

Attachment 4

Consent and Pre-exposure Questionnaire

Form Approved
OMB No.
Exp. Date

Human Exposure to Cyanobacterial Toxins in Water

Parental Permission Form

Introduction

The California Department of Public Health (CDPH) and the Centers for Disease Control and Prevention (CDC) are doing a research study on human exposure to blue-green algae. We know that sometimes blue-green algae grow very quickly to form blooms. Blue-green algae blooms can occur in waters where people swim and play. Sometimes these blooms can make chemicals (called toxins) that make the water taste or smell bad. Sometimes there may be smaller blooms in the water that don't make the water smell or taste bad. But, there still might be a very small amount of the toxins in the water. Through this study, we hope to learn about if the toxins made by blue-green algae can get into your body when you work, swim, or play in the water. We also hope to learn if these toxins can be found in your blood. We are asking your child to be in our study because there is a blue-green algae bloom in the water here today.

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data 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 Reports Clearance Officer; Paperwork Reduction Project (0920-0527); M.S. D-24; 1600 Clifton Road NE, Atlanta, Ga. 30333

Study Purpose

Animals, such as cattle and dogs, can get sick or sometimes even die when they drink water with a lot of blue-green algae toxins in it. People usually stay away from the water when there are blue-green algae blooms because the water smells and tastes bad. But no research has been done to find out what happens if very small amounts of blue-green algae toxins are in water where people swim and play. We are trying to find out if people who swim and play in water that has these toxins in it can feel bad or get sick. We also want to know if people might have these toxins in their blood. We will only need about 30 minutes of your child's time today and about 15 minutes for a phone call about 10 days from now.

Procedures

This study has three parts. One part will be done now and one will be done after you come back from the water today. The third part will be done by phone in about 10 days.

Part 1: First, we will ask your child some questions about <HER/HIM > self. Second, we will ask your child some questions about their symptoms.

Part 2: When your child comes back from activities today, we will ask your child about their symptoms again. We also will ask your child to give a sample (about 10 ml or 2 teaspoons) of their blood. <HER/HIS > blood will be analyzed only for microcystins, the toxin made by the blue-green algae in the water. After these analyses, all left-over blood samples will be thrown away. The samples will not be saved for future analysis.

Part 3: We will call your child on the phone in about 10 days and ask <HIM/HER> about <HER/HIS> symptoms.

We will not give you the results of the tests for microcystins. This is a research study, and

we cannot tell you what it means to have very small amounts of microcystins in your blood.

Who can be in this study

This is a minimal risk study, and if your child can swim and play in the water, <SHE/HE > can be in this study.

Risks/discomforts

Your child may feel a slight sting or “pinch” in <HIS/HER > arm when the blood is drawn. Your child may also get a small bruise where the needle went in. Some people faint when their blood is drawn, but this is rare. However, if your child feels sick after being in the study, please notify your health care provider. There are no known side effects from being in this study.

When we do the survey, none of the private questions we will ask your child are about touchy matters. So none of them should make <HER/HIM > uneasy. But as we said, your child can choose to not answer any of them for any reason.

Benefits

There may be no benefit to your child for being in this study but you/your child helping us carry out this research will give us a chance to find out more about blue-green algae toxins.

Confidentiality

The information for this study is being collected under section 301 of the Public Health Service Act. This act gives federal health agencies, such as CDC, broad authority to do many public health activities, including this type of research. All of the information your child gives us will be kept private to the extent permitted by law. Personal identifying information will remain with CDPH and CDC. No names or personal identifying information will be used in any published reports of this study.

Payment

We will send your child a money order for \$25 (\$5 for today's survey, \$15 for the blood sample, and \$5 for the phone survey) if <SHE/HE> finishes all parts of this study to cover any costs you may have from being in the study. If your child does not do all the parts of the study, we will pay her/him for the parts she/he does.

