Emergency Epidemic Investigation Data Collections
OMB No. 0920-XXXX

Supporting Statement A

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March 20, 2014

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Emergency Epidemic Investigation Data Collections

Justification

Circumstances Making the Collection of Information Necessary

Background. The Centers for Disease Control and Prevention (CDC) is requesting approval for a 3-year period of a new Generic Information Collection Request (ICR) that will have the quick turn-around necessary for conducting Emergency Epidemic Investigations (EEIs) in response to acute public health emergencies resulting from outbreaks or events with undetermined agents, undetermined sources, undetermined modes of transmission, or undetermined risk factors. This ICR will replace the previously OMB-approved Emergency Epidemic Investigations ICR (OMB No. 0920-0008; expiration 7/31/2014), which applied specifically to information collections conducted by CDC under the Epi-Aid mechanism (a specific administrative mechanism enacted to support a field response) and will not be reinstated following expiration.

CDC is frequently called upon to conduct EEIs at the request of one or more external partners (e.g., local, state, tribal, military, port, other federal agency, or international health authorities or other partner organizations) seeking support to respond to urgent public health problems. In response to requests from external partners, CDC readily provides necessary epidemiologic support to facilitate appropriate engagement in epidemiological investigations. Epidemiologic support typically includes technical support in the form of expertise or information collection to help identify the agents, sources, modes of transmission, or risk factors to effectively implement rapid prevention and control measures when the situation is warranted. Such investigations often are dependent on rapid and flexible data collection that evolves during the investigation period. However, there are cases in which CDC will be requested to act as the lead for multi-state investigations. When CDC is the lead agency (or is jointly leading an effort with another Federal partner), the data collection design, protocol, implementation, and analysis of results are subject to CDC's own and OMB's government-wide Information Quality Guidelines.

Supporting effective epidemiologic investigations is one of the most important ways that CDC serves to protect the health of the public. When outbreaks or events occur with undetermined agents, sources, modes of transmission, or risk factors, rapid assessment and timely application of prevention and control measures are fundamental to the overall mission of CDC. The legal justification for EEIs are found in the Public Health Service Act (42 USC Sec. 301 [241] (a) (Authorizing Legislation, **Attachment A**).

A new generic clearance mechanism for processing individual collection requests with 72-hour approval (or more quickly, if needed) is requested to ensure the timely information collection required by an EEI is achieved. During an unanticipated outbreak or event with urgent health consequences where the agents, sources, modes of

transmission, or risk factors are undetermined, immediate action by CDC is necessary to minimize or prevent public harm. CDC must have the ability to rapidly develop data collection tools to understand the scope of the problem and determine appropriate action. CDC seeks approval for this new generic mechanism to ensure that the Agency is poised to mobilize quickly and minimize harm to the public when urgent epidemiologic support is requested by our partners.

Need. It is impossible to predict the next outbreak or event with urgent health consequences. Yet, CDC remains at the cornerstone to provide immediate support for epidemiologic investigations. When faced with complex and immediate demands created by acute outbreaks or events, external partners rely on CDC to respond quickly to their requests for short-term epidemiologic support. CDC is uniquely qualified to provide epidemiologic support given its expertise in a variety of diseases and conditions.

When assistance is requested by external partners, CDC makes every effort to respond by providing the appropriate epidemiologic support, which may include a multitude of resources (e.g., epidemiologists, subject matter experts, biostatisticians, laboratorians) necessary to effectively support the investigation. Ultimately, the overarching goal when providing epidemiologic support is to implement prevention and control measures based on the findings from the investigation to minimize adverse health consequences.

This new generic is specifically designed to support CDC mission-critical function by allowing CDC to deploy to the field to conduct EEIs at the request of, and under the public health authority of, external partners seeking support for a rapid response to urgent public health problems. In these situations, insufficient information is available to allow for development of data collection instruments before the response team travels to the field. Data collection instruments and methods must be rapidly created and implemented, usually while investigators are in the field, to direct appropriate public health action. Often specific questions will change or new questions will evolve during the course of the investigation as new information is revealed. While most EEIs involve 2 to 3 weeks of data collection, data collections might take longer. Data collection for investigations conducted under this new generic will not exceed 90 days. If data collection is required for a longer period of time, a new request will be submitted to OMB explaining the circumstances for the extended data collection and providing the forms that will be used for that collection (by this point, the content and scope of the inquiry should be clearer).

