Information Collection Request

Supporting Statement
Part B

Human Exposure to Cyanobacterial Toxins in Water
OMB No. 0920-0527
Reinstatement with Change

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Project Officer:

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B. Collections of Information Employing Statistical Methods

B.1 Respondent Universe and Sampling Methods

The target population for this study comprises individuals in the U.S. who swim and play in recreational waters with cyanobacterial blooms that produce microcystins.

We will contact local recreational clubs (e.g., jet ski clubs) that typically use recreational waters that meet our criteria. We will also post flyers (Attachment 7) in these areas. When a microcystins-producing bloom is identified in a recreational area we will recruit study participants as they enter the area.

Using a brief screening questionnaire (Attachment 6), we will identify adolescents and adults who plan to swim or engage in recreational activities who meet our inclusion criteria (i.e., are at least 12 years old and plan to engage in recreational activities that involve generating an aerosol that can be inhaled (e.g., swimming, jet skiing).

We estimate that we will have a recruiting rate of about 80%. Thus, for each of the two studies, we expect to interview about 188 people using the screening questionnaire. For each of the two studies, we expect 150 people to agree to do the study activities. If we are able to detect microcystins in human blood and the aerosol samples, the next epidemiologic study will be designed to assess the biological effects from these exposures.

We will obtain informed consent as follows: 1). Informed consent from study participants who are at least 18 years old, and 2). Informed assent and parental consent form study participant who are between the ages of 12 and 18 years old.

B.2 Procedures for the Collection of Information

We will assess the presence of microcystins in recreational waters by analyzing water samples twice each day when we do study activities. In addition, we will analyze water samples for basic microbial water quality information (e.g., coliform bacteria counts).

We will collect health information using a questionnaire. Specifically, trained interviewers will administer questionnaires (see Attachment 2) to assess recent and current health symptoms. In addition, a trained phlebotomist will be hired to collect blood samples. The blood samples will be analyzed for microcystin levels.

Quality Control Procedures

The questionnaires will be administered by trained interviewers. Data coding and preparation will be done by the principal investigator and a statistician within the Health Studies Branch, NCEH. Questionnaire, blood analysis, and water sample analyses data will be double-entered by a contractor specifically hired to input data from this project.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

In the context of this study, response rate is defined as the percentage of people approached to be in the study who meet our eligibility criteria and who complete the study activities. We plan to maximize response rates by contacting recreational clubs with flyers and posting flyers in the relevant recreation areas (see Attachment 7). We plan to give each study participant $25 to reimburse them for any expenses they may incur while participating in study activities.

If a potential study subject is reluctant to participate in the study, the interviewer will discuss their reluctance in an effort to encourage the subject to participate. Based on experience

recruiting and interviewing subjects for our pilot studies, we anticipate the response rate for potential participants will be approximately 80%.

B.4 Test of Procedures or Methods to be Undertaken

All study materials have been evaluated in pilot tests involving 9 respondents. The pilot tests were used to more clearly delineate the recruiting and data collection procedures.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following individuals were consulted in reviewing the statistical procedures for this study:

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The data collection was designed by the Health Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC.

CDC Investigator:

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List of Attachments

Attachment 1	Section 301 of the Public Health Service Act (42 USC 241)
Attachment 2	60-day Federal Register Notice
Attachment 3	Screening Questionnaire
Attachment 4	Consent and Pre-exposure Questionnaire
Attachment 5	Post-exposure Questionnaire
Attachment 6	10-day Post-exposure Questionnaire
Attachment 7	Recruitment Flyer
Attachment 8	CDC IRB Approval
Attachment 9	Public Comments / Response