[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

The National Cancer Institute (NCI) SmokefreeTXT Program Evaluation

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on January 14, 2013 (Volume 78, Page 2678) and allowed 60-days for public comment. Shortly after the publication, two public comments were received requesting a copy of the data collection plans and instruments and one public comment was received in regards to the funding of the study. The comments were responded to with the requested information. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the

item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, contact Erik Augustson, PhD, MPH, Behavioral Scientist/Health Science Administrator, Division of Cancer Control and Population Sciences, 6130 Executive Blvd, EPN-4034, Bethesda, MD 20892-7337 or call non-toll-free number 301-435-7610 or E-mail your request, including your address to: augustse@mail.nih.gov.
Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: The National Cancer Institute (NCI) SmokefreeTXT Program Evaluation, 0925-NEW, NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This study seeks to assess the efficacy of the SmokefreeTXT program, a text message smoking cessation intervention designed for young adult smokers ages 18 to 29. The SmokefreeTXT program is a component of a larger series of eHealth/mHealth tobacco cessation intervention programs.

SmokefreeTXT has been developed (and is managed) by the National Cancer Institute (NCI) Tobacco Control Research Branch (TCRB) at the request of the Office of the Assistant Secretary for Health (OASH) at the Department of Health and Human Services (DHHS). The study seeks to recruit a large sample of adult smokers to examine how exposure to the SmokefreeTXT intervention affects participants' success at quitting smoking. There will be 3-arms to the study; participants will be enrolled for a maximum of 8 weeks of treatment in the SmokefreeTXT program, with frequency and duration of the treatment varying by study arm. The SmokefreeTXT Study will collect self-reported cessation data using the bidirectional aspect of text-messaging service and a series of web-based surveys. All web-based survey data will be collected and stored by a third-party, Research Triangle Institute International (RTI). Respondents will complete a screener, 5 web-based surveys, and an exit survey for a total of 8,353 annual burden hours. The five surveys include: 1) Pre-treatment baseline survey; 2) one week post quit date questionnaire; 3) end of active cessation treatment questionnaire; 4) 12-week post-treatment questionnaire; 5) 24-weeks post-treatment questionnaire.

OMB approval is requested for 2 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 4,250.

Estimated Annualized Burden Hours

Type of Respondents	Survey Instrument	Number of Respondents	Number of Responses Per Respondent	Average Time per Response (in hours)	Total Burden Hours
Adults Aged 18 to 29	Screener/recruitment	10,620	1	5/60	885
	Baseline	2,124	1	30/60	1,062
	1 week post-quit date	1,700	1	15/60	425
	6 weeks post quit date	1,360	1	30/60	680
	12 weeks post-treatment	1,088	1	15/60	272
	24 weeks post treatment	870	1	15/60	218
	Ineligible Script	8,496	1	5/60	708

Dated: March 19, 2013

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Vivian Horovitch-Kelley

NCI Project Clearance Liaison

NCI, NIH

[FR Doc. 2013-07551 Filed 03/29/2013 at 8:45 am; Publication Date: 04/01/2013]