Emergency Submission for

Active Monitoring of Travelers Coming from Ebola-affected Countries and Their Contacts Currently Residing in State, Territorial, and Local Jurisdictions

Supporting Statement A

Justification

Existing Collection in Use without OMB Control Number

Program Contact

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- The goal of this study is to allow CDC to effectively complement ongoing international and travel-related efforts at rapid case identification, contact tracing, and infection control of Ebola Virus Disease in partnership with key respondents who are 62 state and local health departments.
- The intended use of the data/information collected is to ~~a~~ assure that all persons returning from countries affected by the current Ebola outbreak are being actively monitored for fever and symptoms by state or local public health authorities for 21 days after potential Ebola virus exposure.
- The methods used to collect the data/information are on-line data entry and MS Excel forms.
- The subpopulations to be studied are travelers from countries in West Africa affected by the Ebola outbreak and health care workers in the U.S. treating patients affected by Ebola Virus Disease.
- Data/information will be collected for monitoring purposes.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

This is an emergency information collection request (ICR) to allow CDC to effectively complement ongoing international and travel-related efforts at rapid case identification, contact tracing, and infection control in partnership with key respondents who are 62 state and local health departments (SLHDs),[1] all awardees of CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement (CDC-RFA-TP12-1201). This information collection is authorized under Section 319C-1 of the Public Health Service Act (42 USC 241), as amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA, Public Law No. 113-5) (**Attachment A**). Reporting this information to CDC is voluntary; however, the PHEP awardees that do not take part could potentially be ineligible for PHEP supplemental funding for active monitoring. Under the emergency provisions of the Paperwork Reduction Act (PRA), CDC is seeking Office of Management and Budget (OMB) approval for a period of 180 days. If the information collection must continue beyond this period a new ICR will be submitted

[1] There are the 62 PHEP cooperative agreement awardees who are the respondents. For more information on the cooperative agreement program, see: http://www.cdc.gov/phpr/coopagreement.htm.

- All 50 states
- Four major metropolitan areas (Chicago, Los Angeles County, New York City, and Washington, D.C.)
- Eight U.S. territories and freely associated states (American Samoa, Guam, U.S. Virgin Islands, Northern Mariana Islands, Puerto Rico, Federated States of Micronesia, Republic of the Marshall Islands, and Republic of Palau).

for OMB approval before the emergency period ends. This is an existing collection in use without an OMB Control Number.

The CDC has been charged with supporting SLHDs as they engage in active monitoring of travelers arriving at U.S. airports from countries currently affected by the Ebola outbreak, and to ensure that information flows from Quarantine Stations to the states and cities that are the final destinations of these travelers. In the October 27, 2014 revised *Interim Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure* (**Attachment B**), CDC established four levels of risk – "High Risk", "Some Risk", "Low (but not Zero) Risk" and "No Identifiable Risk." The guidance also describes a process of monitoring for signs and symptoms in persons with potential exposure. Daily monitoring of health status and fever is essential to rapidly identify potentially ill people and ensure immediate isolation and rapid referral for medical evaluation of Ebola virus disease (EVD). The potential consequences of not ensuring isolation, evaluation, diagnosis and treatment of persons showing symptoms of EVD are severe, as the early uncontrolled epidemic in West Africa has demonstrated.

Direct Active Monitoring (DAM)
For those persons who are identified during entry screening as being at "High Risk", "Some Risk," or who are healthcare workers treating EVD patients in the U.S. (identified as "Low (but not zero) Risk"), SLHDs are responsible for ensuring that a public health authority (or delegate for healthcare workers) conducts direct active monitoring (DAM) daily. DAM is directly observing each person at least once daily to review the presence of symptoms consistent with EVD (including severe headache, fatigue, muscle pain, weakness, diarrhea, vomiting, abdominal pain, or unexplained hemorrhage); monitoring of temperature; and discussing plans to work, travel, take public conveyances, or be present in congregate locations.

