LeRoy 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–14–14OE]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov*.

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

Monitoring and Reporting System for the Rape Prevention and Education Program Awardees—NEW—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Sexual violence is a major public health problem. According CDC's National Intimate Partner and Sexual Violence Survey (NISVS, OMB# 0920–0822), in the United States, nearly 1 in 5 women and 1 in 71 men have been raped in their lifetime, while 1 in 2 women and 1 in 5 men have experienced severe sexual violence victimization other than rape at some point in their lives, with the majority of victimization starting early in life. According to NISVS, approximately 80% of female victims experienced their first rape before the age of 25 and almost half experienced the first rape before age 18. Among male victims, 28% were first raped when they were 10 year old or younger. NISVS also found that early sexual victimization increases women's risk of adult victimization: Approximately 35% of women who were raped as minors were also raped as adults compared to 14% of women without an early rape history.

State health departments and the community-based organizations funded to implement sexual violence prevention strategies have variable, often low, levels of capacity and infrastructure to engage in program improvement and systematically collect data about sexual violence as well as the prevention strategies they are implementing. Historically, some health departments and funded community-based organizations have not had adequate resources to support a full-time staff person to deliver and implement prevention strategies. Additionally, while sexual violence prevention practitioners have undergone a sea change and expanded their focus from raising awareness of the problem to implementing primary prevention strategies, improved implementation based on best-available practices in prevention is still needed.

CDC, through the Rape Prevention and Education (RPE) Program, supports sexual violence prevention by implementing primary prevention strategies using a public health approach and effective prevention principles. The current cooperative agreement will advance this goal by supporting RPE funded organizations to implement sexual violence prevention strategies that adhere to general principles of effective prevention strategies. These principles include: Addressing modifiable risk and protective factors for perpetration and victimization, addressing multiple levels of the social ecology, emphasizing primary prevention, having sufficient dosage or intensity, being culturally relevant, being developed and implemented with stakeholders and based on best available evidence. Additionally, it aims to improve program evaluation infrastructure and capacity at the state level.

In order to accomplish these goals, the program strategy involves the focused implementation of three main components:

- Component 1—Implementation and program evaluation of sexual violence (SV) prevention strategies using a public health approach (this includes expectations that program evaluation activities are conducted at the state level.
- Component 2—Provision of Training and Technical Assistance to RPE funded organizations on the implementation of SV prevention strategies.
- Component 3—Participation in program support activities.

The primary outcome of interest is the improved ability of RPE funded organizations to use the public health approach and effective prevention principles to implement and evaluate sexual violence prevention strategies.

CDC seeks a 3-year Office of Management and Budget (OMB) approval to collect information electronically from awardees funded under the RPE cooperative agreement. Information will be collected from RPE awardees through an electronic data management information system; the Rape Prevention and Education Management Information System (RPE–MIS). The RPE–MIS will be used to collect information about the staffing resources dedicated by each awardee, as well as partnerships with external organizations. The RPE–MIS requires awardees to define their program objectives in action-oriented SMART (Specific, Measurable, Achievable, Relevant, and Time-Framed) format, identify their target population and associated strategies citing the best available evidence and data sources, establish the link between their objectives, chosen strategies and the target population, and provide quantifiable performance measures associated with the chosen strategies. Information collected through the RPE–MIS will be used to inform performance monitoring, and program evaluation.

Anticipated respondents are a maximum of 55 awardees for the RPE Program. All respondents will be state and territorial health departments or designated personnel from their partner sexual assault coalitions. The time commitments for data entry and training are greatest during the initial population of the RPE–MIS, typically in the first six months of implementation. Estimated burden for the first-time population of the RPE–MIS is fifteen hours. Annual Reporting is estimated at three hours per respondent.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN TO RESPONDENTS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State and Territorial Health Departments or Sexual Assault Coalition Designee.	RPE–MIS: Initial population	55	1	15	825
	RPE–MIS: Annual reporting	55	1	3	165
Total					990

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–14–0905]

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Proposed Project

FoodNet Non-O157 Shiga Toxin-Producing *E. coli Study:* Assessment of Risk Factors for Laboratory-Confirmed Infections and Characterization of Illnesses by Microbiological Characteristics (0920–0905 expires 11/30/14)—Extension—National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Each year many Shiga toxin-producing *E. coli* (STEC) infections occur in the United States, ranging in severity from mild diarrhea, to hemorrhagic colitis and in some cases, life-threatening hemolytic uremic syndrome (HUS). HUS occurs most frequently following infection with serogroup O157; 6% of patients with this type of STEC infection develop HUS, with highest occurrence in children aged < 5 years. HUS has a fatality rate of approximately 5%; up to 25% of HUS survivors are left with chronic kidney damage. STEC are broadly categorized into two groups by their O antigens, STEC O157 and non-O157 STEC. The serogroup O157 is most frequently isolated and most strongly associated with HUS. Risk factors for STEC O157 infections in the United States and internationally have been intensely studied. Non-O157 STEC are a diverse group that includes all Shiga toxin-producing *E. coli* of serogroups other than O157. Over 50 STEC serogroups are known to have caused human illness. Numerous non-O157 outbreaks have been reported from throughout the world and clinical outcomes in some patients can be as severe as those seen with STEC O157 infections, however, little is known about the specific risk factors for infections due to non-O157 STEC serogroups. More comprehensive understanding of risk factors for sporadic non-O157 STEC infections is needed to inform prevention and control efforts.

The FoodNet case-control study is the first multistate investigation of non-outbreak-associated non-O157 STEC infections in the United States. It investigates risk factors for non-O157 STEC infections, both as a group and individually for the most common non-O157 STEC serogroups. In addition, the study characterizes the major known virulence factors of non-O157 STEC to assess how risk factors and clinical features vary by virulence factor profiles. As the largest, most comprehensive, and most powerful study of its kind, it is making an important contribution towards better understanding of non-O157 STEC infections and will provide science-based recommendations for interventions to prevent these infections. Study enrollment began between July and September 2012 (sites had staggered start dates) and is scheduled to run for 36 months. Since we have not yet enrolled enough cases to meet the study objectives, we are requesting an extension.

Persons with non-O157 STEC infections who are identified as part of routine public health surveillance and randomly selected healthy persons in the patients' communities (to serve as controls) are contacted and offered enrollment into this study. Participation is completely voluntary and there is no cost for enrollment. The total burden is 268 hours.