Compensation

If your child is hurt as a result of being in this study, treatment will not be provided by CDPH or CDC. CDC does not normally pay for harm done to your child as a result of being in a research study. Thus, you (or your insurer, Medicare, or Medicaid) will have to pay for any care that is needed. However, by signing this permission form and agreeing to be in this study, you are not giving up any of your child's rights. If you believe that your child has been harmed, please contact CDC's Deputy Associate Director for Science at 1-800-584-8814, (leave a message and someone will return your call) for information on your rights and advice on how to proceed.

Right to refuse or withdraw

Your child is free to join the study or not. Your child may also leave the study at any time, for any reason. If your child decides not to join, or to drop out later, your child will not lose any health care that <SHE/HE > may expect apart from this study. If your child decides not to join or to drop out later, it will not affect your child in any way.

Persons to contact

You will be provided a copy of the permission form. If you or your child have any questions about the study, you may call one of the study investigators: Dr. Sandy McNeel, CDPH, at 510-620-3644 or Dr. Lorrie Backer, Health Studies Branch at 770-488-3410. If you

have questions about your rights as a research subject, you may call the CDC Deputy Associate Director for Science, at 1-800-584-8814.

By signing below, I agree that I have read this permission form. I have been given the chance to ask questions about the study. By signing, I have not given up any of my child's legal rights. I agree to allow my child to be in the study of Human Exposure to Cyanobacterial Toxins in Recreational Waters.

Participant Signature: _____ Date: _____

Flesch-Kincaid reading level: 8.0*

* I did not include the “Persons to Contact” ,paragraph

Human Exposure to Cyanobacterial Toxins in Water

Adolescent Assent Form

Introduction

The California Department of Public Health (CDPH) and the Centers for Disease Control and Prevention (CDC) are doing a research study on human exposure to blue-green algae. We know that sometimes blue-green algae grow very quickly to form blooms. Blue-green algae blooms can occur in waters where people work, swim, and play. Sometimes these blooms can make chemicals (called toxins) that make the water taste or smell bad. Sometimes there may be smaller blooms in the water that don't make the water smell or taste bad. But, there still might be a very small amount of the toxins in the water. Through this study, we hope to learn about if the toxins made by blue-green algae can get into your body when you swim or play in the water. We also hope to learn if these toxins can be found in your blood. We are asking you to be in our study because there is a blue-green algae bloom in the water here today.

Study Purpose

Animals, such as cattle and dogs, can get sick or sometimes even die when they drink water with a lot of blue-green algae toxins in it. People usually stay away from the water when there are blue-green algae blooms because the water smells and tastes bad. But no research has been done to find out what happens if very small amounts of blue-green algae toxins are in water where people swim and play. We are trying to find out if people who work, swim, and play in water that has these toxins in it can feel bad or get sick. We also want to know if people might have these toxins in their blood. We will only need about 30 minutes of your time today and about 15 minutes for a phone call about 10 days from now.

Procedures

This study has three parts. One part will be done now and one will be done after you come back from the water today. The third part will be done by phone in about 10 days.

Part 1: First, we will ask you some questions about yourself. Second, we will ask you some questions about your symptoms.

Part 2: When you come back from your activities today, we will ask you about your symptoms again. We will also ask you to give a sample (about 10 ml or 2 teaspoons) of your blood. Your blood will be analyzed only for microcystins, the toxin made by the blue-green algae in the water. After these analyses, all left-over blood samples will be thrown away. The samples will not be saved for future analysis.

Part 3: We will call you on the phone in about 10 days and ask you about your symptoms.

We will not give you the results of the tests for microcystins. This is a research study, and we cannot tell you what it means to have very small amounts of microcystins in your blood.

Who may be in this study

This is a minimal risk study, and if you can swim and play in the water, you can be in this study.

Risks/discomforts

You may feel a slight sting or “pinch” in your arm when the blood is drawn. You may also get a small bruise where the needle went in. Some people faint when their blood is drawn, but this is rare. However, if you feel sick after being in the study, please notify your health care provider. There are no known side effects from being in this study.

When we do the survey, none of the private questions we will ask you are about touchy matters. So none of them should make you uneasy. But as we said, you can choose to not answer any of them for any reason.

Benefits

There may be no benefit to you for being in this study but your helping us carry out this

research will give us a chance to find out more about blue-green algae toxins.

