Request for Approval for Non-Material/Non-Substantive Change to Existing OMB/PRA Approved Data Collection
National Disease Surveillance Program - II: Disease Summaries
OMB 0920-0004

To Include:

The Harmful Algal Bloom-related Illness Surveillance System
(HABISS)
September 22, 2008

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The currently approved OMB/PRA information collection for CDC's broad surveillance program covers a number of surveillance investigations being conducted by a number of CDC's National Centers. The National Center for Environmental Health (NCEH) is requesting this change due to the need for adding yet another surveillance investigation to this overall information collection. Many of the elements of this new program are similar to those in the existing surveillance package. As in the original package, intensive surveillance was needed for a number of public health conditions because there were a number of unknown factors for those areas, and they were considered important public health concerns. This is the case for harmful algal bloom-related illnesses.

The extent of human illness caused by environmental exposure to algal toxins in drinking and recreational waters is an unknown, but emerging, public health concern. We do know that algal toxins include some of the most potent natural chemicals known and there is potential for exposure in any community using surface water for drinking or recreation. Harmful algal blooms (HABs) occur when an overgrowth of algae creates and environmental or health threat. Symptoms often occur from immersion, inhalation, and ingestion to water and/or food containing the toxin. The adverse health effects from HABs include the known shellfish poisonings, ciguatera fish poisoning, respiratory effects from aerosolized brevetoxins from Florida red tide, and other illnesses associated with exposure to the potent cyanobacterial (blue-green algal) toxins. There is evidence that the frequency and geographic distribution of HABs is increasing, and further increases in HABs are one of the most likely consequences of global climate change.

The CDC National Disease Surveillance Program is based on the premise that diseases cannot be diagnosed, prevented or controlled until existing knowledge is expanded and new ideas developed and implemented. In accordance with the principles of CDC's Surveillance Program, The National Center for Environmental Health (NCEH) is requesting an addendum to the existing approved clearance for 0920-0004, in order to conduct data collection under the Harmful Algal Bloom-related Illness Surveillance System (HABISS). This program addresses the "Healthy People 2010" focus area(s) of Environmental Health. Data collection is authorized by Section 301 of the Public Health Service Act, as is the case for the majority of other surveillance investigations currently covered under 0920-0004.

This data collection activity is a result of several meetings between the state entities and NCEH. Prior to January 2005, the states were using a non-standardized format for collecting state information on harmful algal bloom-related illnesses. Once NCEH identified the necessary stakeholders and designed draft questionnaires, a beta system was carried out in Florida and North Carolina. As more states have become aware of the system, demand for a domestic and international presence has increased. As a result, an addendum clearance package is being submitted in order to allow more entities to begin data collection immediately following OMB approval. The data collection authority for this study is Section 301 of the Public Health Service Act (42 USC 241) (See Attachment 1).

PRIVACY IMPACT ASSESSMENT INFORMATION

Overview of the Data Collection System

HABISS is a web-based surveillance system that allows collection of both human and animal health data as well as environmental data about the harmful algal blooms themselves. Data collection is organized in a modular format that can be expanded to suit the needs of state and local health and environmental protection agencies.

Public health agencies are provided with digital certificates that allow them to enter data into HABISS online. The system is presently being used in pilot programs by Florida, North Carolina, and Virginia. It is ready for online use by more state partners who will be added once OMB approval is obtained.

Items of Information to be Collected

Surveillance items to be collected include agency point of contact(s), geographic coordinates of algal event (s), laboratory algal identification results, time of algal events, time of human or animal exposure, case identifying information of those experiencing human illness (e.g. age/gender/mailing address/phone), route(s) of exposure, clinical signs and symptoms, medical review (s), clinical laboratory results, case definitions, case assessment, diagnosis, and follow-up data. Personal identifiers will be discussed in further detail, in Section A.10. CDC will ensure that several safeguards remain in effect throughout the duration of the surveillance system. These safeguards are also discussed in Section A.10. Screen shots of the web-based surveillance instrument can be found in Attachment 3 of this supporting statement.

Identification of Website and Website Content Directed at Children Under 13 Years of Age

This information collection will involve web-based data collection methods. Only state public health staff in the states who have successfully applied for and obtained funding from CDC and who have obtained digital certificates will be able to enter data into HABISS online. No content is directed to children under 13 years of age.

