RESEARCH SUBJECT INFORMATION AND CONSENT INFORMATION SHEET

TITLE: Investigating Health Impacts of Exposure to Harmful Algal Blooms

PROTOCOL NO.: RI-ET-001
WCG IRB Protocol #20190387

SPONSOR: The Roskamp Institute, Inc.
Sarasota, Florida
United States

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SUMMARY

The purpose of this consent form is to help you decide if you want to be in the research study.

It may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this form to think about or discuss with family or friends before making your decision.

If you say you agree to be a part of this study, you are giving permission (or consent) to be a part of this study. You can agree to take part in this study and change your mind later.

Before deciding whether to be in this research study, it is important that you read and understand this consent form. You should not give verbal consent if you have questions that have not been answered. A study staff member will review this consent form with you.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- This study is not a treatment study, but rather a study measuring the effects of being near harmful algal blooms on the body (central nervous, immune system and respiratory systems).
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study.
- This is not a treatment study, so you will not receive any investigational medication.

PURPOSE

The goal of this project is to study the biological effects of environmental toxins, particularly aquatic toxins, such as brevetoxins (PbTx), microcystin, or their metabolites. These are the toxins that are present in algal blooms that occur in the Gulf Coast of Florida. In particular, the most widely known one, "red tide", is shown to affect the respiratory system and the brain, but how that happens is generally unknown. The objectives of this project include (1) identification of these environmental toxins in blood, (2) blood markers that can detect past/current exposure to these toxins, and (3) to study the short-term and long-term adverse effects on the brain and the respiratory system. The researchers want to see how your body reacts when you are exposed to harmful algal blooms, particularly red tide blooms.

Approximately 400 individuals who meet study criteria will be recruited and enrolled in the study. The second visit will be conducted about 12 months after the first visit, and the total enrollment duration is 4 years to enroll all participants. Individual participation will last about 12-18 months. Depending on the timing of the bloom, you may be asked to return after 9-12 months. Visits may occur earlier or later if there has been recent algae exposure. Semi-annual contact with study staff shall be required to assess safety, changes in medications, and to complete one questionnaire.

PROCEDURES:

MAIN STUDY
You will be asked to complete at least two (2) in-person visits, where the goal is that one visit will take place during the harmful algal bloom period and the other visit will be when there is no harmful bloom. If your area does not get frequent blooms, you may still be asked to participate in the 2 study visits, regardless of bloom status.

These visits may take place at the Roskamp Institute Clinic or their affiliate's location or in a remote site location, such as site-traveling RV (mobile clinic/lab).

You will be required to complete assessments either in person or electronically concerning your health.

The screening/enrollment visit will consist of:

- Reviewing the consent form
- Giving a list of your medical history/medications
- Obtaining vital signs, including height and weight
- Filling out a health survey and assessments for memory, learning, and other measures about general mood, diet, and activities of daily living.
- You may also be asked about your gait, whether you are experiencing migraines, and the general quality of your life.
- Lab samples will be collected (blood).

The in-person study visits will be conducted about every 9-12 months and will include a health survey, including red tide exposure, review of medications and any changes to your health, vital signs (and weight), and collecting a blood sample. During the study, you will complete a variety of cognitive assessments relating to quality of life, memory, learning, mood, diet, and activities of daily life.

There is no study medication (investigational product) given to you as part of this trial.

If you are experiencing symptoms, you may be asked to participate in additional assessments. You may also be asked to complete additional clinical assessments that test your ability to think, pay attention, and your memory. These tests may ask you to fill out forms that ask about your mood and other emotional aspects. A physical and/or neurological exam may be conducted.

In addition, the study investigator may refer you to your primary care physician for an additional work-up, which would be considered part of your regular medical care, and not part of the study. However, the study doctor may ask you to provide a copy of those records to assess your medical conditions or differentiate any effects from the red tide exposure.

You may be asked to return for an unscheduled visit if you experience symptoms/changes with your medical conditions and/or have experienced recent exposure to red tide algae.

Additionally, you will be contacted by phone, mail, or email for the purposes of coordinating study procedures, specifically for scheduled 6-month telephone calls, texts, and emails to check on your health status, fill out questionnaires, appointment reminders, and to update you about

any new information about the study. It is your responsibility to notify study staff of any health changes, including changes to your medication.

The lab samples required are up to 3-4 tablespoons of blood.

SUB-STUDY

You may be asked if you wish to participate in the sub-study. You may be randomly selected to take part in the sub-study, which will measure the amount of aerosolized PbTx (harmful algae) in your body via blood, urine, or fecal sample measurements. All subjects that enter the sub-study will be exposed to harmful algae blooms. It is estimated that approximately 45 of the 400 subjects will complete the sub-study. Sub-study participation will last approximately 4-5 days.