Furthermore, if the investigation expands outside the scope of the initial GenIC (i.e., a request for assistance is received from a new entity or the geographic scope of the investigation is expanded, such as to include additional states), CDC must submit a new GenIC that covers the change.

EEIs covered by this new generic are characterized by undetermined agents (e.g., a microorganism or chemical substance), undetermined sources (e.g., person, animal, object, or substance), undetermined modes of transmission (e.g., direct contact, vector, vehicle, airborne, droplet), or undetermined risk factors (e.g., behavior, genetic

characteristic, environmental exposure). For the purposes of this EEI, the following definitions[1] will apply:

- Agent: the entity (such as a microorganism, chemical substance, or form of radiation) whose presence, excessive presence, or (in the case of deficiency diseases) relative absence is essential for the occurrence of a disease, injury, or other health condition.
- Source: the person, animal, object, or substance from which an agent is transmitted to a host.
- Mode of transmission: the manner in which an agent is transmitted from its source to a susceptible host.
- Risk factor: an aspect of personal behavior or lifestyle, an environmental exposure, or a hereditary characteristic that is associated with an increase in the occurrence of a particular disease, injury, or other health condition.

This new generic covers investigations that meet ***all*** of the following criteria:

- CDC epidemiological assistance is requested by one or more external partners (e.g., local, state, tribal, military, port, other federal agency, or international health authority or other partner organizations).
- The investigation is urgent in nature (i.e., timely data are needed to inform rapid public health action to prevent or reduce injury, disease, or death).
- The investigation is characterized by undetermined agents, undetermined sources, undetermined modes of transmission, or undetermined risk factors.
- One or more CDC staff (including trainees and fellows) will be deployed to the field.
- Data collection is anticipated to be completed in 90 days or less.

This new generic ***excludes*** each of the following:

- Investigations initiated by CDC, without request from an external partner.
- Investigations related to non-urgent outbreaks or events.
- Investigations conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research (e.g., to contribute to generalizable knowledge).
- Investigations conducted without deploying CDC staff (including trainees or fellows) to the field.
- Investigations with data collection expected for greater than 90 days.

The following are examples of past EEIs that met the criteria for this new generic. Example data collection instruments are provided as appendices.

Undetermined Agent: In June 2011 the Arizona Department of Health (AZ-DOH) contacted CDC for assistance with an investigation of a cluster of four cases of suspected Guillain-Barre syndrome (GBS) in residents. GBS is an autoimmune disorder that usually follows an infection and can have life-threatening complications. A number of infectious

[1] Definitions adapted from *Principles of Epidemiology in Public Health* Practice, 3rd Edition. Developed by: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Office of Workforce and Career Development, Career Development Division, Atlanta, GA 30333. Available: http://www.cdc.gov/osels/scientific_edu/ss1978/SS1978.pdf.

precipitants of GBS have been identified, including *Campylobacter jejuni, Mycoplasma pneumoniae*, cytomegalovirus, Epstein-Barr virus, and HIV. The CDC team traveled to Phoenix to support the AZ-DOH with their epidemiologic investigation of the cluster of suspected GBS to identify the cause of the disease and source of exposures to implement appropriate measures to prevent further illnesses.

The team collected or reviewed data at several different steps as the investigation progressed. The data needs at each step were dependent on and dictated by the results of the previous steps. The investigative steps included:

- **Verify the diagnosis and confirm the existence of an outbreak**: medical record abstraction (**Example Chart Abstraction Form, Appendix 1**) and interviews of patients, family and caregivers.
- **Case finding**: Review of laboratory and surveillance data, notification of the medical community and the public through several internet list servers, e-mail distribution systems, and a press release.
- **Hypothesis generation**: use of a food exposure questionnaire and open ended interviews.
- **Hypothesis Testing**: Case-Control Study (**Example Guillain-Barre Syndrome Case-Control Study Questionnaire, Appendix 2**).
- **Environmental Assessment** of water system implicated in case-control study.

In this investigation, the team was faced with an outbreak caused by an unknown agent. To identify the agent, the team needed to gather data to confirm the existence of an outbreak, find case-patients, obtain confirmatory laboratory testing, and conduct hypothesis generating interviews. Based on the results of these initial steps, they then developed a new data collection instrument to complete a case-control study. A water distribution system was implicated. This investigation identified several structural deficiencies in the implicated water distribution system. These defects were corrected resulting in elimination of the agent from the water system and protection of the at-risk population.