2. Purpose and Use of Information Collection

The purpose of this information collection is to gather specific data related to harmful algal blooms using the Harmful Algal Bloom-related Illness Surveillance System (HABISS). As is the case for other conditions within the National Disease Surveillance Program, state and territorial epidemiologists and scientists will be responsible for the collection, interpretation, and transmission of medical and epidemiologic information. NCEH will use the information to monitor and analyze this data in order to better understand the impact of algal blooms on the health of the general public.

States are usually made aware of a suspected HAB-related case from a citizen call, a local public health department, or a local health care provider. In most cases, a state epidemiologist will review the case information with their point of contact. Once the state becomes aware of a known or suspected case, an interview with the citizen is conducted and the data is entered into HABISS (Attachment 3). The state may also contact the laboratory or health care provider

(HCP) associated with the case. The state may extract only relevant data from the HCP's medical review or chart for HABISS. CDC may subsequently review the HABISS data entered by the state, however, CDC will not contact the citizen directly, nor will CDC contact the HCP. Data will be submitted to CDC on an ongoing (real-time) basis , thus encouraging timely data records of harmful algal events. Due to the variability and limited access to suspected case information, the state is not required to complete all survey questions. Any unknown variables will be completed in HABISS as "Don't Know." HABISS records will be completed with as much information as is available. CDC expects some states to be more detailed in their data collection but all will be expected to complete basic survey requirements (including CaseID, date/time of exposure, chief complaint, case assessment). CDC will monitor data on a weekly basis. The states will be required to submit a Monthly Report form (Attachment 4).

Privacy Impact Assessment Information

The information in identifiable form (IIF) will be used only for the purpose of recording and clarifying information that has been submitted to the states, and to avoid duplication of reporting of cases. There are no plans to share the IIF with anyone other than NCEH staff working on the HABISS program. The proposed data collection will have little effect on the respondents' privacy because no sensitive information is being collected.

3. Use of Improved Information Technology and Burden Reduction

This collection of information will be done in the same manner as the previously approved data collection; however there will be greater use of electronic techniques in lieu of paper reporting forms. Case reports captured by the surveillance system may necessitate a follow-up report over the phone. In order to increase efficiency and consequently decrease respondent burden, end-users will be interviewed at their convenience. The surveillance instruments require collection of only the minimum information necessary for the purposes of surveillance system.

4. Efforts to Identify Duplication and Use of Similar Information

Because NCEH staff is in communication with State and Territorial Health Officers, as well as staff of state and local health departments, it is clear that no nationwide collection exists for this field of study. Adverse human health concern that may be linked to the presence of harmful algal blooms is a public health problem, but there is no prior history of national surveillance. Other information on the diseases included in this new change package is available only for limited geographic areas or collected in one-time studies. Communications with experts in Harmful Algal Bloom Illnesses did not bring to light any similar data collection surveillance efforts. No other collective surveillance exists that tracks nationwide HAB-illnesses.

5. Impact on Small Businesses or Other Small Entities

As in the previously approved data collection, no small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

Control and prevention of harmful algal bloom poisoning is dependent on quick identification of changes in human health and environmental data. The frequency requested for submission of data in this package is dependent on the particular epidemiology of the algal poisoning. Without prompt notification to NCEH, generally on a monthly basis, outbreaks might go undetected.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Special circumstances do exist which require information collection to be conducted in a manner more often than quarterly. Prevention efforts are intended to decrease potential human and animal exposure to harmful algal blooms. In order to capture a significant variation in the number of illness cases being reported in a particular state(s), information collection may require *weekly* reporting during and following periods of large algal blooms events. Ordinary conditions are met when no indication of a harmful algal bloom exists in a particular geographic area. Even under ordinary conditions, monthly reporting is felt to be necessary since human/animal illness reports are not always linked to a heavily monitored water body (Attachment 4).

Other than those mentioned previously, there are no other special circumstances associated with this data collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. This is a request for change to an existing approved OMB/PRA data collection; therefore, no Federal Register notice is required.

B. The following individuals were consulted to obtain their views on the availability of data, the clarity of instructions, disclosure, and on the data elements to be recorded and reported.

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9. Explanation of Any Payment or Gift to Respondents

Participants will not receive any cash payment or gift for participating in harmful algal bloom surveillance.

