2014 Emergency Response to Ebola in West Africa: Data Collection for Assisting Foreign and International Entities to Conduct Public Health Activities

OMB 0920-XXXX

Emergency Clearance Request
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Table of Contents

List of Attachments

Attachment A, Section 301 of the Public Health Service Act (42 USC 241)
Attachment B, Viral Hemorrhagic Fever Case Investigation Form_Guinea_French
Attachment C, Viral Hemorrhagic Fever Case Investigation Form_Senegal_French
Attachment D, Viral Hemorrhagic Fever Case Investigation Form_Liberia
Attachment E, Viral Hemorrhagic Fever Case Investigation Form_Sierra Leone
Attachment F, Viral Hemorrhagic Fever Case Investigation Form_Nigeria
Attachment G, Viral Hemorrhagic Fever Case Investigation Form_Short Version_Liberia
Attachment H, Viral Hemorrhagic Fever Contact Listing Form_General
Attachment I, Viral Hemorrhagic Fever Contact Listing Form_Senegal_French
Attachment J, Viral Hemorrhagic Fever Contact Listing Form_Guinea
Attachment K, Viral Hemorrhagic Fever Contact Listing Form_Liberia
Attachment L, Viral Hemorrhagic Fever Contact Tracing Follow-Up Form
Attachment M, Ebola Virus Disease Case Contact Questionnaire
Attachment N, Health Facility Assessment and Case Finding Survey
Attachment O. Ebola Virus Epi Invest SORN

A. Justification

1. Circumstances Making the Collection of Information Necessary

On March 21, 2014, the World Health Organization (WHO) and the Ministry of Health (MoH) of Guinea reported an outbreak of Ebola viral disease (EVD), and shortly thereafter clinical cases were also reported in Liberia. By May, the first cases identified in Sierra Leone were reported. The outbreak expanded to Nigeria on July 25th and Senegal on August 29th. The outbreak continues to accelerate in West Africa and is unprecedented in size.

This emergency ICR is an extension of several collections started under OMB Control Number 0920-1011, "Emergency Epidemic Investigation Data Collections," and will allow CDC to continue ongoing work.

Ebola virus is the cause of a viral hemorrhagic fever disease. Symptoms include fever, headache, joint and muscle aches, weakness, diarrhea, vomiting, stomach pain, lack of appetite, and abnormal bleeding. Symptoms may appear anywhere from 2 to 21 days after exposure to Ebola virus although 8-10 days is most common. Ebola is transmitted through direct contact with the blood or bodily fluids of an infected symptomatic person or through exposure to objects (such as needles) that have been contaminated with infected secretions. Major challenges faced by all partners in the efforts to control the outbreak include its wide geographic spread, weak health-care infrastructures, and community mistrust and resistance

In June 2014, WHO, via the Global Outbreak Alert and Response Network requested additional support from the Centers for Disease Control and Prevention (CDC) and other partners, necessitating the deployment of additional staff members to Liberia, Sierra Leone, Guinea, West Africa, to further coordinate efforts aimed at halting and preventing virus transmission. Persistence of the outbreak necessitates high-level, regional, local and international coordination to bolster response efforts among involved and neighboring nations and other response partners in order to expeditiously end this outbreak. CDC has activated its Emergency Operations Center (EOC) to help coordinate technical assistance and control activities with partners.

WHO has declared the Ebola outbreak in West Africa to be an international public health emergency. The 2014 Ebola outbreak is unprecedented and the first in West Africa. CDC is currently assisting with the investigation, by taking active steps to respond to the rapidly changing situation internationally and domestically by working with other U.S. government agencies, the World Health Organization, and other domestic and international partners to identify sources and risk factors for Ebola infection in order to implement prevention and control measures. The epidemiological objectives are to maintain a centralized database for data collected from all outbreak sites, domestic and international to assist in contact tracing, case report collection, and patient or family interviews.