Confidentiality

The information for this study is being collected under section 301 of the Public Health Service Act. This act gives federal health agencies, such as CDC, broad authority to do many public health activities, including this type of research. All of the information you give us will be kept private to the extent permitted by law. Personal identifying information will remain with CDPH or CDC. No names or personal identifying information will be used in any published reports of this study.

We will send you a money order for \$25 (\$5 for today's survey, \$15 for the blood sample, and \$5 for the phone survey) if you finish all parts of this study to cover any costs you may have from being in the study. If you do not do all the parts of the study, we will pay you for the parts you do.

Compensation

If you are hurt as a result of being in this study, treatment will not be provided by CDPH or CDC. CDC does not normally pay for harm done to you as a result of being in a research study. Thus, you (or your insurer, Medicare, or Medicaid) will have to pay for any care that is needed. However, by signing this consent form and agreeing to be in this study, you are not giving up any of your rights. If you believe that you have been harmed, please contact CDC's Deputy Associate Director for Science at 1-800-584-8814, leave a message and someone will return your call) for information on your rights and advice on how to proceed.

Right to refuse or withdraw

You are free to join the study or not. You may also leave the study at any time, for any reason. If you decide not to join, or to drop out later, you will not lose any health care that you

may expect apart from this study. If you decide not to join or to drop out later, it will not affect you in any way.

Persons to contact

You will be provided a copy of the consent form. If you have any questions about the study, you may call one of the study investigators: Dr. Sandy McNeel, CDPH at 510-620-3644 or Dr. Lorrie Backer, Health Studies Branch at 770-488-3410. If you have questions about your rights as a research subject, you may call the CDC Deputy Associate Director for Science, at 1-800-584-8814.

By signing below, I agree that I have read this consent form. I have been given the chance to ask questions about the study. By signing, I have not given up any of my legal rights. I agree to be in the study of Human Exposure to Cyanobacterial Toxins in Recreational Waters.

Participant Signature: _____ Date: _____

Flesch-Kincaid reading level: 8.0*

* I did not include the “Persons to Contact” paragraph

Human Exposure to Cyanobacterial Toxins in Water

Adult Consent Form

Introduction

The California Department of Public Health (CDPH) and the Centers for Disease Control and Prevention (CDC) are doing a research study on human exposure to blue-green algae. We know that sometimes blue-green algae grow very quickly to form blooms. Blue-green algae blooms can occur in waters where people swim and play. Sometimes these blooms can make chemicals (called toxins) that make the water taste or smell bad. Sometimes there may be smaller blooms in the water that don't make the water smell or taste bad. But, there still might be a very small amount of the toxins in the water. Through this study, we hope to learn about if the toxins made by blue-green algae can get into your body when you work, swim, or play in the water. We also hope to learn if these toxins can be found in your blood. We are asking you to be in our study because there is a blue-green algae bloom in the water here today.

Study Purpose

Animals, such as cattle and dogs, can get sick or sometimes even die when they drink water with a lot of blue-green algae toxins in it. People usually stay away from the water when there are blue-green algae blooms because the water smells and tastes bad. But no research has been done to find out what happens if very small amounts of blue-green algae toxins are in water where people swim and play. We are trying to find out if people who work, swim, and play in water that has these toxins in it can feel bad or get sick. We also want to know if people might have these toxins in their blood. We will only need about 45 minutes of your time today and about 15 minutes for a phone call about 10 days from now.

Procedures

This study has three parts. One part will be done now and one will be done after you come back from the water today. The third part will be done by phone in about 10 days.

Part 1: First, we will ask you some questions about yourself. Second, we will ask you some questions about your symptoms.

Part 2: When you come back from your activities today, we will ask you about your symptoms again. We will also ask you to give a sample (about 10 ml or 2 teaspoons) of your blood. Your blood will be analyzed only for microcystins, the toxin made by the blue-green algae in the water. After these analyses, all left-over blood samples will be thrown away. The samples will not be saved for future analysis.

Part 3: We will call you on the phone in about 10 days and ask you about your symptoms.