10. Assurance of Confidentiality Provided to Respondents

Identifying information such as name, date of birth, mailing address, e-mail, and phone number of those experiencing human illness caused by environmental exposure to algal toxins in drinking and recreational waters will be collected by the state, along with the somewhat personal information regarding the health status of those symptomatic individuals. State Health Agencies need to collect identifying information for personal follow-up contact with respondents to complete the information specified in the surveillance system modules. We will not request or collect social security numbers or photographic identifiers. For aggregate data analysis at NCEH, we will use unique system identifiers assigned by the states. If a given state has not adopted this system of record-keeping, a unique identification number (ID) will be assigned for each record by the surveillance system. Furthermore, state-based personnel with access to the data will only be able to view data from their state. They will not be able to view data from other states. Finally, by year two of this project, NCEH will require the use of unique IDs in lieu of name and address. Presently, only two Federal contractors (the Developer and the Surveillance Coordinator) have access to the identifiable HABISS data. Any future contractors or federal employees working on the surveillance system would be subject to rigorous training and CDC's rules of confidentiality. CDC access to HABISS data will always be limited to a very small number of trained employees.

Privacy Impact Assessment Information

A. In certain states, the web-based system HABISS will supplement and/or replace existing record systems at the state and local health department levels. In addition the two NCEH staff with responsibility for the system will have access to the identifiable data; therefore the Privacy Act does apply. Records will become part of Privacy Act system of records notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems."

As with other surveillance classifications (e.g. influenza, diarrheal, foodborne) under OMB 0920-0004 clearance, this surveillance system is not subject to IRB review and approval.

HABISS will only collect electronic records from state and local government agencies. Paper documents will neither be distributed nor collected by NCEH. HABISS operates on a secure platform, the Rapid Data Collector (RDC), which was engineered specifically for electronic survey design and data collection. Since the states need to use the data personal identifiers for follow-up purposes, it has been requested that the information be securely collected and stored for their later retrieval in HABISS. NCEH has reviewed the various options that might allow personal information to remain with the states, and not be accessible at the Federal level. After having reviewed these options, NCEH has concluded that the resources required to implement such a fundamental change are extensive and are not available at this time. However, the HABISS developer has agreed that a non-transmittable component will be a core consideration for RDC (Rapid Data Collector) 2.0, where HABISS is the flagship surveillance system.

B. A comprehensive Privacy Impact Assessment for the Rapid Data Collector system was completed in 2006. The following technical components and controls remain in place as of May 2008:

- UserID
- Password (including expiration, minimum characters, and a lock feature)

- Firewall
- Encryption
- Public Key Infrastructure

Furthermore, access to HABISS (through RDC) will be limited to users on a permission-only basis. All contractor staff working on the project will agree to safeguard the data and to not make unauthorized disclosures. Data will be safeguarded in accordance with applicable statutes including the Privacy Act. Responses in any future published reports will be presented in aggregate form and no individuals will be identified.

C. State participation in the surveillance collection is voluntary.

D. Individual consent for human case reports will be obtained by the health care professional or state epidemiologist responding to the illness report in question. HABISS is a mechanism for the states to conduct surveillance, and therefore, CDC will not collect consent directly from any individuals.

11. Justification for Sensitive Questions

Questions of a highly sensitive nature will not be asked. Social security numbers and photographic identifiers will neither be requested nor collected. Epidemiologic characteristics such as age, sex, and geographic location are routinely collected because of their significance in resolving public health problems. At times questions to be asked will include collection of race and ethnicity data, which may be considered sensitive by some persons, but are routinely collected in HHS/CDC data collections. If race/ethnicity is not an integral part of the State's epidemiologic investigation, it will not be collected. Clinical laboratory data are essential to proper identification and control of HAB-illnesses and will be submitted to NCEH.

12. Estimates of Annualized Burden Hours and Costs

A. Burden hours are included in Table 1. Approximately 10 State and/or local public health agencies will participate in harmful algal bloom surveillance activity. Ongoing data collection -- completing HABISS web-based forms (e.g., the Human Illness Report, Information about the Case, Patient Reported Environmental Conditions, etc.) is estimated to take each state an average of 8 hours a month. In addition to ongoing data collection, NCEH will request that each State report to CDC on a monthly basis. An average of eight burden hours per month to complete the forms was used to estimate the total burden expense (in hours) taking into account the investigation/reporting process associated with the forms. Based on preliminary testing at NCEH, monthly reporting to CDC is estimated to take 30 minutes per month.

Table 1: ESTIMATE OF ANNUALIZED BURDEN HOURS				
Form Name	**Number of Respondents**	**Number of Responses / Respondent**	**Average Burden per Response(hrs)**	**Total Burden (hrs)**
HABISS Data Entry	10	12	8	960
Monthly Reporting	10	12	30/60	60
Total				1020

B. Burden costs are included in Table 2. Approximately 10 State and/or local public health agencies will participate in harmful algal bloom surveillance activity. In addition to ongoing data collection, NCEH will request that each State report on a monthly basis.