Undetermined Source: In September of 2006, a physician in a Panamanian hospital noted an unusual cluster of patients with unexplained acute renal failure frequently accompanied by severe neurological dysfunction. Twelve (57%) of 21 patients died of the illness. Local investigators suspected a toxic exposure but did not know the likely source of the toxic exposure. CDC was contacted in early October for assistance with the investigation.

Prior to the arrival of the CDC team, the Panamanian authorities verified the diagnosis and confirmed the existence of an outbreak. The CDC team activities included:

- **Hypothesis generation**: medical record, autopsy, and laboratory record review for the 21 patients. Data from these initial activities suggested the possibility of exposure to diethylene glycol (DEG), a solvent commonly used in antifreeze.
- **Hypothesis Testing**: Case-Control Study.
- **Laboratory Analysis**: clinical and environmental specimens sent to CDC for testing.

In this investigation, the team was faced with an outbreak suspected to be caused by a toxic agent that was quickly identified as DEG. To identify the source of this, the team developed a new data collection instrument to complete a case-control study. The source was identified as contaminated cough syrup. This was the largest known mass poisoning with DEG in the last 70 years and led to the recall of 60,000 potentially contaminated medications. The investigation revealed a widespread outbreak; 119 case-patients were identified, of whom 78 (65.5%) died.

UndeterminedTransmission or Undetermined Risk Factor: In August 2012, CDC was notified of a cluster of 8 cases of hantavirus pulmonary syndrome (HPS) among visitors to Yosemite National Park. Three of these case-patients had died.

The agent hantavirus, which was first seen in the US in 1993, causes a severe life threatening lung infection. The reservoir for this agent is infected rodents and the usual route of transmission is aerosolized rodent excreta. In this investigation the team was faced with a known agent and a likely source for the agent. However, the specific mode of transmission and risk factors for the at risk population were undetermined.

Before the CDC team arrived the local authorities interviewed the initial case-patients and their family members. They determined that case-patients had all stayed at the Curry Village campground in Yosemite. The field activities of the team included:

- **Case Description:** Data for case-patients identified by the hospital staff were abstracted using an existing OMB-approved standard case-abstraction form (OMB No. 0920-0009).
- **Hypothesis Generating:** Data from the case report forms were used to identify potential common sources of exposure.
- **Case-Control Study:** A case-control study was conducted using non-ill traveling companions of the case-patients as controls (**Example Hantavirus Pulmonary Syndrome Questionnaire, Appendix 3**).
- **Environmental Study:** An environmental assessment (animal trapping and environmental inspection) was conducted in the areas of Yosemite visited by the case-patients.

The case-control study implicated exposure to a new type of housing unit, the “Signature Tent Cabin” (STC) as a significant risk factor. The environmental assessment revealed that this new type of housing had foam insulation and evidence of active rodent infestation, particularly tunneling and nesting. Live rodents were observed in the wall foam insulation. Rodents trapped at these sites tested positive for infection with hantavirus.

In this example, the team was faced with known agents and a likely source but did not know the specific risk factors for exposure nor likely modes of transmission. Data collected in this epidemiologic investigation implicated a common location for exposure (the STCs) and the environmental inspection confirmed a plausible mode of transmission. The investigators recommended a number of immediate corrective actions including

permanently closing the STCs, techniques for rodent control, improved disease surveillance in the park, and public information. Their actions led to control of the outbreak and helped to prevent future exposure to this deadly disease.

The timeline and procedures for seeking an approval under this new generic are detailed in Section 7, "Special Circumstances Relating to the Guidelines of 5 CFR 1320.5."

1.1 Privacy Impact Assessment

Overview of the Data Collection System

The primary purpose of each EEI conducted in response to an outbreak or event with undetermined agents, sources, transmissions, or risk factors is to rapidly collect sufficient information to identify and implement effective prevention and control measures to minimize public harm. The characteristics and nature of each outbreak or health-impacting event is unique and therefore effective and rapid response requires highly flexible data collection methods and instruments. The choice of data collection mode may be influenced by:

- What is already known about the problem when the team arrives in the field.
- The severity of the event and the need for immediate actionable data that can be used to guide control efforts.
- The location, size, and characteristics of the affected population (e.g. rural vs. urban, small community vs. state wide).
- Resources available to the local health authorities and the team in the field.