The sub-study will focus on how your body and brain react to being out in red tide all day long. The sponsor is interested in this aspect of the study to see how red tide toxins or other algal toxins can enter your body during different intensities of red tide blooms. This will be achieved by measuring how much algal toxins are present in your blood during the day. Your screening/enrollment visit will serve as your baseline visit. When the bloom is present in your area, study staff will contact you via phone or email to initiate the sub-study. Sub-study initiation will consist of questions regarding your medications, confirming eligibility, a health survey, and a pregnancy test if applicable.

Approximately 5 days after sub-study initiation (day 5), you will be provided with a personal air monitor for measurements of your body's exposure to red tide toxin when you are exposed to the bloom. You will be asked to spend an entire day outside near the water, such as at a local beach or park, as you normally would. On this day of the bloom, for one whole day, you shall be asked to spend as much as 8 hrs. outside during the red tide blooms, which may already be part of your regular job and activity. Study staff will be with you at your relevant location near the bloom for the study procedures.

Air quality samples will be taken close to the suspected exposure location. During the 5th day, you will be asked to provide blood, nasal swabs, and urine/fecal samples (as available) at every 2-hour interval, for a minimum of 3 timepoints (i.e., at 0hr, 2hr, 4hr, 6hr, and 8hr), but can be adjusted if required. During this time, the sub-study health survey will be completed at each timepoint and, thereafter, any change in sign/symptom reporting will be collected during the day.

After day 5, you may be asked to come to the Roskamp clinic, or study staff will meet with you at your relevant location for the following 3 days (day 6, 7, and 8), but this can be adjusted if required. During this time, you will be asked to avoid being outside or going near the red tide bloom areas as much as possible. At these visits, blood, nasal, urine, and fecal samples will be collected as applicable. The sub-study health survey will also be administered to you, as well as vital signs, and we will assess any changes in your concomitant medications. You will be given packaging to collect urine and fecal samples at home (if needed) and return to the site. The blood samples may also be used for preparation of DNA for genetic testing and for measuring environmental toxins (for example PbTx and its breakdown product). There is no investigational product provided as part of these studies, and the study is for research purposes only. This study will not involve testing of your whole genome (all your genes). You will not receive the results of these tests.

Additional Risks for Sub-study:
For the Sub-Study, for multiple timepoints, to facilitate blood collection, the following may be used, if you prefer this method over standard blood collection:

Intravenous Catheter

- **Methods:** Placement of an intravenous (IV) catheter to facilitate vein access for blood samples.
- **Risks**: While this procedure is generally safe, it carries potential risks, including but not limited to infection, bruising, bleeding, pain, or injury to surrounding tissues or veins.
- **Limitations**: Requires proper flushing to prevent clotting and may be suitable for long-term use.

By signing this sub-study consent form, you acknowledge and accept these risks. Study staff will take all reasonable precautions to minimize complications.

Please date and initial below if you agree to be randomly selected for this Sub-study.
You will also sign the last page of the consent form for the sub-study.

Initials: _____ Date: _____

POSSIBLE FUTURE USE OF SAMPLES
It is anticipated that all samples will be consumed for the experiments in this study. However, if any samples remain, they will be banked at the Roskamp Institute. Although no future studies are planned at this point, improvements in technology may facilitate validation of our findings, in which case it will be logical to apply that technology to further analyze the samples. Therefore, if the need arises, Sponsor will request appropriate approval/exemptions before conducting any experiments where applicable. Your anonymized data and associated samples may be shared with other researchers working on harmful algal bloom toxins. By signing this consent form, you agree to allow your samples to be used at Sponsor's discretion for this study.

RISKS
The known risks of exposure to harmful algae bloom/red tide include the following: Skin and eye irritation, gastrointestinal and respiratory irritations, acute gastroenteritis with accompanying neurologic symptoms upon consumption of contaminated shellfish, respiratory distress, such as reversible upper respiratory syndrome with symptoms of coughing, sneezing, and feelings of irritation to the airways.

People are often exposed by direct skin contact with contaminated waters, drinking contaminated water, breathing in airborne droplets of the toxins, or eating contaminated shellfish. Once exposure has stopped, symptoms usually resolve anywhere from 15 minutes to within a few days.

There are minimal risks related to providing lab samples, as well as related to visit assessments. These risks include bruising, bleeding, pain, or infection at the puncture site and the risk of light-headedness or fainting from having your blood drawn. The study staff will draw blood while seated and will apply pressure to the puncture site immediately after the blood is drawn.

