Method of Collection

To achieve the goals of this project, the following data collection will be implemented: Collect information from users who populate the RoPR database system, which will achieve all of the above goals.

The purpose and the use of the RoPR is to provide a readily available public resource strictly for patient registries, following the model of ClinicalTrials.gov, allowing for the increased availability and efficacy of patient registries. The information being collected in the RoPR Record is visible to the public visiting the RoPR Web site, and is readily available for public use. The RoPR is an ongoing data collection initiative.

Estimated Annual Respondent Burden

Between July 2014 and June 2015, 59 respondents entered their RoPR record manually.

Each respondent need enter his or her new RoPR record only once. The RoPR system sends an automated reminder to any registry owner who has not updated his or her RoPR record in the past year. Approximately, 57.25% of RoPR records were estimated to have been eligible for updates between July 2014 and June 2015, either on the registry owner’s own initiative, or prompted by the automated reminder. As the RoPR continues to grow and more patient registry records are added over time, this percentage represents a growing, cumulative number.

Prior to the deployment of the live RoPR system, Quintiles conducted six (6) usability sessions with RoPR stakeholders using a web-based prototype.

In February 2015, Quintiles conducted a knowledge transfer webinar for registry contacts to learn how to enter new records into the RoPR. As a result of the knowledge gained during these processes, it is estimated that it takes users 45 minutes to manually enter a new RoPR record; and 15 minutes to upload a new RoPR record (an average of 30 minutes using either method). It takes 15 minutes for a user to review and make updates to an existing RoPR record.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

<table>
<thead>
<tr>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Minutes per response (average)</th>
<th>Total burden hours (average)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New RoPR Record (manually—entered or uploaded electronically method)</td>
<td>59</td>
<td>1</td>
<td>30/60</td>
<td>29.5</td>
</tr>
<tr>
<td>Review/update existing RoPR Record</td>
<td>79</td>
<td>1</td>
<td>15/60</td>
<td>19.75</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>138</strong></td>
<td><strong>1</strong></td>
<td><strong>49.25</strong></td>
<td></td>
</tr>
</tbody>
</table>

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

<table>
<thead>
<tr>
<th>Form name</th>
<th>Number of respondents</th>
<th>Total burden hours</th>
<th>Average hourly wage rate †</th>
<th>Total cost burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>New RoPR Record (manually—entered or uploaded electronically method)</td>
<td>59</td>
<td>29.5</td>
<td>$36.54</td>
<td>$1,077.93</td>
</tr>
<tr>
<td>Review/update existing RoPR Record</td>
<td>79</td>
<td>19.75</td>
<td>36.54</td>
<td>721.67</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>138</strong></td>
<td><strong>44.25</strong></td>
<td></td>
<td><strong>$1,799.60</strong></td>
</tr>
</tbody>
</table>