Examples of data collection modes employed during EEIs include face-to-face interview, telephone interview, self-administered paper-and-pencil questionnaire, and self-administered Internet questionnaire. Often, multiple data collection modes are employed in a single EEI. For example, hypothesis-generating telephone interviews may be conducted initially, and the data collected from those may be used to develop a paper-and-pencil questionnaire. Example data collection instruments are provided in **Appendices 1-6**.

Respondent type will vary by EEI. For example, respondents may include the general public, patients, clinicians, hospital staff, laboratory staff, or caregivers. Respondents also may be defined by a behavior (e.g., ate at Restaurant X during a certain time period or attended Conference Y) or geographic characteristic (e.g., resident of Town Z).

Information in identifiable form (IIF) may be collected from or about members of the public. IIF is only collected when essential to the objective of the EEI. Data are collected in collaboration with, or at the request of, external partners requesting epidemiological support. Personal identifiers are not transmitted to CDC unless this is necessary for public health purposes. Data collected in the course of an EEI are considered private. Inadvertent release of this information may constitute an invasion of the subject's privacy. IIF are not included in any report from the EEI.

External partner policies and procedures for data storage and security are followed during each field investigation. Though the type of access control(s) implemented vary according to local policies and procedures, examples include technical controls (e.g., password protection, storage on Virtual Private Network), physical controls (e.g., storage in locked cabinets or rooms), and administrative controls (e.g., daily offsite file back-ups, signed confidentiality agreements by staff who have access to files). Information collection is conducted according to a security plan developed in consultation with the relevant local health authorities. Only staff with approval from the study lead has access to the data. Approvals are granted based on roles or a "need to know basis."

IIF transmitted to CDC are treated in a private manner, unless otherwise compelled by law. CDC maintains privacy by using unique, study identification numbers on all data collection forms. Personal identifiers and the linkage to the study identification number are maintained separately in locked file cabinets or in encrypted computer files. All personal identifiers are stripped from the data prior to establishing a final data analysis file. Results are only published in aggregate form.

Data are permanent federal records and are maintained in accordance with CDC's records control schedule (http://isp-v-maso-apps/RecSched/ViewSchedule.aspx?RID=29). The process for handling security incidents is defined in the system's Security Plan. Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy related events are directed to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

Items of Information to be Collected

The information collected varies by EEI depending on the nature of the outbreak or event. Data to be collected align with the objectives of the investigation to 1) identify and understand the patterns of disease or injury occurrence, 2) prevalence of risk factors, 3) the etiologic agents or sources, or 4) the modes of transmission. Data collection may include both quantitative and qualitative data elements. Examples of information to be collected include descriptive information to characterize person, place, and time; symptomology information (e.g., to characterize illness, diagnoses); laboratory samples; medical conditions or symptoms of illness; environmental factors; risk behaviors; patterns of behavior, and potential exposures. Examples of IIF categories for which data may be collected include: name, mailing address, e-mail address, phone numbers, medical information and notes, and biological specimens.

2. Purpose and Use of Information Collection

The purpose of this ICR is to conduct EEIs of outbreaks or events with adverse health consequences and characterized by undetermined agents, undetermined sources,

undetermined modes of transmission, or undetermined risk factors. EEIs are initiated following a request for epidemiological support by external partners. When existing data sources fail to provide enough information for the implementation of effective prevention and control measures, new data must be collected. The primary objective of each EEI is to collect sufficient information to develop and implement effective prevention and control strategies to minimize adverse health consequences. To accomplish this objective, data on the conditions surrounding and preceding the onset of an outbreak or event must be collected rapidly. Due to the acute nature of the response, except in rare circumstances, each data collection instrument is administered to each respondent only once. Data are collected by CDC in collaboration with or under the authority of the external partners, and the data collection mode varies by EEI. Example data collection instruments from previous EEIs of outbreaks or events characterized by undetermined agents, undetermined sources, undetermined modes of transmission, and undetermined risk factors are provided in **Appendices 1-6**. Findings of an investigation may be presented or published (e.g., scientific journal article or report).

The negative consequences of not having the information are increased or sustained morbidity and mortality associated with the outbreak or event. While EEI findings are not always generalizable outside of the target population, they will be generalized to the extent it is appropriate. Another negative consequence of not having the information is the failure to implement prevention and control measures in future situations that lead to additional outbreaks or events and associated morbidity and mortality.