The collections of information included in this package are essential to the CDC's ability to effectively contribute to the broader US response to the current Ebola virus disease (EVD) crisis in Guinea, Liberia, Sierra Leone, Nigeria and Senegal, as well as to respond to specific requests by individual foreign and US entities requesting data collection in the context of the outbreak. The scale of the current EVD outbreak was accelerated due to the lack of logistical support and expertise. Core public health interventions, in Guinea, Liberia, Sierra Leone, Nigeria and Senegal, such as identifying patients and diagnosing with laboratory tests, isolation when confirmed and contact tracing are essential to control the spread of EVD. The estimates in this package represents an upper-bound and were not arrived at through epidemiological modeling or other scientific techniques. The estimate is a contingency to ensure that CDC has requested adequate public burden in the event that more contact investigations are needed. These data collections are authorized under the provisions of Section 301 of the Public Health Service Act, (42 USC 241) (Attachment A).

2. Purpose and Use of Information Collection

The investigation will follow a case series study design, where The Viral Hemorrhagic Fever Case Investigation Forms **(Attachments B, C, D, E,F, and G)** and the Viral Hemorrhagic Fever Contact Listing Forms **(Attachments H, I, J, K)** will be collected for every patient meeting the suspect case definition criteria, as stated below in the bulleted section. Forms are collected through interview of patients or family members if patients have died or are infants, in either French or the local language. Relevant clinical data, including the patient's date of onset, date of death, hospitalization and funeral information, and contacts that the patient had prior to developing illness all are collected, in an effort to determine the risk factors that led to this patient's infection. If diagnostic testing confirms that this patient has EVD, a separate contact tracing form **(Attachment L)** is completed to collect information of people who had direct unprotected contact with the patient while they were ill and prior to treatment in a facility with barrier nursing. These contacts are then followed daily for onset of fever and other EVD symptoms, and will be investigated as cases and treated under barrier nursing precautions if they develop illness. The Ebola Virus Disease Case Contact Questionnaire **(Attachment M)** will be used to assess the risk of exposure in identified contacts provided by patients to further inform the need for monitoring and movement restrictions, if necessary, in identified contacts. The Health Facility Assessment and Case Finding Survey **(Attachment N)** will be used to assess the capabilities of cases found through use of the tracing form and Contact Questionnaire and the capacity of health facilities to triage such cases safely and properly. The information will be collected via direct oral interviews or by request written surveys by public health personnel and healthcare providers

Case definitions and administrative locations within the country vary by country so specific Viral Hemorrhagic Fever Case Investigation Forms and Viral Hemorrhagic Fever Contact Listing Forms are required based on region. Respondents are selected on the basis of meeting case definition criteria which may vary slightly by country and/or location. Cases are categorized into one of three case definitions:

- Suspected - (alive or dead person with fever and at least three additional symptoms, or fever and a history of contact with a person with hemorrhagic fever or a dead or sick animal, or unexplained bleeding);
- Probable - (meets the suspected case definition and has an epidemiologic link to a confirmed or probable case);
- Confirmed - (suspected or probable case that also has laboratory confirmation).

Based on the criteria provided above, it is probable that some case contacts may meet suspect case definition, thereby requiring their information to be collected using the The Viral Hemorrhagic Fever Case Investigation Form. Respondents may also include any contacts identified through the case investigation process

The following is in this request: Confirmed and Contact Tracing

- Viral Hemorrhagic Fever Case Investigation Forms for Guinea in French, Senegal in French, Liberia, Sierra Leone, Nigeria, and a Short Version for Liberia since the outbreak is larger there **(Attachments B, C, D, E,F,G)**
- Viral Hemorrhagic Fever Contact Listing Form (General), one for Senegal in French, one for Guinea, and one for Liberia **(Attachments H, I, J, K)**,
- Viral Hemorrhagic Fever Contact Tracing Follow-Up Form **(Attachment L)**,
- Ebola Virus Disease Case Contact Questionnaire **(Attachment M)**,
- Health Facility Assessment and Case Finding Survey **(Attachment N),**

3. Use of Improved Information Technology and Burden Reduction

Information Technology for data collection may be used where available internationally. In particular, electronically fillable forms and databases have been created for the Viral Hemorrhagic Fever Case Investigation, Viral Hemorrhagic Fever Contact Listing, and Viral Hemorrhagic Fever Contact Tracing Follow-Up Forms. However, in most international locations, it is expected that hardcopy forms will be completed and transmitted through fax, email, or other means.