Active Monitoring (AM)
For all travelers assessed as being at "Low (but not zero) Risk", SLHDs are responsible for conducting active monitoring (AM) -- receiving daily reports of temperature monitored with a Food and Drug Administration (FDA)-regulated thermometer and presence/absence of symptoms.

This emergency ICR covers the reporting to the CDC from all of the 62 SLHDs with a person requiring either level of monitoring; daily reports on persons falling into CDC's Ebola Risk Categories of "Some" and "High" (**Attachment B**) who require DAM; and weekly aggregated reporting of the numbers of persons in the "Low (but not Zero) Risk" category [under AM or DAM (i.e., healthcare workers treating EVD patients in the U.S.)] for EVD symptoms**.** These forms are designed to work in concert with forms recently approved in Emergency Package OMB Control No. 0920-1034 (Active Monitoring of Travelers Coming from Sierra Leone, Liberia, Guinea, and Mali; expiration date 04/30/~~2014~~2015).

Exposure Risk Category	Type of Monitoring	Frequency of Reporting to CDC
High ~~or Some~~	Direct Active Monitoring	Daily
Some or Low (U.S. HCW)	Direct Active Monitoring	Weekly
Low	Active Monitoring	Weekly

1. A daily data collection form [**Attachment C or D** - Daily Direct Active Monitoring (DAM) Recording and CDC Reporting Form (Excel & Web)] to include:
    - Individual traveler information (SLHD assigned to conduct DAM, whether they are "High" ~~or "Some"~~ risk category, reason for risk category assignment, date of last exposure, date of entry into US, citizen status, date 21 days after last exposure). Individual traveler information is collected on the first day via Epi-X, and only updated if there is a change. Health departments will also include information on travel plans during the monitoring period.
    - Information about the health departments' plans for the person if they become symptomatic including whether a hospital has been identified, the hospital name, whether a patient transfer plan has been identified.
    - Daily updates of whether DAM was completed on preceding day and reason for loss to follow-up, if applicable
    - Presence of symptoms, referral for evaluation and testing if applicable

2. A weekly data collection form [**Attachments E or F**- Weekly Active Monitoring (AM) CDC Reporting Form (Word & Web)] for reporting aggregate number of persons in the "High", "Some" and "Low (but not Zero)" exposure risk category (under AM or DAM) during the preceding week in response to a weekly email notification [**Attachment G** – Weekly Notification Email], to include:
    - Number of recent travelers from West Africa in the "Low (but not Zero)" exposure risk category who were actively monitored during the reporting period
    - Number of healthcare workers treating patients in the U.S. who were under direct active monitoring (also in the "Low, but not Zero Risk" category)
    - Number of any other group in the "High", "Some" and "Low (but not Zero) Risk" exposure category according to CDC's Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure (**Attachment B**) (e.g., persons on an aircraft with a symptomatic EVD patient, persons with brief direct contact with a person in early stages of the disease, etc.)
    - For the three groups described above:
        - Number of persons monitored during the reporting period, and brief description of reason why monitoring was *unsuccessful* for any period of time for any persons ~~with "Low (but not Zero) Risk" exposure~~ along with outcome

- Information about persons ~~with "Low (but not Zero) Risk" exposure~~ who were lost to follow up, with whom initial contact was never made, or who were transferred to another jurisdiction or left the US during the reporting period
- Number of persons ~~with "Low (but not Zero) Risk" exposure~~ reporting symptoms, who were laboratory tested for EVD, or who became a laboratory-confirmed case~~d~~ of EVD

2. Purpose and Use of Information Collection

This request will provide CDC with information necessary to assure that all persons returning from countries affected by an Ebola outbreak are being actively monitored for fever and symptoms by state or local public health authorities for 21 days after potential Ebola virus exposure.
Furthermore, information on the number and location of persons under direct active monitoring or active monitoring will allow CDC to effectively identify resource needs for SLHDs. Such resources could include expedited approval to redirect Public Health Emergency Preparedness cooperative agreement funds for Ebola-related activities, reassignment of CDC-funded field staff to Ebola activities and deployment of Public Health Associate Program staff to assist SLHDs with Ebola preparedness and response activities (**Attachment H -** CDC Assistance Memo for State Ebola Preparedness and Response).