In order to highlight patient registry concerns about using the RoPR system and turning user feedback into future system maintenance and upgrade initiatives (increasing the usability of the RoPR and lowering the burden of entering patient registry information), plans for a voluntary user satisfaction survey is being considered for development and deployment in 2Q 2016. Its full nature and design is still in the concept stage and so this survey is not part of the Estimated Annualized Respondent Hourly/Cost Burden noted in Exhibits 1 and 2.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ’s information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ’s estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency’s subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon Arnold,
Deputy Director.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day—15–15BFV; Docket No. CDC–2015–0085]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).
The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the proposed information collection request entitled “A Study of Viral Persistence in Ebola Virus Disease (EVD) Survivors”. The purpose of this information collection is to gather the necessary information for the CDC and the international community to begin the activities necessary to reach the goal of zero new EVD cases throughout West Africa. Once that goal is reached, the 42-day countdown to declare West Africa Ebola free can begin. “Persistence of Ebola Virus in Body Fluids of Ebola Virus Disease (EVD) Survivors in Sierra Leone”. This information collection will be the first systematic examination of the post-recovery persistence of Ebola virus and the risks of transmission from a cohort of convalescent Ebola survivors during close or intimate contact. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search existing data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project
 Persistence of Ebola Virus in Body Fluids of Ebola Virus Disease (EVD) Survivors in Sierra Leone—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description
 Much progress has been made in the year since the CDC first responded to the Ebola outbreak in West Africa, but the agency’s efforts must continue until there are zero new cases of Ebola virus disease (EVD). As the CDC’s 2014 Ebola virus response draws closer to the international goal of zero new EVD cases in 2015, the agency must intensify its efforts to identify and prevent every potential route of human disease transmission and to understand the most current community barriers to reaching that final goal. “Persistence of Ebola Virus (EBOV) in Body Fluids of EVD Survivors in Sierra Leone” will be the first systematic examination of the post-recovery persistence of EBOV and the risks of transmission from a cohort of convalescent Ebola survivors during close or intimate contact. This activity is currently approved by OMB for emergency use under OMB Control Number 0920–1064—Persistence of Ebola Virus (EBOV) in Body Fluids of EVD Survivors in Sierra Leone, which expires on November 30, 2015. It is important to fully understand how long the virus stays active in body fluids other than blood in order to target and refine public health interventions to arrest the ongoing spread of disease. The research study is comprised of three modules based on the body fluids to be studied: A pilot module of adult males (semen) and two full modules: Module A of adult men and women repeating collections and questionnaires every two weeks (semen, vaginal secretions, and saliva, tears, sweat, urine, rectal swab), and Module B of lactating adult women repeating collections and questionnaires every three days (sweat and breast milk). Participants for each module will be recruited by trained study staff from Ebola treatment units and survivor registries. Participants will be followed up at study sites in government hospitals. Specimens will be tested for EBOV ribonucleic acid (RNA) by reverse transcription polymerase chain reaction test (RT–PCR) in Sierra Leone at the CDC laboratory facility in Bo. All positive RT–PCR samples will be sent to CDC for virus isolation. Each body fluid will be collected until two negative RT–PCR results are obtained. Participants will be followed until all their studied body fluids are negative. They will receive tokens of appreciation for their participation at the initial visit and again at every subsequent follow-up visit [e.g., 120,000 Leones (approximately $28 US dollars) and a
supply of condoms]. For Module A, men and women will be recruited in equal numbers for this study until more information on gender effects of viral persistence is available. A trained study data manager will collect test results for all participants in a laboratory results form.

Results and analyses are needed to update relevant counseling messages and recommendations from the Sierra Leone Ministry of Health, World Health Organization and CDC. The study will provide the most current information that is critical to the development of public health measures, such as recommendations about sexual activity, breastfeeding, and other routine activities and approaches to evaluation of survivors to determine whether they can safely resume sexual activity. These approaches in turn are expected to reduce the risk of Ebola resurgence and mitigate stigma for thousands of survivors. The information is likewise critical to reducing the risk that Ebola would be introduced in a location that has not previously been affected. The total estimated annualized burden hours are 2,474.

### ESTIMATED ANNUALIZED BURDEN HOURS

<table>
<thead>
<tr>
<th>Form name</th>
<th>Type of respondent</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilot participants</td>
<td>Survivor Questionnaire</td>
<td>80</td>
<td>1</td>
<td>30/60</td>
<td>40</td>
</tr>
<tr>
<td>Pilot participants</td>
<td>Survivor Follow-up Questionnaire</td>
<td>80</td>
<td>12</td>
<td>10/60</td>
<td>160</td>
</tr>
<tr>
<td>Module A male participants</td>
<td>Survivor Questionnaire</td>
<td>175</td>
<td>1</td>
<td>30/60</td>
<td>88</td>
</tr>
<tr>
<td>Module A male participants</td>
<td>Survivor Follow-up Questionnaire</td>
<td>175</td>
<td>12</td>
<td>10/60</td>
<td>350</td>
</tr>
<tr>
<td>Module A female participants</td>
<td>Survivor Questionnaire</td>
<td>175</td>
<td>12</td>
<td>10/60</td>
<td>350</td>
</tr>
<tr>
<td>Module A female participants</td>
<td>Survivor Follow-up Questionnaire</td>
<td>175</td>
<td>1</td>
<td>30/60</td>
<td>88</td>
</tr>
<tr>
<td>Module B female participants</td>
<td>Survivor Questionnaire</td>
<td>100</td>
<td>1</td>
<td>30/60</td>
<td>50</td>
</tr>
<tr>
<td>Module B female participants</td>
<td>Survivor Follow-up Questionnaire</td>
<td>100</td>
<td>12</td>
<td>10/60</td>
<td>200</td>
</tr>
<tr>
<td>Data manager</td>
<td>Laboratory Results Form</td>
<td>1</td>
<td>6,890</td>
<td>10/60</td>
<td>1,148</td>
</tr>
<tr>
<td><strong>TOTALS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2,474</td>
</tr>
</tbody>
</table>