4. Efforts to Identify Duplication and Use of Similar Information

All collections of information are unique and specific to the 2014 Ebola public health emergency.

5. Impact on Small Businesses or Other Small Entities

There is no anticipated impact on small businesses.

6. Consequences of Collecting the Information Less Frequently

CDC activities regarding the international Ebola response would be significantly hindered if it were not able to collect the information necessary to prohibit the spread of this disease.

Ebola does not have a known, proven treatment. Standard treatment for Ebola is still limited to treating the symptoms as they appear and supportive care. Symptoms may appear anywhere from 2 to 21 days after exposure to Ebola virus, although 8-10 days is most common. A strong, coordinated response is essential to interrupt the outbreak. Consequences of collecting information less frequently will inhibit the response required to contain the spread of the disease and do everything possible to limit, if not stop deaths due to this disease. There are no legal obstacles to reduce the burden.

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

There are no special circumstances and this request complies with the regulation.

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

This is a request for an emergency clearance and public comment has been waived for this six month clearance. However, a 60 day public notice will be published simultaneously to give the public an opportunity for comment during the data collection period.

9. Explanation of Any Payment or Gift to Respondents

There are no gifts or payments to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act applies to this ICR. Records are covered under CDC Privacy Act system notice 09-2-0113 "Epidemic Investigation Case Records Systems Notice" **(Attachment O)**

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 investigation number are maintained separately in locked file cabinets or in encrypted computer files. All personal identifiers are stripped from data prior to establishing a final data analysis file. Respondents are informed that response is not mandatory, it is collected on a voluntary basis
If applicable, respondents are informed that biospecimen samples are collected to provide information for the purpose of prevention and control of the Ebola virus outbreak, and no information will be used for the primary purpose of conducting research to contribute to generalizable knowledge.

Information in identifiable form will be collected in case investigation, contact and tracing forms. This includes hospital records, to collect relevant clinical information patient's name, or their family member, head of household, occupation, date of birth, sex, phone number, and residential information. Access to data will be limited to authorized public health project staff. All electronic data will be stored on secure servers Hospital records may be used to collect relevant clinical information in the case report form
In the case of the Ebola outbreak in the countries that are included in this package, data collected will be uploaded into Epi-Info, when available, to be able to track and identify ill patients. Epi-Info is a suite of software tools for public health professionals which includes a screen form design module, data entry module, analysis module, reporting module, and a mapping module as well as several utilities. The modules can be used independently for ad hoc data gathering and analytical needs, or they can be used as a rapid development environment for quickly programming public health focused outbreak and surveillance data applications. When information technology is not available, hardcopy forms will be completed and transmitted through fax, email, or other means when data bases are not available and will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

11. Justification for Sensitive Questions

Some questions regarding a potential patients behaviors prior to becoming ill may be considered of a sensitive nature; such as caring for other sick individuals, attending to or participating in funerals, consulting spiritual or traditional healer and zoonotic contacts are required in order to identify an ill patient and any contacts that have been in contact with an exposed Ebola patient up to the 21 day incubation period. The 21 day incubation period is required to ensure that symptoms are not present after exposure to Ebola virus.

12. Estimates of Annualized Burden Hours and Costs

The total burden estimated for this is 54,282 hours, which is based on an estimate that the form will be administered to 4000 people in Guinea, Liberia, and Sierra Leone and 500 people in Senegal as well as Nigeria over the next six months. The estimates in this package represents an upper-bound and were not arrived at through epidemiological modeling or other scientific techniques. The estimate is a contingency to ensure that CDC has requested adequate public burden in the event that more contact investigations are needed. Respondents are selected on the basis of meeting case definition criteria which may vary slightly by country and/or location. Respondents will also include any contacts identified through the case investigation process.