2.1 Privacy Impact Assessment

Information is collected in collaboration with the external partners requesting epidemiological support. When external partners are the lead on the investigation, the information is collected under their authority and shared with CDC. The information will be used to develop prevention and control measures to minimize or prevent subsequent morbidity and mortality associated with the outbreak or event.

Procedures are in place to protect respondent privacy thereby minimizing direct impact to respondent privacy in the collection of these data.

3. Use of Improved Information Technology and Burden Reduction

Because the events necessitating the collection of information are of an emergency nature, most data are collected by medical record abstraction, interviews or self-administered paper-and-pencil questionnaires. During EEIs, there often is not sufficient time to develop, test, and launch electronic systems for collection of data. However, EEIs employ online or electronic submission of responses when feasible. When this mode is utilized, it is password-protected. An example of an online survey used in a previous EEI is included in **Appendix 6**. To minimize burden, existing data from medical records, for instance, may be used to pre-populate data collection tools.

Data collection protocols are designed to be as unobtrusive as possible, and only the minimal information necessary is collected to reduce burden to the respondent. The

specific data collection protocol is tailored to meet the immediate needs of the local health authorities responding to the public health problem. The choice of data collection methodology and mode may be influenced by:

- What is already known about the problem.
- The severity of the event and the need for immediate actionable data that can be used to guide control efforts.
- The location, size, and characteristics of the affected population (e.g. rural vs urban, small community vs. state wide).
- Resources available to the local health authorities and the team in the field.

4. Efforts to Identify Duplication and Use of Similar Information

Literature searches and discussions with external partners initially are 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 outbreak or event, because each situation is unique in many aspects (e.g. agents, locations, affected populations, sources of agent, modes of transmission, risk factors, and environmental factors).

Each investigation contributes to the general knowledge about a particular type of outbreak or event, and data collections are designed to incorporate knowledge gained from similar situations in the past. This knowledge can be used to develop a hypothesis generating questionnaire that can be used for initial data collection. Information collected during the initial data collection is often then used to develop a customized data collection instrument that is designed to collect information specific to the situation.

A CDC staff person will serve in the role of EEI Information Collection Request Liaison (ICRL). The ICRL will be responsible for maintaining a data collection instrument library (**Appendices**), which will include the final data collection instruments administered in EEIs under this generic clearance. In the event an information collection is requested by a CDC program, the ICR will require the program to determine whether data already have been collected that could be used. Step-by-step instructions for conducting an EEI under this generic clearance are presented in **Attachment C.**

5. Impact on Small Businesses or Other Small Entities

In some emergency epidemiologic investigations, information may be collected from persons in small businesses or other small entities, such as restaurant workers or staff in a physician’s office. Every effort is made to minimize the burden on all respondents during the collection of information during outbreaks or events. Information collected is held to the absolute minimum required to inform effective prevention and control measures.

6. Consequences of Collecting the Information Less Frequently

EEIs involve one-time, rapid data collection efforts related to a specific outbreak or event. Not collecting this information impedes CDC from carrying out its mission critical function of protecting the health of the public by identifying effective prevention and control measures to reduce adverse health consequences during an outbreak or event. If during an emergency investigation, it is determined that an investigation would need to extend beyond the approved 90-day data collection period, a new GenIC request will be submitted.

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

As discussed in Section A.1, this new generic ICR covers EEIs conducted in response to an urgent outbreak or event characterized by undetermined agents, sources, modes of transmission, or risk factors initiated in response to a request for assistance from external partners, and is not limited only to those EEIs classified as an Epi-Aid. This generic ICR does not cover investigations conducted for the purposes of program evaluation, surveillance, needs assessment or research conducted primarily to contribute to generalizable knowledge.

EEI data collection often needs to be initiated within hours or days of the request. Given the need for rapid data collection to minimize threats to public health, respondents are asked to respond to requests for data in fewer than 30 days.