Leroy A. Richardson,  
Chief, Information Collection Review Office,  
Office of Scientific Integrity, Office of the  
Associate Director for Science, Office of the  
Director, Centers for Disease Control and  
Prevention.

[FR Doc. 2015–23572 Filed 9–18–15; 8:45 am]  
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention  
[60 Day–15–15BFD; Docket No, CDC–2015–  
0082]

Proposed Data Collection Submitted  
for Public Comment and  
Recommendations

AGENCY: Centers for Disease Control and  
Prevention (CDC), Department of Health  
and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease  
Control and Prevention (CDC), as part of  
its continuing efforts to reduce public  
burden and maximize the utility of  
government information, invites the  
general public and other Federal  
agencies to take this opportunity to  
comment on proposed and/or  
continuing information collections, as  
required by thePaperwork Reduction  
Act of 1995. This notice invites  
comment on the proposed collection  
Active Monitoring of Travelers Coming  
from Ebola-affected Countries and Their  
Contacts Currently Residing in State,  
Territorial, and Local Jurisdictions.

DATES: Written comments must be  
received on or before November 20,  
2015.

ADDRESSES: You may submit comments,  
identified by Docket No. CDC–2015–  
0082 by any of the following methods:  
• Federal eRulemaking Portal:  
Regulation.gov. Follow the instructions  
for submitting comments.  
• Mail: Leroy A. Richardson,  
Information Collection Review Office,  
Centers for Disease Control and  
Prevention, 1600 Clifton Road NE., MS–  
D74, Atlanta, Georgia 30329.

Instructions: All submissions received  
must include the agency name and  
Docket Number. All relevant comments  
received will be posted without change  
to Regulation.gov, including any  
personal information provided. For  
access to the docket to read background  
documents or comments received, go to  
Regulations.gov.

Please note: All public comment  
should be submitted through the  
Federal eRulemaking portal  
(Regulations.gov) or by U.S. mail to the  
address listed above.

FOR FURTHER INFORMATION CONTACT: To  
request more information on  
the proposed project or to obtain a copy  
of the information collection plan and  
instruments, contact the Information  
Collection Review Office, Centers for  
Disease Control and Prevention, 1600  
Clifton Road NE., MS–D74, Atlanta,  
Georgia 30329; phone: 404–639–7570;  
Email: ombr@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the  
Paperwork Reduction Act of 1995 (PRA)  
(44 U.S.C. 3501–3520), Federal agencies  
must obtain approval from the Office of  
Management and Budget (OMB) for each  
collection of information they conduct  
or sponsor. In addition, the PRA also  
requires Federal agencies to provide a  
60-day notice in the Federal Register  
concerning each proposed collection of  
information, including each new  
proposed collection, each proposed  
extension of existing collection of  
information, and each reinstatement of  
previously approved information  
collection before submitting the  
collection to OMB for approval. To  
comply with this requirement, we are  
publishing this notice of a proposed  
data collection as described below.

Comments are invited on: (a) Whether  
the proposed collection of information  
is necessary for the proper performance  
of the functions of the agency, including  
whether the information shall have  
practical utility; (b) the accuracy of  
the agency's estimate of the burden of  
the proposed collection of information;  
(c) ways to enhance the quality, utility,  
and clarity of the information to be  
collected; (d) ways to minimize the  
burden of the collection of information  
on respondents, including through the  
use of automated collection techniques  
or other forms of information  
technology; and (e) estimates of capital  
or start-up costs and costs of operation,