DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15BBU]; [Docket No. CDC-2015-0069]

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 request entitled "*Efficacy Study of a Mobile Application to Provide Comprehensive and Medically Accurate Sexual Health Information for Adolescent Girls*". The study will examine the

efficacy of the mobile application in achieving two behavioral outcomes: use of effective contraception and clinic utilization.

DATES: Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0069 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, N.E., 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, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: 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

Efficacy Study of a Mobile Application to Provide Comprehensive and Medically Accurate Sexual Health Information for Adolescent

Girls – New – National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

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 websites, sexual health promotion educational materials or in clinics.

The study will randomize a sample of 1,200 girls, ages 14-18, 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 the 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 three points in time: at baseline, and at three- and six-month follow-ups.

Efficacy testing will respond to the following research questions: Research Question #1 is: Does exposure to Crush increase consistent contraception use among participants? We hypothesize that participants in the intervention group will report increased intent to use effective contraception at three and six months post-intervention. Research Question #2 is: Does exposure to Crush increase clinic utilization rate among participants? We hypothesize that participants in the intervention group will report higher rates of intent to 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*:* Is media content more attractive to participants? 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, three and six month follow-up. Survey questions will assess behavior, attitudes, social norms about sexual behavior, contraception 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 13-20 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 visited and duration of each visit by User ID and IP address. Web analytics are generated for any website and are a standard evaluation mechanism for assessing the traffic patterns on webpages. 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.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Girls Ages 14-18 Years	Enrollment	1,200	1	5/60	100
	Consent	1,200	1	5/60	100
Control Group	Baseline Survey	600	1	13/60	130
	3-Month Follow-up Survey	600	1	20/60	200
	6-Month Follow-up Survey	600	1	20/60	200
Intervention Group	Baseline Survey	600	1	13	130
	3-Month Follow-up Survey	600	1	20	200
	6-Month Follow-up Survey	600	1	20	200
Total					1,260

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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