We will not give you the results of the tests for microcystins. This is a research study, and we cannot tell you what it means to have very small amounts of microcystins in your blood.

Who should not be in this study

This is a minimal risk study, and if you can swim and play in the water, you can be in this study.

Risks/discomforts

You may feel a slight sting or “pinch” in your arm when the blood is drawn. You may also get a small bruise where the needle went in. Some people faint when their blood is drawn, but this is rare. However, if you feel sick after being in the study, please notify your health care provider. There are no known side effects from being in this study.

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Compensation

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Right to refuse or withdraw

You are free to join the study or not. You may also leave the study at any time, for any reason. If you decide not to join, or to drop out later, you will not lose any health care that you may expect apart from this study. If you decide not to join or to drop out later, it will not affect you in any way.

Persons to contact

You will be provided a copy of the consent form. If you have any questions about the study, you may call one of the study investigators: Dr. Sandy McNeel, CDPH at 510-620-3644 or Dr. Lorrie Backer, Health Studies Branch at 770-488-3410 {or Andrew Reich, Florida Department of Health at 850-245-4444 ext 2295 or other state partner}. If you have questions about your rights as a research subject, you may call the CDC Deputy Associate Director for Science, at 1-800-584-8814.

By signing below, I agree that I have read this consent form. I have been given the chance to ask questions about the study. By signing, I have not given up any of my legal rights. I agree to be in the study of Human Exposure to Cyanobacterial Toxins in Recreational Waters.

Participant Signature: _____ Date: _____

Date: ___/___/___
mm dd yyyy

Time of Interview: ___AM PM

Place of Interview: _____

First, I would like to thank you for being in our study. I would like to remind you that you may refuse to answer any of the questions.

This study takes place in two parts. Today I am going to ask you questions about work or recreation activities around water and some health questions. I'll do that now and again when you are done for the day. I'd like to follow up with you in about 10 days to ask some health questions. I will telephone you to get that information. Is that all right?

May I please have your name and phone number:

Last Name First Name MI

Telephone Number: _____
Daytime

Evening

Cell Phone

Beeper

Your name & phone number will only be used to call you back in 10-14 days. After that time, we will remove your name & phone number from our records and it will not be kept as any part of this research study.

Now, I would like to ask you some questions about yourself.

Did you visit a water recreation area in the last 7 days?	Age (yrs)	Sex	With which racial group do you most closely identify?	Are you of Hispanic origin?
Y N DK R		F M	1. American Indian/Alaska Native 2. Asian 3. Black or African American 4. Native Hawaiian/other Pacific Islander 5. White 6. Don't know 7. Refused	Y N DK R

Now, I would like to know if you have done any of these water-related activities in the last 7 days.

This area	Public pool	Back yard Pool	Beach	Lake	River	Spa/Hot Tub
Y N DK R	Y N DK R	Y N DK R	Y N DK R	Y N DK R	Y N DK R	Y N DK R

PRE WATER ACTIVITY SURVEY

Now I'm going to ask you some questions about water-related activities you may have done for work or recreation.

Then, I will read from a list of health symptoms. I'd like to know if you have had any of these in the past 7 days or if you have them today.

Interviewer Initials:_____

First, I have a few questions about your work-related and recreational activities that involve water.

1. In the last year, have you been boating on lakes, rivers, or reservoirs?

NO	1
IF NO, GO TO QUESTION 2	
YES	2
DON'T KNOW	8
REFUSED	9

1a. Can you tell me the name or names of the lakes, rivers, or reservoirs you boat on?

2. In the last year, have you been fishing on lakes, rivers, or reservoirs?

NO	1
IF NO, GO TO QUESTION 3	
YES	2
DON'T KNOW	8
REFUSED	9

2a. Can you tell me the name or names of the rivers, lakes, or reservoirs you fish on?

2b. Do you eat the fish you catch on these lakes, rivers, or reservoirs?

NO	1
YES	2
DON'T KNOW	8
REFUSED	9

3. In the last year, have you worked or been swimming, water skiing, or jet skiing on lakes, rivers, or reservoirs?

NO	1
IF NO, GO TO QUESTION 4	
YES	2
DON'T KNOW	8
REFUSED	9

3a. Can you tell me the name or names of the lakes, rivers, or reservoirs you work, swim, water ski, or jet ski on?

