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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[30Day-16-160J]

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. 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.” On January 19, 2016, a 30-day Federal Register Notice was published under the revised title “The Girl Power Project Efficacy Trial.” The burden table in the 30-day Notice was incorrect due to omission of information collection conducted to screen potential study participants for eligibility. This Notice corrects the error and provides an updated estimate of total burden to respondents.

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 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. Interested participants will initially complete screening questions to confirm their eligibility. CDC estimates that 3,000 respondents will be screened in order to reach the target number of 1,200 enrolled study participants. Information collection for enrolled participants consists of three self-administered online surveys at conduct at baseline, three months after baseline, and six months after baseline. 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 Identification (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 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. The total estimated annualized burden hours are 802.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Girls 14-18 years old	Screening Questions	3,000	1	1/60
	Enrollment Questions	1,200	1	5/60
Intervention Group	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

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 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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