

- BACKGROUND:
- INFORMATION NEEDS:

**DATES:** Electronic or written comments should be received on or before March 8, 2016.

**ADDRESSES:** You may submit comments identified by CDC-2015-0075 and Docket Number NIOSH-288 by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, OH 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number (CDC-2015-0075; NIOSH-288). All relevant comments received will be posted without change to [www.regulations.gov](http://www.regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [www.regulations.gov](http://www.regulations.gov). All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226.

**FOR FURTHER INFORMATION CONTACT:**

Gayle DeBord, NIOSH, Division of Applied Research and Technologies, Robert A. Taft Laboratories, 1090 Tusculum Avenue, MS-R2, Cincinnati, Ohio 45226, Phone: (513) 841-4256 [not a toll-free number], Email: [hazardousdrugs@cdc.gov](mailto:hazardousdrugs@cdc.gov).

*Background:* The purpose of the RFI is to seek information relative to the development of a performance evaluation protocol for CSTDs using air cleaning or filtration technologies. The draft protocol released for public comment on September 8, 2015 [80 FR 53802] is applicable to barrier-type CSTDs only. This RFI expands the scope of the previous RFI to seek information to support development of a companion protocol that would apply to CSTDs using air cleaning or filtration technologies, thus covering the remainder of the currently known CSTD marketplace.

*Information Needs:* Additional data and information are needed to assist NIOSH to develop or adapt a test protocol for evaluating the efficiency of air cleaning or filtration technologies CSTDs. In particular, NIOSH requests submission of existing test protocols developed for efficacy testing of air cleaning or filtration technologies CSTDs.

The National Institute for Occupational Safety and Health seeks

public comments in response to the following questions. Please feel free to comment on any or all of the questions below:

1. Are there any other types of CSTDs available that would not fit into the two categories described, *i.e.*, (1) barrier systems, and (2) air-cleaning or filtration technologies?

2. Is there an existing test protocol for evaluation of the protective efficacy of air-cleaning or filtration technologies CSTDs? Can this test protocol, and/or the details of the underlying procedures and test data be shared with NIOSH?

Please apply the following questions to a protocol you have developed, one you are aware of, or one you believe to be feasible to develop:

3. Are there any special restrictions, limiting assumptions or requirements for expertise required to conduct the protocol?

4. What are the performance criteria used with the protocol tests to determine acceptability and judge conformity?

4. Does the protocol apply to compounding operations, administration activities or both?

5. Does this protocol use a surrogate or does it require testing against the actual hazardous drugs?

6. If a surrogate is used,

a. Does the surrogate represent all hazardous drugs or a subset?

b. Which criteria are used in selection of the surrogate?

c. Describe how the selection criteria address the degree to which the surrogate or surrogates are representative of the class of hazardous drugs to which they apply.

d. Does the surrogate introduce any potential worker exposure hazards?

7. List the hazardous drugs for which this protocol has been used.

a. How were these hazardous drugs selected?

b. Were there any hazardous drugs for which the test protocol was not or would not be successful or compatible?

c. During protocol application, in what state were the hazardous drugs, *e.g.*, full strength as delivered, full strength reconstituted, patient dose with diluent, or drug cocktail?

8. What procedure(s) can be used to verify that the protocol is applicable for new hazardous drugs as they are identified and brought to market?

9. Can the test protocol be used effectively for different formulations of the same active pharmaceutical ingredient?

10. If applicable, are you willing to share details of your test protocol with NIOSH? Would you be willing for the protocol details to be shared publicly or

would you require the test protocol details to be protected as proprietary information?

11. If applicable, are you willing to share test results from the application of your air cleaning or filtration technologies CSTD test protocol with NIOSH?

12. Are you interested in being a collaborative partner with NIOSH on the development of an air cleaning or filtration technologies CSTD test protocol?

Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or to issue a grant. Information obtained as a result of this RFI may be used by the government for program planning on a non-attribution basis. Please do not include any information that might be considered proprietary, confidential, or personally identifying (such as home address or social security number).