To comply with the regulation 5 CFR 1320.5 and at the same time ensure that public health data are collected in a timely manner as necessary to protect the health of the public, EEIs covered by this generic ICR will adhere to the following timeline and processes:

1. At the request of external partners, CDC decides to organize and deploy a team to provide epidemiological assistance to our partners.
2. HHS, the OMB-OIRA Desk officer, and his/her designated back up are notified of the EEI immediately via e-mail from CDC, followed by receipt of the GenIC "Request for Emergency Epidemic Investigation" form (**Attachment D**) describing the problem and the planned response.
3. The OMB-OIRA desk officer or designee responds with approval or comments on the proposed EEI within 72 hours. OMB may provide approval and comments orally (followed by e-mail for written documentation) or e-mail directly to CDC. This may occur before the GenIC request is submitted and received by OMB through the official ICR tracking system. If no response is received within 72 hours, the information collection is considered OMB-approved. For responses to outbreaks or events where more immediate action is necessary to prevent or reduce morbidity or mortality, OMB is asked to respond within 24 hours. To invoke this more rapid approval timeline, CDC notifies HHS and OMB of this need in the initial EEI notification email.
4. At the completion of the EEI, the investigators submit the final data collection instrument(s) and associated burden using the "Burden Memo" form (**Attachment E**) to the ICRL.
5. CDC maintains a library of data collection instruments that includes all final data collection instruments conducted under this generic ICR. This library and the

updated burden numbers based on data collected via the "Burden Memo" (**Attachment E**) is submitted to OMB quarterly as a non-substantive change to the generic ICR.

A CDC staff person serves in the role of EEI ICRL. The ICRL oversees the clearance process for individual GenICs. Information about the generic ICR and how to submit a GenIC is distributed to CDC program officials (**Steps for Conducting an EEI, Attachment C**). The ICRL maintains a library of data collection forms that may be accessed by CDC programs initiating new investigations. Upon the completion of an investigation, the ICRL places the data collection instruments into the library. Information collected as part of an EEI includes that necessary to identify the agents, sources, modes of transmission, or risk factors associated with an outbreak or public health event. Each EEI request is closely reviewed by the ICRL based on a predefined set of criteria to ensure only GenICs for EEIs appropriate for this generic ICR are submitted to OMB for approval.

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

A 60-day Federal Register Notice was published in the Federal Register on July 12, 2013, Vol. 78, No. 134, page 41930 (**Attachment B**). One non-substantive comment was received from the general public and a standard response was provided by CDC.

9. Explanation of Any Payment or Gift to Respondents

Respondents receive no gift or payment for their participation in any information collections.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act applies to this ICR. Records are covered under CDC Privacy Act system notice 09-20-0113, "Epidemic Investigation Case Records Systems Notice" (**Attachment F).**

Data are treated in a private manner, unless otherwise compelled by law. CDC maintains privacy by using unique, study identification numbers on all data collection forms. Personal identifiers and the linkage to the study identification number are maintained separately in locked file cabinets or in encrypted computer files. All personal identifiers are stripped from the data prior to establishing a final data analysis file. Results are published in aggregate form only. All efforts are taken to ensure that the proposed research complies with all human subject requirements, and the Privacy Act checklist is completed.

IRB Approval
IRB approval generally is not required for EEIs (**IRB Letter, Attachment G**). These investigations usually are considered responses to public health emergencies and not research based on the definition provided by the Federal Policy for the Protection of

Human Subjects (45 CFR 46). For individual investigations, the appropriate CDC and external partners Human Subjects Review contacts are consulted for an official research determination.

10.1 Privacy Impact Assessment Information

Respondents are informed that response is not mandatory; it is collected on a voluntary basis and consent is obtained in a manner consistent with Human Subjects Protection regulations as specified in the IRB protocol, if applicable. If applicable, respondents are informed that biospecimen samples are collected to provide information during an outbreak or event that could lead to prevention and control measures and that they will not be used for the primary purpose of conducting research to contribute to the generalizable knowledge. If biospecimen samples collected during the EEI are stored, respondents will be informed and consent will be obtained. A template consent form for biospecimen storage is included in **Attachment H**. While other consent form formats are acceptable (i.e., use of this template is not required), the key information elements (in bold in the template) must be included.

IIF is not transmitted to CDC unless it is necessary for public health purposes. If IIF are transmitted to CDC, the information is sent using a password-protected electronic file. The password to unlock the file is provided via telephone and not in written form. Other safeguards may be implemented to minimize the possibility of unauthorized access, use, or dissemination of the information being collected, following consultation with the CDC CIO Privacy Impact Assessment contact.