The Viral Hemorrhagic Fever Case Investigation Form_Guinea_French **(Attachment B)**,), The Viral Hemorrhagic Fever Case Investigation Form_Liberia **(Attachment D)**, Viral Hemorrhagic Fever Case Investigation Form_Sierra Leone **(Attachment E)** have a total of 4,000 respondents each and 1334 burden hours each, it is estimated that response time for each of these forms will be no longer than 20 minutes, based on existing data collected under Generic Clearance 0920-1011. The Viral Hemorrhagic Fever Case Investigation Form_Senegal_French **(Attachment C)** and the Viral Hemorrhagic Fever Case Investigation Form_Nigeria **(Attachment F)** have a total of 500 respondents each with 167 burden hours each. As we are on the front end of what has been labeled the largest epidemic in West Africa, to date, the respondent totals may be overestimated, however, there is no way to derive an exact number of affected persons, so a generalized estimate was used for each region.

The Viral Hemorrhagic Fever Case Investigation Form_Short Version_Liberia **(Attachment G)** is a shortened version needed in more populated areas where response is critical, due to a mass number of sick and/or confirmed patients, the long form is not conducive to treating large amounts of people in a timely fashion, so the short form was developed to ascertain the required information, in hopes that additional information may be obtained at a later time. It is anticipated that there will be 4,000 respondents, one response per respondent with a total of 667 burden hours, due to the need to quickly treat as many patients as possible, a shortened version of the form was developed for this region, as the infected totals were significantly higher. The Viral Hemorrhagic Fever Contact Listing Forms_General **(Attachment H)** will be used in Sierra Leone and Nigeria because it is a standard form that will be used in both regions, we estimate a total of 4,000 respondents combined with one response per respondent to total 1,000 burden hours. The Viral Hemorrhagic Fever Contact Listing Form_Senegal_French **(Attachment I)** has an estimated 500 respondents to total 125 burden hours, the Viral Hemorrhagic Fever Contact Listing Form_Guinea **(Attachment J)** and The Viral Hemorrhagic Fever Contact Listing Form_Liberia **(Attachment K)** have 12,000 respondents per form, each form being administered 1 time each with a total of 3,000 burden hours per form.

The Viral Hemorrhagic Fever Contact Tracing Follow-Up Form **(Attachment L)** estimates 21 responses per respondent due to the fact that symptoms may appear up to 21 days after exposure to the Ebola virus, so follow up will happen on a daily basis, until the 21 day incubation period has been reached, total burden hours for this form are 42,000 burden hours.

The Ebola Virus Disease Case Contact Questionnaire **(Attachment M)** has a total of 50 respondents who will be comprised of person(s) who have had direct or some form of contact with a confirmed patient, based on existing information, it is estimated that most patients have no more than 5-10 contacts during the time symptoms were presented and treatment began, this questionnaire will be administered once per respondent with a total of 4 burden hours.

The Health Facility Assessment and Case Finding Survey **(Attachment N)** has a total of 300 respondents that consist of public health personnel and healthcare providers, the survey will be administered once per respondent with 150 total burden hours. This information is based on existing data previously collected. The total burden estimate for the International Ebola Emergency package is 54,282 hours. The total is based on the six month period requested for this emergency clearance. This estimate represents an upper-bound and was not arrived at through epidemiological modeling or other scientific techniques. The estimate is a contingency to ensure that CDC has requested adequate public burden in the event that more contact investigations are needed

