

Emergency Epidemic Investigations
OMB No. 0920-0008

A. Justification

1. Circumstances Making the Collection of Information Necessary

The investigation of emergency problems is an integral part of the overall mission of the Centers for Disease Control and Prevention (CDC) and is authorized by the Public Health Service Act (42 USC Sec. 301 [241] (a) (Attachment A). Early recognition of adverse health conditions and rapid application of prevention and control measures are fundamental to CDC's contribution to healthy people in a healthy world. Epidemics and natural and man-made disasters create extraordinary demands for health services. Because of the immediacy, complexity, and sheer volume of these demands, frequently states and foreign countries look to CDC for short-term epidemiologic and laboratory expertise in a broad variety of diseases and conditions and expertise in dealing with rare infections and unknown agents. During epidemic investigations, emphasis is placed on the etiology and transmission of diseases so that prevention and control measures can be rapidly instituted.

During most emergency situations, CDC specialists (epidemiologists, biostatisticians, laboratory specialists, etc.) work under the aegis of a State or local health department. Often such investigations are completed by the State or local government, with technical assistance from CDC. Occasionally, an investigation must be continued or is multi-state or global in nature. (In these cases, CDC collects or sponsors the collection of information from the public.) We are requesting a three year extension of the current OMB approval which allows us to collect data during emergency situations. We are making one change for this request. A new form is being added requesting state and local officials to assess the promptness of investigations (Attachment E).

The circumstances in which emergency data collection authority is used include those in which:

- The agent is unknown and CDC must provide assistance in collecting and analyzing data on the conditions surrounding and preceding the onset of the problem
- The outbreak involves more than one state and uniform data is needed
- A delay in data collection would result in the loss of epidemiologic information essential to assist laboratory investigations

- A delay in investigation would hamper the ability of public health officials to provide information to the public and implement control measures
- A delay in data collection would result in disassembly of the respondent population.

CDC is requesting that this clearance maintain the 90-day outbreak investigation period under this clearance. If more than 90 days is necessary to complete an outbreak investigation CDC will begin procedures to conduct a full clearance request (regular or emergency).

2. Purpose and Use of the Information

One of the objectives of CDC's epidemic services is to provide for the prevention and control of epidemics and protect the civilian population from public health crises such as man-made or natural biological disasters and chemical emergencies. This is carried out in part by training investigators, maintaining laboratory capabilities for identifying potential problems, collecting and analyzing data, and recommending appropriate actions to protect the health and save lives. Data on the conditions surrounding and preceding the onset of a problem must be collected in a timely fashion so that information can be used to develop prevention and control techniques, to interrupt disease transmission, and to help identify the cause of the outbreak, etc.

In general, CDC is the Federal Agency most likely to receive the request to assist in investigating unusual clusters of morbidity or mortality, large outbreaks, and incidents affecting more than one State. The following are examples of categories and circumstances of emergency investigations carried out in recent years:

1. Outbreaks of diseases with unknown etiology and transmission, highly contagious, and high case fatality
2. Known diseases which are highly contagious, virulent and unknown source of infection or mode of transmission
3. Questionable increase in number of cases of known diseases
4. Incidences of infectious outbreaks among children
5. Health effects associated with forest fires
6. Outbreaks of sudden illness in employment surroundings
7. Outbreaks of illness in hospital neonatal nurseries
8. Outbreaks of illness in cruise ships

3. Use of Information Technology and Burden Reduction

Since the events necessitating the collection of information are of an emergency nature, most data collection is done by direct interview or

written questionnaire. Interviews are conducted to be as unobtrusive as possible and only the minimal information necessary is collected.

4. Efforts to Identify Duplication and Use of Similar Information

Literature searches and discussions with State and local public health officials are initially conducted to determine the extent of existing information. If found, previous information is used whenever appropriate to contribute to an investigation. However, an emergency situation generally requires the collection of data specific to the particular epidemic or emergency since each event is unique in many aspects.

Use of Similar Information

Each investigation does contribute to the general knowledge about a particular type of problem or emergency, so that data collections are designed taking into account similar situations in the past. Some questionnaires have been standardized, such as investigations of outbreaks aboard aircraft or cruise vessels.

5. Impact on Small Businesses or Other Small Entities

Every effort is made to minimize the burden on all respondents to the collection of information in emergency or epidemic situations. If during an emergency investigation, the need for further study is recognized, a formal project will be designed and a separate clearance request will be submitted to OMB (regular or emergency).

6. Consequences of Collecting the Information Less Frequently

Emergency investigations are one-time efforts related to a specific outbreak or circumstance. If during the emergency investigation, the need for further study is recognized, a project is designed and separate OMB clearance is required.

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

The data collections covered by this OMB clearance are consistent with the guidelines.

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

- A. The 60-day Federal Register Notice was published in the *Federal Register* on August 2, 2006 (Volume 71, Number 147, p. 43487). (Attachment B). There were no public comments.

B. As previously stated, CDC participates in the investigation at the request of the State or local health department or country, and the data collection plan is developed in collaboration with the health department(s) or country. Other Federal agencies, such as the Food and Drug Administration, the Department of Agriculture, the Environmental Protection Agency, Department of Homeland Security or Department of State are also involved in some investigations. These collaborating agencies are concerned with the overall conduct of epidemic investigations and specific aspects of the investigation related to their authorities. They generally have little input into actual questionnaire development of the epidemiologic investigations conducted by CDC.

9. Explanation of Any Payment or Gift to Respondents

Respondents are not remunerated.

10. Assurance of Confidentiality

The CDC Confidentiality and Privacy Officer has reviewed this application and has determined that the Privacy Act is applicable. Full names are not always collected; but at times this measure is necessary, particularly for correlation with laboratory reports. It should be noted that when CDC staff participate in epidemic investigations at the request of the State or local health departments and collect individually identified data, those records are being added to the already established record system of the health department, and the Privacy Act is not applicable. Names are generally retained by the collaborating state or local health department.

However, individually identified data are often brought to CDC for analysis, and under those circumstances, the Privacy Act does apply. Records are covered under CDC Privacy Act system notice 09-20-0113, "Epidemic Investigation Case Records" (Attachment C). In limited circumstances, confidentiality may be pledged for some epidemiologic surveys. The authority of such data collection is Sections 304 and 306, with confidentiality assured under Section 308(d) of the Public Health Service Act. There have been no cases requiring an assurance of confidentiality since the last OMB submission.

11. Justification for Sensitive Questions

Questions which might be considered sensitive (e.g., sexual behavior or attitudes) are included only when considered necessary for the particular epidemic or emergency situation being investigated. Respondents are informed that participation is voluntary, and are not personally identified in any published reports of the study.

12. Estimates of Annualized Burden Hours and Costs

A. Attachment D lists a brief description, number of respondents, and burden information for each use of the emergency epidemic investigation requiring clearance since the last submission. Copies of the forms are also included. The following table presents a summary of the total burden we are requesting for this clearance:

| Respondents | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours |
|-------------------------------------|---------------------------|--|---|---------------------------|
| General Public | 15,000 | 1 | 15/60 | 3,750 |
| Requesting State or Local officials | 100 | 1 | 15/60 | 25 |
| Total | | | | 3,775 |

It is difficult to predict the number of epidemic investigations which might occur in any given year. Historically, in the last year, the EIS Program coordinated 400 Epidemic Assistance Investigations (Epi-Aids) and state-based field investigations, with approximately 15,000 respondents. Epidemics are prevented and controlled by mobilizing and deploying CDC staff, primarily EIS officers to respond rapidly to disease outbreaks and disaster situations.

The hourly wage was based on the U.S. national average for 2006 taken from the Bureau of Labor Statistics website.

| Respondents | Total Burden Hours | Hourly Wage | Total Cost Burden |
|------------------------------------|---------------------------|--------------------|--------------------------|
| General Public | 3,750 | \$25.08 | \$94,050 |
| Requesting State or Local Official | 25 | \$25.08 | \$627.00 |
| Total | | | \$94,677 |

13. Estimate of Other Total Annual Cost Burden to Respondents or Record keepers

There are no capital or maintenance costs.

14. Annualized Cost to the Federal Government

The annual cost to the Government is estimated to be \$350,000. The cost factors considered are related to routine procedures of the medical epidemiologists and statistical personnel in planning investigations; forms design and copy preparation, printing and distribution of questionnaires; editing, coding, tabulation, analysis and presentation of the information.

15. Explanation for Program Changes or Adjustments

This request reflects a total burden hour increase of 25 hours since the last submission. We are making one change for this request. A new form is being added requesting state and local officials to assess the promptness of investigations.

16. Plans for Tabulation and Publication and Project Time Schedule

The epidemiologic data are used to provide information that is necessary in controlling an epidemic or emergency and preventing further unnecessary morbidity and premature mortality. Therefore, the collection of data, as soon as possible after the onset of the epidemic or emergency, is critical to the epidemiologic analysis of the data and is the responsibility of the principal epidemiologist. Any publication of data derived from epidemic studies is subject to the review of State health departments, CDC, or foreign countries.

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

We are not requesting an exemption to the display of the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certifications statement.

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Most of the investigations of epidemics or emergencies require the interviewing of all individuals affected by the condition in question. On some occasions, however, there is the need to interview a sample of affected individuals and matched controls. When statistical methods are employed in the collection of information, expert statistical assistance is available at CDC relating to sampling methodology, selection of controls and questionnaire design.

2. Procedures for the Collection of Information

In most cases, data is collected by self-administered questionnaire or personal interview. Specific procedures depend on the time and resources available, number of persons involved, and other circumstances critical to the emergency at hand.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Because of the cooperation of state and or local health departments, and the general interest and concern surrounding most epidemics or emergencies, response rates are very high (90 – 95%). Respondents are informed that their response is voluntary and that their privacy will be protected by Federal law.

4. Test of Procedures or Methods to be Undertaken

Pilot tests of procedures are usually not carried out because of the lack of time available before an investigation proceeds. However, for investigations which are similar, standard forms may be used as well as revised versions of forms used in previous investigations.

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

The CDC epidemiologists conducting investigations are trained in biostatistics and epidemiology. In most cases there is extensive collaboration with health officials of the State or local health department requesting assistance. All investigations are supervised by experienced epidemiologists with expert statistical resources available.

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| ATTACHMENT A | Authorizing Legislation |
| ATTACHMENT B | Federal Register Notice |
| ATTACHMENT C | Epidemic Investigation Case Records System Notice |
| ATTACHMENT D | Epidemic Investigations 2003 – 2005 |
| ATTACHMENT E | State and Local Officials Questionnaire |