Attachment 5 Consent Form

Relief of Florida Red Tide Symptoms Using Loratidine, an Over-the-counter Medicine to Relieve Allergies and Congestion Consent Form

Version 5-15-08
Flesch-Kincaid Reading Level 7.8*
* I did not include the title or the paragraph under "Persons to Contact"

Exposure to Aerosolized Brevetoxins During Red Tide Events Consent Form

Background

The Centers for Disease Control and Prevention (CDC) and the Florida Department of Health (FDOH), are doing a research study on the health effects of red tide. We know that rough waves during a red tide bloom can make tiny water drops with the toxins made by the red tide. These water drops can be blown onshore by the wind and breathed in by people. We hope to learn more about how red tide toxins in the air can affect people. We are asking you to be in our study because you have worked with us before on red tide studies.

Study Purpose

Many people get symptoms when they are on the beach during a red tide. We have heard that taking over-the-counter medicines for allergies or nasal congestion may make people feel better. If we can show this in a study, then public health officials will be able to tell healthy local community members and beach visitors that they can use these medicines to relieve the symptoms of exposure to Florida red tide.

Procedures

If you have not already done so, we will give you a survey about your health history. We will give you either a single adult dose (1 tablet containing 10mg) of Loratadine or a placebo before you start work. We will ask you to do a symptom survey before and after your shift. Forty-eight hours later, we will repeat study activities except that, if you received Loratidine on the first day, you will now get a placebo, and if you received the placebo on the first day, you

will now get the Loratidine. We will do this study two times, one time when there is a red tide in Florida and one time when there is no red tide in the area.

Who should not be in the study

If you have liver or kidney disease, you should not be in this study. Also, if you have ever had an allergic reaction to medicine with an antihistamine in it, you should not be in this study. Finally, if you are pregnant, you should not be in this study.

Otherwise, if you are able to work you can help us with this study.

Risks or discomforts

The risk from this study is a possible allergic reaction to Loratidine or possible side effects from the Loratidine. The most common side-effects are drowsiness, headache, affects on your motor skills, retention of urine, dry mouth, blurred vision, and gastrointestinal distress.

Benefits

You will get no direct benefit by being in this study. By helping us with this study, you will help us learn what happens to people on the beach during a red tide.

Confidentiality

All of the information you give us will be kept as private as the law allows. No names or personal information will be used in any reports of this study. CDC is allowed by a law called the Public Health Service Act to do a lot of public health activities including this research study. This law allows us to ask you about a lot of things including your health. Being in this study is your choice. Nothing will happen to you if you don't want to be in the study. If you are in the study, you don't have to answer any questions you don't want to.

Reimbursement

We will give you $25 for each day for which you complete the study activities (a total of $100 if you complete study activities on all four days).

Right to refuse or withdraw

You are free to join this 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, nothing will happen to you and it will not affect your job in any way.

Adverse reactions

If a study participant has an adverse reaction to Loratidine, we will immediately call for emergency assistance, either from available lifeguards or by calling 911.

Persons to contact

We will give you a copy of the consent form. If you have any questions about the study, you may call Dr. Lorrie Backer, at (770) 488-3426. If you have questions about your rights as a research subject or about the role of the Institutional Review Board, you may call the CDC Human Research Protection Office, at 1-800-584-8814 (leave a message saying that you are calling about protocol 2805), or the Florida Department of Health Review Council for Human Subjects at (850) 245-4585, or toll free in Florida at (866) 433-2775.

By signing below, I agree that I have read this consent form, and have been given a copy to keep. 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 Exposure to Aerosolized Brevetoxins During Red Tide Events.

Participant Signature: _____ Date: _____