Dated: January 12, 2016.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

[FR Doc. 2016-00827 Filed 1-15-16; 8:45 am]

**BILLING CODE 4163-19-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-16-15BBU]

#### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and

clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

### Proposed Project

The Girl Power Project Efficacy Trial—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

The 60-day **Federal Register** Notice, published on August 12, 2015, was titled “Efficacy Study of a Mobile Application to Provide Comprehensive and Medically Accurate Sexual Health Information for Adolescent Girls.”

### Background and Brief Description

Despite drastic reductions in teen births across all racial and ethnic groups, Black and Latino girls continue to have disproportionately high rates of teen births. Increasing girls’ access to medically accurate and comprehensive sexual health information is the first step in sustaining momentum in teen pregnancy reduction among all racial and ethnic groups, and in promoting healthy sexual behaviors, especially among minority girls.

CDC plans to collect the information needed to test the efficacy of a comprehensive and medically accurate mobile application, titled *Crush*, in increasing adolescent girls’ contraception use and clinic visitation for sexual and reproductive health services. The information disseminated via *Crush* is similar to the sexual health information youth can access via other

Web sites, sexual health promotion educational materials or in clinics.

The study will randomize a sample of 1,200 girls, ages 14–18 years, into two groups: the intervention group and the control group. The intervention group will have access to *Crush* and will receive weekly sexual health information via text to their phones for six months. The control group will have access to a fitness mobile application (“app”) and will receive general health information via text to their phones for six months. Participants are expected to access either app frequently throughout a six month period. As part of the analysis, sexual behavior and key psychosocial factors will be assessed at three points in time: at baseline, and at three- and six-month follow-ups.

Efficacy testing will respond to the following research questions:

1. Does exposure to *Crush* increase consistent contraception use among participants?

2. Does exposure to *Crush* increase clinic utilization rate among participants?

3. Is media content more attractive to participants than text-based content?

For research questions 1 and 2, we hypothesize that participants in the intervention group will report increased intent to use effective contraception and utilize clinic services at three and six months post-intervention.

The study will also include a usability testing component to identify the content and features of *Crush* that are most attractive to participants, the frequency in which *Crush* was used, and the navigation patterns within *Crush*. Participants will create an account in the Enrollment Database. This database will host participants’ enrollment information, basic demographic information, and will also track their navigation pattern to monitor *Crush* visitation frequency and visit duration. Navigation data will be used to assess intervention exposure and dosage to specific content areas of *Crush*. To test real-world utilization of *Crush*, control group participants will gain access to *Crush* six months after enrolling into the study, but will not receive weekly text messages. The study will track visitation frequency and duration of each visit. Usability testing will respond to Research Question #3. We hypothesize that participants in the intervention group will spend more

time using media features than text-based content.

All information will be collected electronically. This study will collect data through two mechanisms: (1) Self-administered online surveys, and (2) the *Crush* enrollment database. Participants will complete a total of three self-administered online surveys at baseline, and at three and six month follow-ups. Survey questions will assess behavior, attitudes, social norms about sexual behavior, contraception use and clinic utilization, and satisfaction with *Crush*.

The mobile response surveys will be sent to participants via text message which they can complete on a smartphone. The estimated burden per response is 5–15 minutes. Survey responses will be matched by each participant’s unique identifying number. Each participant will receive up to two survey reminders starting one week after the initial survey link is sent, for two consecutive weeks. There are minor differences in survey content for the control and intervention groups.

Each participant will create a profile in the database upon enrollment. This database will collect initial demographic and contact information, informed consent signatures, and information about the participant’s navigation pattern through *Crush*. Any information entered directly into *Crush* interactive features will not be stored in the system. The database only collects web analytics data about page visits and duration of each visit by User ID and Internet Protocol (IP) address. Web analytics will only be collected from participants navigating *Crush* and only when they are logged in as users. Web analytics are generated for any Web site and are a standard evaluation mechanism for assessing the traffic patterns on Web pages. This technology permits development of an objective and quantifiable measure that tracks and records participants’ exposure to *Crush*. This study component does not entail any response burden to participants.

Findings will be used to inform the development and delivery of effective health communications.