11. Justification for Sensitive Questions

Questions that might be considered sensitive (e.g., regarding risk behaviors, attitudes, or medical condition diagnoses) are included only when necessary for the public health response. For example, in investigation of an outbreak of hepatitis A with unknown sources, risk behaviors, or modes of transmission, it is essential to collect information on established risk factors for hepatitis A including HIV status, anal sex, and injection drug use. Before administering data collections, 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. Participants also are informed the data are being collected in response to an outbreak or event with adverse health consequences, and that the information they provide may help to identify effective prevention and control strategies. If the respondent participates, consent is assumed. Social security numbers are not collected.

12. Estimates of Annualized Burden Hours and Costs

CDC projects 60 EEIs in response to outbreaks or events characterized by undetermined agents, undetermined sources, undetermined modes of transmission, or undetermined risk factors annually. The projected average number of respondents is 200 per EEI, for a total of 12,000 respondents. CDC estimates the average burden per response is 0.5 hours and

each respondent per investigation (that burden may be spread across multiple queries as the investigation progresses). The actual burden for a specific investigation might be greater than 0.5 hours per response for some investigations and less than 0.5 hours per response in other investigations. Therefore, the total estimated annual burden in hours is 6000. These estimates are based on the average reported burden for EEIs characterized by undetermined agents, undetermined sources, undetermined modes of transmission, or undetermined risk factors conducted during the previous two years. The actual number of respondents in each information collection and the number of responses per respondent varies depending on the purpose of each individual GenIC.

Table A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Emergency Epidemic Investigation Participants	Emergency Epidemic Investigation Data Collection Instruments	12,000	0.5	6,000
Total				6,000

The U.S. median national wage for all occupations in 2012 based on data from the Bureau of Labor Statistics (available at http://www.bls.gov/oes/current/oes_nat.htm#00-0000) is $16.71. This wage is assumed for all EEI participants because of the variety of types of participants expected. With a maximum annual respondent burden of 6,000 hours, the overall annual cost of respondents' time for the proposed collection is estimated to be a maximum of $100,260 (6,000 burden hours x $16.71).

Table B. Estimated Annualized Burden Cost

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Emergency Epidemic Investigation Participants	Emergency Epidemic Investigation Data Collection Instruments	6,000	$16.71	$100,260
Total				$100,260

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

There are no anticipated costs to respondents other than time.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The cost factors considered are related to routine procedures of the investigators in planning investigations; design, preparation, printing, and distribution of data collection instruments; and editing, coding, tabulation, analysis, and presentation of the information. The annual cost is estimated based on the salaries and wages table for federal employees for 2013 (http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2013/general-schedule/2013-gs-hourlyovertime-rates-by-grade-and-step/) On average, CDC staff and contractors contribute 864 hours per EEI, for a total annualized cost to the Government of $1,510,099 (see Table A-14.1).

Table C. Estimated Annualized Cost to the Government

Staff or Contractors	Average Hours per EEI	Average Hourly Rate	Number of EEIs Annually	Total Annualized Cost
Supervisory Epidemiologists (GS-14, step 1)	80	$41.94	60	$201,312
Statisticians (GS-13, step 1)	32	$34.34	60	$65,933
Epidemiologists (GS-12, step 1)	640	$28.88	60	$1,108,992
Laboratory Staff (GS-09, step 1)	32	$19.92	60	$38,246
Students/Fellows (GS-09, step 1)	80	$19.92	60	$95,616
Total	864			$1,510,099

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The epidemiologic data collected in each EEI provides information necessary for an effective public health response to an outbreak or event with adverse health consequences and with undetermined agents, sources, modes of transmission, and risk factors. Therefore, collecting data as soon as possible after the onset of the outbreak or event is critical to the epidemiologic analysis. The duration of the data collection varies by EEI, but does not exceed 180 days. If it is determined an investigation will extend beyond 90 days, the lead investigator will submit a new GenIC.

For each EEI, the lead investigator is responsible for developing an analysis plan and conducting the data analysis. Any publication of data derived from an EEI is subject to review by relevant local health authorities, CDC, or collaborating federal agencies.

CDC will record the existence of each dataset in its enterprise inventory, per OMB M-13-13, and where permitted by law, make de-identified datasets available to the public. The Agency disseminates the findings when appropriate, strictly following the Agency's "Guidelines for Ensuring the Quality of Information Disseminated to the Public." Requests to release the information that is not available on CDC's web site (e.g., congressional inquiry, Freedom of Information Act requests) will be addressed on a case by case basis.

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.