One state- or local-level epidemiologist on behalf of every jurisdiction to which AM responsibilities have been assigned will be required to submit an aggregated weekly report that includes information about the number of people with "High", "Some" and "Low (but not Zero) Risk" exposure required to be directly actively or actively monitored, along with the numbers of people with whom initial contact was never established, who were lost to follow up for 48 hours or more, or who developed symptoms during the reporting period. This information will be used to the following ways:

1) To provide a mechanism whereby CDC can ensure that people who are at low, but not zero, risk for developing EVD can be rapidly isolated to prevent further spread of the disease and to ensure that they are quickly referred for further testing and treatment, if necessary.
2) To demonstrate that the public health system can effectively monitor those who are low, but not zero, risk for spreading Ebola disease, thus avoiding the need to implement other measures (such as travel bans) that are likely to increase the risk of importation of EVD by interfering with the ability to tackle the outbreak at its source, in West Africa.

The same SLHD contacts will also provide daily reports of similar information for persons with "High Risk"~~. "Some Risk"~~ exposure who are under DAM~~,~~. This information will be used for

the same purposes. CDC will distribute all collected information from both sets of reports: 1) back to the state health department, so they can investigate discrepancies and issues with non-compliance to monitoring; 2) to the CDC State Coordination Task Force for coordination between jurisdictions for people with travel plans; 3) to the CDC Office of the Director for internal tracking and dissemination to other Federal offices.

3. Use of Improved Information Technology and Burden Reduction

When an arriving traveler is assigned to monitoring and a risk exposure category is determined at one of the U.S. Quarantine Stations, SLHD respondents will be sent an Excel™ file with the traveler's unique coded U.S. Quarantine Station identification (ID) number. This information system is sent securely through the Epidemic Information Exchange (Epi-X), and is only sent to a state that has in-bound travelers from Guinea, Sierra Leone, Liberia, or Mali.

For "High Risk" and "Some Risk"
In turn, the CDC State Coordination Task Force will send one Excel™ data collection form to each jurisdiction with a traveler assigned to daily direct active monitoring due to "High Risk" or "Some Risk" exposure (**Attachments C & D**). The forms will be pre-populated with information gathered from the CDC Quarantine Station entry screening process for incoming travelers.

Because CDC will be able to provide states with much of the information about individual travelers and because this information will remain static for each person's 21-day monitoring period, it was determined that this would reduce respondent burden compared with having to enter direct active monitoring information for each person on a daily basis into a web-based system. In other words, after an individual's first day in DAM, SLHDs have only two fields to complete for each person in the "High Risk" and "Some Risk" groups each day: "Were they reached for direct active monitoring" and "Did they have any symptoms."

Collection will move from the excel form (Att C) to the web-form (Att D) and daily data will remain populated in the web database,. The web version uses the pre-existing Countermeasures and Response Administration (CRA) platform, with which most of the respondents are already familiar. CRA is CNA certified for data security.

For "Low (but not Zero) Risk"
SLHDs will submit aggregate counts using the optional Word form or web-based data entry system (**Attachments E or F**) once a week. Each Wednesday, they will report aggregate counts of persons monitored the prior week (Monday-Sunday). All 62 PHEP awardees will be asked to submit a report of weekly counts. Those with no persons being monitored (in the "Low (but not Zero) Risk" category) will simply respond "0" to all questions.

4. Efforts to Identify Duplication and Use of Similar Information

These data collections are designed to work in concert with the approved **Active Monitoring of Travelers Coming from Sierra Leone, Liberia, and Guinea** (OMB Control No. 0920-1034; expiration date 4/30/2015). The Interactive Voice Reporting system approved in OMB Control No. 0920-1034 provides one tool that state and local health departments may choose to use to conduct active monitoring; however, state and local health departments may choose to implement another system for active monitoring. Individuals who have been placed under active monitoring will only report into one data collection system, thus there is no duplication. The weekly ~~"Low, but not Zero, Risk"~~ data collection forms included in this package (**Attachments E or F**) asks for aggregated information with no personally identifying information (PII).