Table A – Estimate of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours
General Public	Viral Hemorrhagic Fever Case Investigation Form_Guinea_French	4,000	1	20/60	1334
General Public	Viral Hemorrhagic Fever Case Investigation Form_Senegal_French	500	1	20/60	167
General Public	Viral Hemorrhagic Fever Case Investigation Form_Liberia	4,000	1	20/60	1334
General Public	Viral Hemorrhagic Fever Case Investigation Form_Sierra Leone	4,000	1	20/60	1334
General Public	Viral Hemorrhagic Fever Case Investigation Form_Nigeria	500	1	20/60	167
General Public	Viral Hemorrhagic Fever Case Investigation	4,000	1	10/60	667

	Form_Short Version_Liberia				
General Public	Viral Hemorrhagic Fever Contact Listing Form_General	4,000	1	15/60	1000
General Public	Viral Hemorrhagic Fever Contact Listing Form_Senegal_French	500	1	15/60	125
General Public	Viral Hemorrhagic Fever Contact Listing Form_Guinea	12,000	1	15/60	3000
General Public	Viral Hemorrhagic Fever Contact Listing Form_Liberia	12,000	1	15/60	3000
General Public	Viral Hemorrhagic Fever Contact Tracing Follow-Up Form	12,000	21	10/60	42000
General Public	Ebola Virus Disease Case Contact Questionnaire	50	1	5/60	4
General Public	Health Facility Assessment and Case Finding Survey	300	1	30/60	150
Total					54,282

B. The proposed estimated annual cost to respondents is $393,547. The International Labor Comparisons program has been discontinued. Therefore, the United States federal government mandated nationwide minimum wage level of $7.25 has been used to determine the cost per respondent. Table B– Estimated Annualized Costs to the Respondents

Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in Hours)**	**Hourly Wage Rate**	**Total Respondent Costs**
General Public	Viral Hemorrhagic Fever Case Investigation Form_Guinea_French	4,000	1	20/60	$7.25	$9,672
General Public	Viral Hemorrhagic Fever Case Investigation Form_Senegal_French	500	1	20/60	$7.25	$1,211
General	Viral Hemorrhagic	4,000	1	20/60	$7.25	

Public	Fever Case Investigation Form_Liberia					$9,672
General Public	Viral Hemorrhagic Fever Case Investigation Form_Sierra Leone	4,000	1	20/60	$7.25	$9,672
General Public	Viral Hemorrhagic Fever Case Investigation Form_Nigeria	500	1	20/60	$7.25	$1,211
General Public	Viral Hemorrhagic Fever Case Investigation Form_Short Version_Liberia	4,000	1	10/60	$7.25	$4,836
General Public	Viral Hemorrhagic Fever Contact Listing Form_General	4,000	1	15/60	$7.25	$7,250
General Public	Viral Hemorrhagic Fever Contact Listing Form_Senegal_French	500	1	15/60	$7.25	$906
General Public	Viral Hemorrhagic Fever Contact Listing Form_Guinea	12,000	1	15/60	$7.25	$21,750
General Public	Viral Hemorrhagic Fever Contact Listing Form_Liberia	12,000	1	15/60	$7.25	$21,750
General Public	Viral Hemorrhagic Fever Contact Tracing Follow-Up Form	12,000	21	10/60	$7.25	$304,500
General Public	Ebola Virus Disease Case Contact Questionnaire	50	1	5/60	$7.25	$29
General Public	Health Facility Assessment and Case Finding Survey	300	1	30/60	$7.25	$1,088
TOTAL						$393,547

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

There are no additional record keeping/capital costs to respondents known at this time.

14. Annualized Cost to the Government
The average annual cost to the federal government is based on the federal GS pay scale for the federal employees involved in the development, oversight and analysis of the data collections is $339,695.00.

15. Explanation for Program Changes or Adjustments
This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule
Containment measures and core public health intervention is active in Guinea, Liberia, Nigeria, Sierra Leone and Senegal. Additional data collections outlined in this request will begin as soon as clearance has been approved. Publications have not been identified to date, but understanding the complexity and the scale of this Ebola outbreak, publications could be possible at a later time.

17. Reason(s) Display of OMB Expiration Date is Inappropriate
Not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submissions
There are no exceptions to the certification.