Now, I have a few questions about some dietary supplements you may or may not be using.

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

- NO 1
- IF NO, GO TO QUESTION 5
- YES 2
- DON'T KNOW 8
- REFUSED 9

4a. 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

4b. How much of the supplement do you take?

- | | AMT. | UNITS (PILL, TSP., ETC.) |
|------------|------|--------------------------|
| DON'T KNOW | 8 | |
| REFUSED | 9 | |

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

- NO 1
- IF NO, GO TO END
- YES 2
- DON'T KNOW 8
- REFUSED 9

For each supplement, can you tell me what the supplement is, when you started taking it, how much you take, and how often you take it?

Supplement	When started?	How much?	How often?
____/____	DAILY mm / yyyy	1 AMT UNITS	MORE THAN 1/WEEK 2 MORE THAN 1/MONTH 3 OCCASIONALLY 4 DON=T KNOW 8 REFUSED 9

____/____	DAILY mm / yyyy	1 AMT UNITS	MORE THAN 1/WEEK 2 MORE THAN 1/MONTH 3 OCCASIONALLY 4 DON=T KNOW 8 REFUSED 9
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Now, please tell me if you have experienced any of the following symptoms within the last 7 days.

Symptom or Problem	When did it start?	When did it end?	Do you still have the symptom or problem?
First I have some general health questions.			
Fever Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Chills Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Headache Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Sore throat Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Ear ache Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Discharge or fluid running from ear Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R

Symptom or Problem	When did it start?	When did it end?	Do you still have the symptom or problem?
	DD MM YY	DD MM YY	
Abdominal pain Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Nausea Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Vomiting Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Diarrea Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Diarrea with blood Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Other (specify)_____ Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Now, I have a few questions about eye symptoms			
Blurred Vision			

Symptom or Problem	When did it start?	When did it end?	Do you still have the symptom or problem?
Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Irritation or pain Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Redness or discharge from eyes Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Conjunctivitis Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Other eye problems (specify)_____ Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R

Now I have a few questions about breathing-related symptoms

Cough or choke Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Shortness of breath Y N	DK R	DK R	Y N

Symptom or Problem	When did it start?	When did it end?	Do you still have the symptom or problem?
DK R	___/___/ DD MM YY	___/___/ DD MM YY	DK R
Nasal congestion or runny nose Y N DK R	DK R ___/___/ DD MM YY	DK R ___/___/ DD MM YY	Y N DK R
Throat irritation Y N DK R	DK R ___/___/ DD MM YY	DK R ___/___/ DD MM YY	Y N DK R
Other (specify) _____ Y N DK R	DK R ___/___/ DD MM YY	DK R ___/___/ DD MM YY	Y N DK R

Thank you. Now, I have some questions about problems you might have with your nerves

Agitation Y N DK R	DK R ___/___/ DD MM YY	DK R ___/___/ DD MM YY	Y N DK R
Confusion Y N DK R	DK R ___/___/ DD MM YY	DK R ___/___/ DD MM YY	Y N DK R
Dizziness Y N DK R	DK R ___/___/ DD MM YY	DK R ___/___/ DD MM YY	Y N DK R

Symptom or Problem	When did it start?	When did it end?	Do you still have the symptom or problem?
	DD MM YY	DD MM YY	
Lethargy Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Loss of consciousness Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Weakness Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Seizures Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Numbness Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Tremor Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R

Great. Now, just a few questions about skin problems.

Itchy skin			
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Symptom or Problem	When did it start?	When did it end?	Do you still have the symptom or problem?
Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Red skin Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Hives or welts Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Skin irritation/pain Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Rash (describe) _____ Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Infected cuts or scrapes Y N DK R	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R
Other (specify) _____ Y N DK	DK R ____/____/ DD MM YY	DK R ____/____/ DD MM YY	Y N DK R

Symptom or Problem	When did it start?	When did it end?	Do you still have the symptom or problem?
R	DD MM YY	DD MM YY	

Thank you for being in our study.