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

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

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

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

† * Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29–0000. National Compensation Survey: Occupational wages in the United States May 2014, ''U.S. Department of Labor, Bureau of Labor Statistics.'' Available at: *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000..*

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.

[FR Doc. 2015–23574 Filed 9–18–15; 8:45 am]

BILLING CODE 4160–90–P

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).

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 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.

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

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0085 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 *Regulations.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: *omb@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, 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 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

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

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 the Paperwork 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 *Regulations.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: *omb@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,