The information requested in the Direct Active Monitoring form for "High Risk" ~~and "Some Risk"~~ exposure is not being collected by any other agency across all 62 SLHDs; there is no duplication.

5. Impact on Small Businesses or Other Small Entities

No impacts on small businesses are anticipated.

6. Consequences of Collecting the Information Less Frequently

CDC activities regarding the domestic Ebola response would be significantly hindered if it were not able to collect the information necessary to prohibit the spread of this disease in the U.S. If CDC does not collect this information, there is a risk infected persons will not notify proper public health authorities in time, lengthening the time before treatment can be initiated, possibly spreading the disease to the general public. A strong, coordinated response is essential to interrupt the outbreak.

Although not all 62 SLHDs will have any Ebola cases, the consequence of collecting information less frequently than daily for DAM and weekly for AM for those jurisdictions that must will inhibit the response required to contain the spread of the disease and do everything possible to limit, if not stop preventable 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
None

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

The Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officials (NACCHO) were asked to comment on this information collection within a 21-day period in order to expedite this emergency clearance. Comments and suggestions received from these organizations were considered and did not cause any change to the current description of this information collection.

This is a request for an emergency clearance and public comment has been waived for this six month clearance.

9. Explanations of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondents. The SLHDs are performing this activity as part of the CDC PHEP cooperative agreement.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this data collection.

This data collection is not research and does not require CDC Institutional Review Board (IRB) approval.

10.1 Privacy Impact Assessment Information

Daily direct active monitoring will be collected via one of three methods. Each jurisdiction will receive a daily Excel spreadsheet (**Attachment C**) containing information for the new persons in the jurisdiction who are under direct active monitoring. Respondents will be asked to either 1) complete between 1 and 5 fields (as appropriate) in the spreadsheet and to return the spreadsheet by email; or 2) to respond directly via email with the pertinent information; or 3) update the information using a web-based system. (see Att. D)

- Daily data collection forms (**Attachments C & D**) include:
  - Individual traveler information (State assigned ID, Health Declaration ID (DQMQ-ID), State conducting DAM, risk category, reason for risk category assignment, hospital identified, date of last exposure, date of entry into US, citizen status, date 21 days after last exposure)
  - Daily updates of whether DAM was completed on preceding day and reason for loss to follow-up, if applicable

- Presence of symptoms, referral for evaluation and testing if applicable, Date of data entry

Data for the weekly active monitoring reporting will be collected through a web-based tool (**Attachment F**). A Word document is provided to respondents as a courtesy so they can use it for information gathering prior to submitting their information online. CDC will not require the Word document to be completed and returned (**Attachment E**). Respondents will receive a weekly email on Tuesdays (**Attachment G**) containing a link to the web-based active monitoring tool **(Attachment F)**.

- A weekly data collection form [**Attachments E or F**] for reporting aggregate number of persons in the "High", "Some" and "Low (but not zero)" exposure risk category (under AM or DAM) during the preceding week, to include:
  - Number of recent travelers from West Africa in the low (but not zero) exposure risk category who were actively monitored during the reporting period
  - Number of healthcare workers treating patients in the U.S. who were under active monitoring (also in the low[but not zero] risk category)
  - Number of any other group (not travelers or healthcare workers) in the "High", "Some" and "Low (but not zero)" risk exposure category according to CDC's Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure (For example, persons on an aircraft with a symptomatic EVD patient, persons with brief direct contact with a person in early stages of the disease, etc.)
  - For the three groups described above:
    - Number of persons successfully monitored each day during the reporting period, and brief description of reason why monitoring was *unsuccessful* for any period of time for any persons ~~with low (but not zero) risk exposure along with outcome~~
    - Information (DGMQ-ID, traveler's citizenship status, outcome) about persons ~~with low (but not zero) risk exposure~~ who were lost to follow up, with whom initial contact was never made, or who were transferred to another jurisdiction or left the US during the reporting period
    - Number of persons ~~with low (but not zero) risk exposure~~ reporting symptoms, who were laboratory tested for EVD, or who became a laboratory-confirmed cased of EVD.

