Testing Challenges, Exercises and/or Validation Studies every year consisting of five to 500 simulated samples provided by the LRN Program Office. It is necessary to conduct such challenges in order to verify the testing capability of the LRN Laboratories. The rarity of biological or chemical agents perceived to be of bioterrorism concern prevents some LRN Laboratories from maintaining proficiency as a result of day-to-day testing. Simulated samples are therefore distributed to ensure proficiency across the LRN. The results obtained from testing these simulated samples must also be entered into Results Messenger for evaluation by the LRN Program Office.

During a surge event resulting from a bioterrorism or chemical terrorism attack, LRN Laboratories are also required to submit all testing results using LRN Results Messenger. The LRN Program Office requires these results in order to track the progression of a bioterrorism event and respond in the most efficient and effective way possible and for data sharing with other Federal partners involved in the response. The number of samples tested during a response to a possible event could range from 10,000 to more than 500,000 samples depending on the length and breadth of the event. Since there is potentially a large range in the number of samples for a surge event, CDC estimates the annualized burden for this event will be 2,250,000 hours or 625 responses per respondent.

There is no cost to the respondents other than their time. The total estimated annualized burden is 2,382,300 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Forms	Number of respondents	Average number of responses per respondent	Average burden per response (hours)	Total burden hours
Public Health Laboratories	Biennial Requalification	150	1	2	300
Public Health Laboratories	General Surveillance Testing Results.	150	25	24	90,000
Public Health Laboratories	Proficiency Testing/Validation Testing Results.	150	5	56	42,000
Public Health Laboratories	Surge Event Testing Results	150	625	24	2,250,000
Total					2,382,300

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. 2015–28154 Filed 11–4–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–16BX; Docket No. CDC–2015–0092]

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 a proposed information collection entitled ''Monitoring and Reporting for the Core State Violence and Injury Prevention Program Cooperative Agreement.'' CDC will use the information collected to monitor cooperative agreement awardees and to identify challenges to program implementation and achievement of outcomes.

DATES: Written comments must be received on or before January 4, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0092 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

Monitoring and Reporting for the Core State Violence and Injury Prevention Program Cooperative Agreement—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Unintentional and violence-related injuries and their consequences are the leading causes of death for the first four decades of life, regardless of gender, race, or socioeconomic status. More than 192,000 individuals in the United States die each year as a result of unintentional injuries and violence, and more than 31 million others suffer non-fatal injuries requiring emergency department visits each year. Given these factors, the Public Health Service Act (PHS Act) provides an important opportunity for states to advance public health across the lifespan and to reduce health disparities. Support and guidance for these programs have been provided through cooperative agreement funding and technical assistance administered by CDC's National Center for Injury Prevention and Control (NCIPC). The goal of this ICR is to collect information needed to monitor cooperative agreement programs funded under the Core State Violence and Injury Prevention Program (Core SVIPP) (CDC–RFA–CE16–1602).

Information to be collected will provide crucial data for program performance monitoring and provide CDC with the capacity to respond in a timely manner to requests for information about the program from the Department of Health and Human Services (HHS), the White House, Congress, and other sources. Awardees will report progress and activity information to CDC on an annual schedule using an Excel-based fillable electronic templates. Each awardee will submit three information collection tools: Annual Progress Report, Evaluation and Performance Management Plan, and Injury Indicator Spreadsheets. In Year 1, each awardee will have additional burden related to initial collection of the reporting tools. Initial population of the tools is a one-time activity, after completing the initial population of the tools, pertinent information only needs to be updated annually for each report.

CDC will use the information collected to monitor each awardee's progress and to identify facilitators and challenges to program implementation and achievement of outcomes. Monitoring allows CDC to determine whether an awardee is meeting performance and goals and to make adjustments in the type and level of technical assistance provided to them, as needed, to support attainment of their performance measures. With the tools, the use of a standard set of data elements, definitions and specifications at all levels will help to improve the quality and comparability of performance information that is received by CDC for multiple awardees and multiple award types by ensuring that the same information is collected on all strategies and performance measures with slightly different areas of emphasis, depending on the awardee type (BASE, Enhanced with 1 Component, or Enhanced 2 Components).

OMB approval is requested for three years. Participation in the information collection is required as a condition of funding. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Core SVIPP BASE Awardees	Initial Population—Annual Progress Report.	20	1	22	440
	Annual Progress Report	20	1	11	220
	Evaluation and Performance Management Plan.	20	1	2	40
	Injury Indicator Spreadsheet	20	1	14	280
Core SVIPP 1—Enhanced Component Awardees.	Initial Population—Annual Progress Report.	5	1	73	365
	Annual Progress Report	5	1	58	290
	Evaluation and Performance Management Plan.	5	1	3	15
	Injury Indicator Spreadsheet	5	1	14	70
Core SVIPP 2—Enhanced Component Awardees.	Initial Population—Annual Progress Report.	5	1	146	730
	Annual Progress Report	5	1	116	580
	Evaluation and Performance Management Plan.	5	1	4	20
	Injury Indicator Spreadsheet	5	1	14	70
Total					3,120

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. 2015–28153 Filed 11–4–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before December 7, 2015.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–0990–New–30D for reference.

Information Collection Request Title: Information Collection Request Title: Evaluation of the Office on Women's Health Coalition for a Healthier Community Initiative.

Abstract: This collection is to provide data for the national evaluation of the U.S. Department of Health and Human Services (HHS), Office on Women's Health (OWH) Coalition for a Healthier Community (CHC) Initiative. The initiative supports 10 communities with grants to support coalitions in implementing gender-based public health systems approaches, evidence-based health interventions, and outreach and education activities to reduce barriers to and enhance facilitators of improvements in women and girls' health. Each of the grantees has implemented an IRB-approved local evaluation; however, OWH is seeking to collect core data across grantees to examine the extent to which the Government's investment has resulted in achieving OWH-related *Healthy People 2020* priorities and yields lessons learned upon which to plan future initiatives related to its mission.

Likely Respondents: The proposed collection includes plans for interviews with key staff (project directors, project coordinators, local evaluators), coalition members (including chairs and co-chairs), and community leaders connected to the coalitions. These respondents will also complete online surveys about their perceptions of the changes in their community as a result of coalition activities. Program participants and other community members exposed to the coalitions' activities through social media will also complete online surveys. Project directors and local evaluators also annually provide information to OWH on their coalition's functioning, the status of the cost-effectiveness analysis for their coalition's interventions, and the coalition's plans for sustainability. The following table summarizes the ''Total Estimated Annualized Burden—Hours'' by form and type of respondent.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden hours
1—Key Persons Discussion Guide for Telephone Interviews	90	2	1	180
2—Key Persons, Coalition Members, and Community Leaders Online Survey	200	1	20/60	67
3—Coalition Participants and Other Community Members Online Survey	510	1	20/60	170
4—Grantee Annual Report on Coalition Functioning, Cost-Effectiveness, and Sustainability Planning	10	2	2	40
Total				457

Terry Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2015–28156 Filed 11–4–15; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. FDA–2015–D–3638]

Minutes of Institutional Review Board Meetings: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Availability

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, and the Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, and the Food and Drug Administration (FDA) are announcing the availability of a draft guidance entitled ''Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs.'' The draft guidance is intended for institutions and IRBs that are responsible for the review and oversight of human subject research conducted or supported by the U.S. Department of Health and Human Services (HHS) or regulated by FDA. The purpose of the