OMB approval is requested for one year. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 752.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Girls 14–18 years old Intervention Group	Enrollment Questions	1,200	1	5/60
	Baseline Survey	600	1	15/60
	3-Month Survey	480	1	10/60
	6-Month Survey	384	1	15/60
Control Group	Baseline Survey	600	1	15/60
	3-Month Survey	480	1	10/60
	6-Month Survey	384	1	15/60

**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. 2016–00866 Filed 1–15–16; 8:45 am]

BILLING CODE 4163–18–P

**DEPARTMENT OF HEALTH AND  
 HUMAN SERVICES**

**Centers for Disease Control and  
 Prevention**

[Docket Number CDC–2016–0002; NIOSH–  
 214]

**Request for Information on NIOSH  
 Center for Direct Reading and Sensor  
 Technologies: Sensors for Emergency  
 Response Activities**

**AGENCY:** National Institute for  
 Occupational Safety and Health  
 (NIOSH) of the Centers for Disease  
 Control and Prevention (CDC),  
 Department of Health and Human  
 Services (HHS).

**ACTION:** Request for information (RFI)  
 and comment.

**SUMMARY:** The National Institute for  
 Occupational Safety and Health  
 (NIOSH), part of the Centers for Disease  
 Control and Prevention (CDC), requests  
 information to enhance the value of the  
 NIOSH Center for Direct Reading and  
 Sensor Technologies and is seeking  
 input regarding specific issues on the  
 availability, capability, suitability,  
 barriers, limitations, and opportunities  
 for current or future direct reading  
 devices and sensor technologies that can  
 be utilized for emergency response. This  
 RFI is intended to inform the planning  
 of a document to evaluate current and  
 future sensor technologies used in  
 emergency response.

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**DATES:** Electronic or written comments  
 should be received on or before March  
 21, 2016.

**ADDRESSES:** You may submit comments  
 identified by CDC–2016–0002 and  
 Docket Number NIOSH–214 by any of  
 the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, OH 45226–1998.

*Instructions:* All information received in response to this notice must include the agency name and docket number (CDC–2016–0002; NIOSH–214). All relevant comments received will be posted without change to [www.regulations.gov](http://www.regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [www.regulations.gov](http://www.regulations.gov). All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226.

**FOR FURTHER INFORMATION CONTACT:**  
 D. Gayle DeBord, NIOSH, Division of Applied Research and Technologies, Robert A. Taft Laboratories, 1090 Tusculum Avenue, MS–R2, Cincinnati, Ohio 45226, Phone: (513) 841–4256 [not a toll-free number], Email: [GDeBord@cdc.gov](mailto:GDeBord@cdc.gov).

*Background:* The NIOSH Center for Direct Reading and Sensor Technologies (<http://www.cdc.gov/niosh/topics/drst/default.html>) was created in May 2014 to coordinate the development of recommendations on the use of these 21st century technologies in occupational safety and health. The mission of the Center is to develop a national research agenda, provide guidance on the selection of sensors and direct-reading monitors and guidance for validation, quality control and

training. Within the overall scope of its activities, the Center plans to develop a document to evaluate current and future sensor technologies used in emergency response.

**Information Needs:** Specifically, emergency responders are increasingly relying on direct-reading instruments and other sensor technologies to rapidly evaluate potentially life-threatening hazards and exposures.

Recommendations to support the proper selection, use, validation, calibration and interpretation of these technologies are lacking. The use of new generations of sensors has increased exponentially in the past few years. While other Federal agencies and organizations have developed some recommendations on this topic, newer sensor technologies have not been thoroughly evaluated and guidance has not focused on interpretation of data or appropriate for the intended purpose. Other factors that need to be considered are that multiple strategies of environmental sampling will be necessary in any response effort; and that an understanding of the advantages and limitations of newer direct-reading and sensor technologies is needed to select the appropriate strategies. Additionally, training for these new sensor technologies and environmental sampling strategies may be lacking.

The National Institute for Occupational Safety and Health seeks public comments in response to the following questions. Please feel free to comment on any or all of the questions below:

**A. Utilization of Sensors in Emergency Response**

A1. What sensors have the most immediate impact on emergency response?

A2. What applications/situations such as determination of the need for evacuation, use of personal protective equipment, or end-of-service-life of protective equipment are particularly in need of sensors?