Table 2: ESTIMATE OF ANNUALIZED BURDEN COSTS			
Type of Respondents	**Total Burden Hours**	**Hourly Wage Rate**	**Total Burden Costs ($)**
State Epidemiologists	1020	$40.00	$40,800

The burden of this surveillance activity is to be included in OMB No. 0920-0004 (Expiration 10/2010).

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital or maintenance costs incurred by respondents or record keepers due to the fact the health departments already have in place an existing computer system. HABISS will be utilizing the system already in place.

14. Annualized Cost to the Government

CDC will award up to $150,000 in grant funding to each state to support the HABISS program. Up to ten states are expected to receive grant awards by year's end of 2008. Total grant money distributed from CDC will not exceed $1.5M.

Monthly reports to CDC may result in action taken by NCEH in response to the required CDC mandate in maintaining preventive health activities and surveillance systems. The action taken will vary, depending on the specifics and severity of the reports.

Additional expenses will be incurred by CDC in order to operate a successful surveillance program. Three staff will contribute to this program: a Senior Scientist (5% contribution=$6000, a contracted Surveillance Coordinator (75% contribution=$37,000) and a contracted Developer (5% contribution=$5000). Lesser expenses may include computer resources, telephone calls, and training materials (approximately $2,000).

The estimated annual cost to the government is $1,550,000.

15. Explanation for Program Changes or Adjustments

This is a new surveillance data collection being added to the existing surveillance summaries. It will add 1,020 hours to the current total burden hour estimate (21,107 hrs) for all forms within 0920-0004, making the new total 22,127 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

Statistical Analysis Plan:

CDC will aggregate the data sent to us by the states every quarter (in 3 month cycles). The states will conduct their own statistical analyses and present the data per state needs.

A. 16-1	
Activity	**Time Schedule**
Activation	1 - 2 months after OMB approval
HABISS User Training	2 – 3 months after OMB approval
Surveillance Activity	Ongoing data collection

Summary Reports	Every 3 months after OMB approval
Yearly HABISS Evaluation	Each year after OMB approval

In order to provide HAB surveillance training to the state users, NCEH may choose to host a workshop in lieu of telephone-based instruction (Attachment 5). We also plan to publish selected summary reports on CDC's website during the second year of this project. In addition, summary reports will be included as part of CDC's ongoing reports of waterborne diseases.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Exemption from displaying the expiration date for the OMB approval of forms is not being requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification for Paperwork Reduction Act Submissions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

The HABISS coordinator will conduct periodic statistical analyses on the data in the system. Statistical analyses will be done using SAS (SAS Institute, Cary, NC) and Microsoft Access. Quarterly summary statistics will include:

- Number of possible, probable, and confirmed human cases per state
- Mean age of case
- Numeric distribution of signs/symptoms
- Numeric distribution of mechanism of exposure
- Temporal trends / standard epidemiologic curves
- Geographic trends
- Other descriptive statistics

The HABISS coordinator may employ the following methodology:

- Data transformation
- Case classification
- Baseline estimation
- Underlying pattern detection

1. Respondent Universe and Sampling Methods

This activity is not research; respondents are neither recruited nor sampled. Furthermore, no sample selection is involved in this surveillance study. The surveillance instructions will be distributed to the States that are awarded funding for HABISS data entry. State and local department staff submits these reports to NCEH on monthly basis.

2. Procedures for the Collection of Information

Data on disease and preventable conditions are collected in accordance with jointly approved plans by CDC and the Council of State and Territorial Epidemiologist (CSTE). Changes in the surveillance program and in reporting methods are affected in the same manner. At the beginning of this surveillance program CSTE and CDC decided which diseases warranted surveillance. These diseases are reviewed and revised based on variations in the public's health.

3. Methods to Maximize Response Rates and Deal with Non-response

There is not a method to deal with non-response since the state entities will submit surveillance data as part of their HABISS grant activity. Therefore, the response rate is expected to be close to 100%.

4. Tests of Procedures or Methods to be Undertaken

A beta version of HABISS was carried out in Florida and North Carolina. No further procedures or methods are needed at this time.

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

Individuals consulted on statistical aspects:

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List of Attachments

Attachment 1 Authorizing Legislation: Section 301 of the PHS Act

Attachment 2 Federal Register Notice

Attachment 3 Screen Shots of the Data Collection Instrument

Attachment 4 Monthly Reporting Form

Attachment 5 Introductory Letter to States