CDC will distribute all collected information from both sets of reports: 1) back to the state health department, so they can investigate discrepancies and issues with non-compliance to monitoring, and so they can compare their own numbers with the national totals ; 2) to the CDC State Coordination Task Force for coordination between jurisdictions for people with travel plans; 3) to the CDC Office of the Director for internal tracking and dissemination to other Federal offices

11. Justification for Sensitive Questions

No information will be collected that is of a personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

A. The estimate for burden hours is based on a pilot test of the information collection instrument by 7 PHEP jurisdictions receiving the highest numbers of travelers returning from the Ebola-affected nations. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 5 minutes for direct active monitoring and 15 minutes for active monitoring reporting. Based on these results, the estimated time range for actual respondents to complete the active monitoring reporting form is 5 to 15 minutes. For the purposes of estimating burden hours, the upper limit of this range (i.e., 15 minutes) is used. This will ensure that sufficient burden hours will be approved by OMB. This is an emergency request for OMB approval lasting 180 days, for one-half the annualized burden hours incurred over a full 12-month period of daily and weekly reporting.

Table A-12A: Estimated 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
State and Local Health Departments	Attachment C - Daily Direct Active Monitoring (DAM) Recording and CDC Reporting Form (Excel)	25	183	5/60	381
	Daily Direct Active Monitoring (DAM) Recording and CDC Reporting (email)	12	183	4/60	146
	Attachment D - Daily Direct Active Monitoring (DAM)	25	183	4/60	305

	Recording and CDC Reporting Form (Web)				
	Attachment F - Weekly Active Monitoring (AM) CDC Reporting Form (Web)	62	26	13/60	350
Total					1,183

B. Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf). Based on DOL data, an average hourly wage of $45 is estimated for all 62 respondents. Table A-12 shows estimated burden and cost information. A total of 1,183 burden hours are requested for the 180-day emergency approval.

Table A-12B: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State and Local Health Departments	Attachment C- Daily Direct Active Monitoring (DAM) Recording and CDC Reporting Form (Excel)	381	$45.00	$17,145
	Daily Direct Active Monitoring (DAM) Recording and CDC Reporting (email)	146	$45.00	$6,570
	Attachment D - Daily Direct Active Monitoring (DAM) Recording and CDC Reporting Form (Web)	305	$45.00	$13,725
	Attachment F - Weekly Active	350	$45.00	$15,750

	Monitoring (AM) CDC Reporting Form (Web)			
TOTALS				$53,191

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

There will be no direct costs to the respondents other than their time to participate in each information collection.

14. Annual Cost to the Federal Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of the CDC staff during data collection and analysis activities. The estimated cost to the federal government is $84,882 for the 180-day emergency approval. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Cost to the Federal Government

Staff (FTE)	Average Hours per Week	Average Hourly Rate	Average Cost
Active Monitoring Lead (GS 15): Oversight for data collection	10	57.52	$14,955
Active Monitoring Reporting Lead Health Scientist (GS 14 - equivalent): Instrument development, OMB package creation, data collection and analysis	40	48.90	$50,856
Data Analyst (GS 14)	15	48.90	$19,071
Estimated Total Cost of Information Collection			$84,882

Salary estimates were obtained from OPM salary scale at the following web address: http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2014/general-schedule/

15. Explanation for Program Changes or Adjustments

This is a new emergency request for an information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

CDC will provide daily and weekly tabulations as soon as approval is received. There have been no publications identified to date; however publications could be possible at a later time.

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

Not applicable.

18. Exceptions for Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.