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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-17JA; Docket No. CDC-2016-0122]

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 effort 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 the Evaluation of "Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males: Columbia University Young Men's Project". The main goal of this study is to adapt, implement, and evaluate an

innovative computer-assisted motivational interviewing (CAMI-TPP) intervention to engage young males in behaviors that prevent unintended teen pregnancy.

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

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0122 by any of the following methods:

- Federal eRulemaking Portal: Regulations.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: 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

Evaluation of "Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males: Columbia University Young Men's Project" - New - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Reproductive Health, Centers for Disease Control and Prevention (CDC), is seeking OMB review and approval for a new information collection to carry out an evaluation of the Columbia University Young Men's Teen Pregnancy Prevention project funded by the "DP15-007 Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males" cooperative agreement. Approval is being requested for three years (Years 2-4) of a 5-year project. During Year 3, a request will be made for an extension of information collection to cover Years 4-5.

Although teen birth rates (defined as live births per 1,000 15-19-year-old U.S. females) are declining, the U.S. teen birth rate remains higher than in other developed countries (Penman-Aguilar, Carter, Snead, & Kourtis, 2013). Furthermore, geographic, socioeconomic, and racial/ethnic disparities in teen birth rates persist. In 2012, non-Hispanic black and Hispanic

teen birth rates were still more than two times higher than birth rates for non-Hispanic white teens (Martin, Hamilton, Osterman, Curtin, & Mathews, 2013).

In 2014 teen fatherhood occurred at a rate of 11.3 births per 1,000 men aged 15-19 (Hamilton, Martin, Osterman, Curtin, & Mathews, 2015) and resulted in approximately 156,000 births. According to the 2006-2010 National Survey of Family Growth, 15% of males fathered a child while younger than age 20 and rates of fathering a child were highest among non-Hispanic Black and Hispanic teens (Martinez, Daniels, & Chandra, 2012). Data suggest that teen fathers attend fewer years of school and are less likely to graduate from high school than teens who are not fathers (Fletcher & Wolfe, 2012). In addition, males just beyond their teen years (aged 20-24) father a higher proportion of children born to teen mothers than males aged 19 and younger (Elo, King, & Furstenburg, 1999; Males, 1995). Thus, it is important to reach both teenage as well as young adult males in their early twenties (hereafter collectively referred to as "young men") in teen pregnancy prevention efforts.

Initiatives to prevent teen pregnancy have focused primarily on the role of female teens; however, young men can also play an important role and should be actively engaged in preventing teen pregnancy. Partner involvement in contraceptive decision making can increase use of effective methods of

pregnancy prevention, including the use of dual protection (i.e., using condoms plus hormonal methods to prevent both pregnancy and sexually transmitted infections [STIs]) (Kerns 2003, Harper 2004, Kraft 2010, Coxand Cox 2010). Increased use of effective contraception may be based on improved contraception-related communication, joint responsibility and decision making between partners, as well as male partners' knowledge and attitudes about contraceptive methods (including condoms), support for use of moderately or highly effective methods, and desire for pregnancy prevention. Nevertheless, few interventions have focused on young men or been shown to be effective in reducing teen pregnancy. The HHS Teen Pregnancy Prevention Evidence Review, (<http://tppevidencereview.aspe.hhs.gov/ReviewProtocol.aspx>) conducted in 2012 by Mathematica Policy Research on behalf of the HHS (U.S. Department of Health and Human Services, 2012) and updated in 2014 identified 35 rigorously evaluated interventions found to have an impact on sexual risk behaviors, teen pregnancy, and/or STIs. Most interventions were evaluated among young male and female participants; only one intervention was designed and evaluated specifically for males (Magura, Kang, & Shapiro 1994). Most of the 35 interventions were designed as HIV/STI prevention interventions and provide participants with information about condoms but little about other contraceptive

options. They also do not address the shared responsibility of contraceptive decision making or sexual and reproductive health services.

While programs that address male-specific risk and protective factors for teen pregnancy (e.g., Gottesgen & Philiber, 2001; Ricardo, Nascimento, Fonseca & Segundo, 2010; Smith, Weinman, Buzi, & Benton, 2004; Tello, Cervantes, Cordova, & Santos, 2010) have been developed, there are no published results from rigorous evaluations of these interventions. If found to be efficacious, this study will add a male-focused program to the evidence review. This information collection request aims to address this gap in the literature through a randomized controlled trial (RCT) of a computer-assisted motivational interviewing application for mobile phones to prevent fathering an unintended pregnancy (CAMI-TPP) by males aged 15 to 24 years in comparison to a control group (CAMI-Fitness).

CAMI will be conducted in a racially and ethnically diverse population of young males aged 15 to 24 years in New York City, NY. Young males will be recruited at 3 sites in New York City: the Young Men's Clinic in Washington Heights and among students at the school-based health centers of two inner-city NYC high schools--George Washington Educational Campus in Washington Heights and John F. Kennedy campus in the Bronx. Participants

will be assessed at baseline, immediately post-intervention (12 weeks), and at three follow-ups (24 weeks, 36 weeks, and 60 weeks) after participation in the 12-week intervention.

Participants will also complete weekly online check-ins for 60 weeks from the time of enrollment in the project. Weekly check-ins have been used in past studies to increase retention during the study period and are very brief.

The knowledge generated from this project will inform the HHS Teen Pregnancy Prevention Evidence Review. If the intervention is found to be efficacious, it will provide Teen Pregnancy Prevention grantees of the Office of Adolescent Health, CDC, and Administration for Children and Families with a new intervention to reduce the number of young men who father a teen pregnancy.

OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 2,598.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours (in hours)
Young Men Aged 15-24 years	Eligibility Screener	2,428	1	5/60	202

Consented and Enrolled Young Men aged 15-24 years	Baseline Assessment	315	1	32/60	168
	Therapeutic Alliance Assessment	315	2	5/60	53
	Satisfaction - Coaching	315	4	2/60	42
	Satisfaction - Weekly Check-ins	315	1	5/60	26
	12-week Assessment	315	1	30/60	158
	Satisfaction - Assessments	315	1	7/60	37
	24-week Assessment	315	1	28/60	147
	36-week Assessment	252	1	26/60	108
	60-week Assessment	190	1	26/60	82
Consented and Enrolled Young Men aged 15-24 years	Weekly Check-in	315	60	5/60	1,575
Total					2,598

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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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