Another risk is possible fatigue and other related cognitive symptoms due to visit length and cognitive tests.

Currently, there is limited research on studying the effects of red tide exposure during pregnancy in humans. The investigator is not asking you to make any changes to your behavior or daily activities but encourages you to stay informed and take precautions as necessary. Please inform study staff of pregnancy, and any changes you may experience. It is always a good idea to consult with your doctor for personalized advice and to discuss any concerns you may have regarding exposure to red tide.

Other Risks
This is not a treatment study. You should continue to see your regular doctor(s) during the study for your medical care.

Confidentiality: To maintain confidentiality to the extent possible, the study records will be kept at the site, and you will be given a study number to protect your personal information. Records will be stored in a locked office and only accessible to study staff. Electronic records are password-protected with de-identified data.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study. You may be asked to review and sign a new consent form if this occurs.

BENEFITS
It cannot be promised that you will receive any medical benefits from being in this study. Information learned from this study may help future patients with exposure to environmental toxins.

COSTS
Tests and procedures that are done only for the study will not be billed to you or your insurance company. You should continue to see your treating physicians during the study.

PAYMENT FOR PARTICIPATION
You will be reimbursed for your participation at each visit up to $80/visit as a gift card on the day of your completed study visit.

For participants participating in the sub-studies, an additional stipend is available of $125 (as a gift card) at the end of the sub-study procedures.

ALTERNATIVE TREATMENT
This is not a treatment study. Your alternative is not to be in this study.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES
Federal regulations give you certain rights related to your health information. These include the right to know who will have access to your information and how they use it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you directly.

FREQUENTLY ASKED QUESTIONS

How Sponsor Will Store and Use Your Samples and Information:

Your whole blood, serum, plasma, and blood cells will be stored with number codes that cannot identify you directly. No results will be released from your blood, plasma, or serum to you or your family. Sponsor will also store your samples for future studies using new technologies as they become available to us. Your samples will be coded before they are processed in the laboratory, so that no one who works with any of the blood/urine/fecal/cell samples will be able to identify their source.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Who may use and give out information about you?

The study doctor and the study staff.

Who might get this information?

The sponsor of this research. "Sponsor" means any person or company that is:

- working for or with the sponsor, or
- owned by the sponsor.

Your information may be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- WCG Institutional Review Board (WCG IRB)
- The National Institute of Environmental Health Sciences (NIEHS)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to permit to use and giving out of my health information?

Then you will not be able to be in this research study.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

CONFIDENTIALITY
Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study.

Study/Medical Records, which identify you and the consent form signed by you, will be looked at and/or copied for research or regulatory purposes by:

- The Sponsor, The Roskamp Institute, Inc.
- The U. S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies,
- The National Institute of Environmental Health Sciences (NIEHS)
- WCG Institutional Review Board (WCG IRB).

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations. By signing this consent form, you authorize such access.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- If it is in your best interest
- If you do not consent to continue in the study after being told of changes in the research that may affect you

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

SOURCE OF FUNDING FOR THE STUDY
The sponsor, The Roskamp Institute, Inc., and grant funds were also received from the National Institute of Environmental Health Sciences (NIEHS).

QUESTIONS
Contact The Roskamp Institute at (941) – 256 – 8010 for any of the following reasons:

- If you have any questions about your participation in this study,
- If you feel you have had a research-related injury, or
- If you have questions, concerns, or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

WCG Institutional Review Board (WCG IRB)
Telephone: 1-855-818-2289
E-mail: clientcare@wcgclinical.com

WCG IRB is a group of people who independently review research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not give consent to participate in this study unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent information sheet for your records.

MAIN STUDY CONSENT

I have read this consent form (or it has been read to me). All questions about the study have been addressed. I freely consent to be in this research study.

I authorize the release of my medical and research records for the purpose of this study. By signing this consent form, I have not given up any of my legal rights.

Your signature documents your consent to take part in the main research study:

Signature of adult subject capable of consent	Date
Printed name	
Signature of Person Conducting Informed Consent Discussion	Printed Name of Person Conducting Informed Consent Discussion	Date

SUB-STUDY

- ☐ I also agree to participate in the Sub-Study if asked to participate:
- ☐ I do not agree to participate in the Sub-Study if asked to participate:

Signature of adult subject capable of consent	Date
Printed name	
Signature of Person Conducting Informed Consent Discussion	Printed Name of Person Conducting Informed Consent Discussion	Date