know	Refused

Now I have a couple of questions about drinking alcohol. One drink is equivalent to a 12-ounce beer, a 5-ounce glass of wine, or a drink with one shot of liquor.

10. During the past 30 days, on how many days did you have at least one drink of alcohol?

- 0 days
- 1 or 2 days
- 3 to 5 days
- 6 to 9 days
- 10-19 days
- 20-29 days
- All 30 days
- Don't know
- Refused

11. During the past week (7 days), about how many alcoholic drinks did you have?

- 0
- 1-2
- 3-5
- 6-9
- 10+
- Don't know
- Refused

Thank you, now a couple of questions about cigarette smoking.

12. Have you smoked at least 100 cigarettes in your entire life?

No	1
Yes	2
Don't know	8
Refused	9

13. Do you smoke cigarettes now?

- Every day
- Some days
- Not at all
- Refused

13a. [If every day or some days] About how many cigarettes do you usually smoke per day?

- 1 pack, about 20 cigarettes
- More than 1 pack
- Less than 1 pack per day
- Don't know

14. How many 8-ounce cups of beverages do you drink each day? A beverage includes water, coffee, juice, soda, etc.
___ cups

Now, I have a few questions about your household and living environment.

15. An air cleaner or air purifier can filter out pollutants like dust, pollen, mold and chemicals. It can be attached to the furnace or free standing. It is not, however, the same as a normal furnace filter. Is an air cleaner or purifier regularly used inside your home?

No	1
Yes	2
Don't know	8
Refused	9

16. Is a dehumidifier regularly used to reduce moisture inside your home?

No	1
Yes	2
Don't know	8
Refused	9

17. Do you have an air conditioner in your home?

No	1
Yes (go to question 15a)	2
Don't know	8
Refused	9

16a. If YES. What kind of air conditioner is it?

Central unit	1
Window or portable/free standing unit	2
Swamp cooler/evaporative cooler	3
NA	4
Don't	8
Refused	9

Finally, just two more questions about you.

18. What is your height (in feet and inches)?

___ feet ___ inches

19. What is your weight in pounds?

___ pounds

Those are all the questions I have now. Thank you again for helping us with our study. Now, I'd like to make an appointment so you can provide your baseline blood and urine specimens, pulmonary function data, and get study instructions.

Date:

Time:

Place: