Emergency Epidemic Investigations
OMB No. 0920-0008

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Supporting Statement A

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The investigation of emergency problems is an integral part of the 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 human-made disasters create extraordinary demands for health services. Because of the immediacy, complexity, and 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, as well as 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.) CDC is requesting a revision of the current OMB approved information collections that allow us to collect data during emergency situations for three-years.

The post Epi-Aid follow-up questionnaire is modified to better measure and address overall satisfaction, communication, response, and team composition and professionalism of the Epi-Aid team. Although modified, the burden of response time remains the same – primarily because more multiple-choice (versus open-ended) questions were added. The questionnaire will be completed online by state and local health officials, reducing the paper burden.

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

Since OMB last approved this data collection in January 2010, CDC's Epidemic Intelligence Service has conducted hundreds of epidemic investigations to protect the public's health worldwide. Investigations have identified the causes of outbreaks of *E. coli*, tuberculosis, salmonella and more, and findings have slowed or stopped the spread of disease, and resulted in reduced morbidity and mortality among people in affected areas.

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

1.1 Privacy Impact Assessment

1. The data collection methods used to collect the required data can be either by personal interview, telephone consultation, mail or secure online survey.
2. Data collected will consist of various fields depending on the outbreak that is being investigated. Examples of that data might be but not limited to race, gender, age etc.

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 human-made or natural biological disasters and chemical emergencies. CDC meets this objective, in part, by training investigators, maintaining laboratory capabilities for identifying potential problems, collecting and analyzing data, and recommending appropriate actions to protect 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, 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 during recent years:

1. Outbreaks of diseases with unknown etiology and transmission, which are highly contagious, and which have high case fatality
2. Known diseases which are highly contagious, virulent, and have 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 on cruise ships

2.1 Privacy Impact Assessment

1. The information will be shared with state and local health departments to develop a rapid response to outbreaks and develop prevention and control mechanisms against future outbreak.
2. There is no direct impact to the respondent privacy in the collection of this data.

3. Use of Information Technology and Burden Reduction

Because the events necessitating the collection of information are of an emergency nature, most data collection is done by direct interview or written questionnaire (Attachment D). Interviews are conducted to be as unobtrusive as possible, and only the minimal information necessary is collected. We are transitioning the state and local questionnaire (Attachment E) to 100 percent electronic reporting only. By implementing electronic data collection for the state and local form, this allows for additional information/data to be collected, without increasing the burden, as demonstrated by pilot testing.

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, because each event is unique in many aspects.

Each investigation does contribute to the general knowledge about a particular type of problem or emergency, and data collections are designed to incorporate knowledge gained from 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 questionnaires and interviews administered during the collection of information in emergency or epidemic situations. If during an emergency investigation the need for further study is recognized, CDC will design a formal project and submit a separate clearance request to OMB (regular or emergency).

6. Consequences of Collecting the Information Less Frequently

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

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

This request fully complies with the regulation 5 CFR 1320.5.

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 10, 2012, vol. 77, No. 155, pp. 47847 (Attachment B). As of October 4, 2012 information when this document was finalized, CDC received one non-substantive comment was received and a standard reply was sent.

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 the Department of State are involved in some investigations. These collaborating agencies are concerned with

the overall conduct of epidemic investigations and aspects of the investigation related to their authorities. They generally have little input into development of questionnaires and interviews for 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 collection of names 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. The use of this authority must be approved by the CDC Director. No cases requiring such as assurance of confidentiality have occurred since the previous OMB submission.

IRB approval is not required for the Emergency Epidemic Investigations (Attachment F). These investigations are not considered research, based on the description and justification, and also on the definition of research defined by the Federal Policy for the Protection of Human Subjects (45 CFR 46).

10.1 Privacy Impact Assessment Information

Respondents are informed that the information provided is not mandatory but collected on a voluntary basis. Any information collected will be secured in a locked and secure are according to the safe guards of the privacy act statement.

11. Justification for Sensitive Questions

Questions that might be considered sensitive (e.g., regarding sexual behavior or attitudes) are included only when considered necessary for the particular epidemic or emergency situation being investigated. Before administering questionnaires or interviews, investigators inform respondents (either verbally or in writing) that participation is voluntary, and that respondents are not personally identified in any published reports of the study.

12. Estimates of Annualized Burden Hours and Costs

A. Attachments D and E list a brief description, number of respondents, and burden information for each use of the emergency epidemic investigation requiring clearance since the previous submission. Copies of the forms developed for this data collection project are attached as appendices to this information collection request. The following table presents a summary of the total burden CDC is requesting for this clearance:

Estimated Annualized Burden Hours

Respondents	**Form Name**	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden (in hours)**
General Public	Emergency Epidemic Investigations	15,000	1	15/60	3750
State and local officials	Epi-Aid Satisfaction Survey for Requesting Official	100	1	15/60	25
Total					3775

Predicting the number of epidemic investigations that might occur in any given year is difficult. During the past year, the Epidemic Intelligence Service (EIS) Program coordinated 400 Epidemic Assistance Investigations (Epi-Aids) and state-based field investigations, with approximately 25,000 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 2012 taken from the Bureau of Labor Statistics website. http://www.bls.gov/oes/current/oes191041.htm#nat

Estimated Annualized Burden Cost

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Burden Costs
General Public	Emergency Epidemic Investigations	3750	$33.49	$125,587.50
Requestors of Epi-Aids	Epi-Aid Satisfaction Survey for Requesting Official	25	$33.49	$837.25
Total				$126,424.75

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; design, preparation, printing, and distribution of questionnaires; and editing, coding, tabulation, analysis, and presentation of the information.

15. Explanation for Program Changes or Adjustments

CDC is requesting a revision to the state and local questionnaire (Attachment E). The post Epi-Aid follow-up questionnaire was modified to better measure and address overall satisfaction, communication, response, and team composition and professionalism of the Epi-Aid team. Although modified, the burden of response time remains the same – primarily because more multiple choice (versus open-ended questions) were added. The questionnaire would be completed online by state and local health officials.

16. Plans for Tabulation and Publication and Project Time Schedule

The epidemiologic data provide information that is necessary for controlling an epidemic or emergency and preventing further unnecessary morbidity and premature mortality. Therefore, collecting data as soon as possible after the onset of the epidemic or emergency is critical to the epidemiologic analysis. Data analysis is the responsibility of the principal epidemiologist. Any publication of data derived from

epidemic studies is subject to review by state health departments, CDC, foreign countries, or collaborating federal agencies.

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

CDC is 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.

ATTACHMENTS

ATTACHMENT A	Authorizing Legislation
ATTACHMENT B	Federal Register Notice
ATTACHMENT C	Epidemic Investigation Case Records System Notice
ATTACHMENT D	Emergency Epidemic Investigations
ATTACHMENT E	Epi-Aid Satisfaction Survey for Requesting Official
ATTACHMENT F	(IRB) Research Determination