Supporting Statement A For:

The National Cancer Institute (NCI) SmokefreeTXT (Text Message) Program Evaluation

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LIST OF ATTACHMENTS

List of Attachments

* Indicates a survey.

This is a request for OMB to approve the new submission titled, "The National Cancer Institute (NCI) SmokefreeTXT Program Evaluation" for two years. The Office of the Assistant Secretary for Health (OASH) at the Department of Health and Human Services (DHHS) has requested the National Cancer Institute (NCI) Tobacco Control Research Branch (TCRB) develop and manage the SmokefreeTXT evaluation program, as part of a larger series of eHealth/mHealth tobacco cessation intervention programs. This evaluation has implications for international work that HHS deems crucial in designing and implementing similar programs in a variety of other countries. In addition, HHS is interested in increasing the visibility of the SmokefreeTXT domestic program as part of the resources it promotes via large scale promotional campaigns. This study seeks to assess the efficacy of a text message smoking cessation intervention designed for young adult smokers ages 18 to 29. Study plans include examining 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. Self-reported cessation data will be collected using the text-messaging service and web-based surveys. Respondents will complete 5 web-based surveys for: pre-treatment/baseline, 1 week post quit, 6 weeks post quit, 12 week and 24 week post-treatment questionnaires.

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Public Health Service Act, Section 410 (285) and Section 412 (285a-1) authorizes the National Cancer Institute (NCI) to conduct and support research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

A mission of the Division of Cancer Control and Population Sciences at the NCI is to reduce the risk, incidence and death from cancer, and the mission of the Tobacco Control Research Branch's mission (TCRB), a part of Division of Cancer Control and Prevention Sciences (DCCPS), is to lead and collaborate on research, and to disseminate evidence-based findings to prevent, treat, and control tobacco use. One way of carrying out this mission is by developing and disseminating evidence-based cessation interventions to the public to control tobacco use, as well as contribute to the growing body of scientific evidence supporting new

mechanisms and technologies for delivering evidence-based treatments and disseminating information to the public.

Currently, tobacco use is the leading cause of preventable illness and death in the United States; smoking causes an estimated 20% of all cancer deaths, including 90% of all lung cancer deaths in men and 80% of all lung cancer deaths in women. Young adults ages 18 to 24 have the second highest smoking prevalence (22.2%) among adults (Thorne, Malarcher, Maurice, & Caraballo, 2008). Having acknowledged that many young adults start smoking, despite prevalent warnings, a new generation of researchers and intervention developers are striving to understand how to help them stop. Young adulthood is a critical period in which individuals transition from adolescence to adulthood, and establish health behaviors that could continue for the rest of their lives (Arnett, 2000; Hammond, 2005; Villanti, McKay, Abrams, Holtgrave, & Bowie, 2010). Cessation during young adulthood is especially critical, as studies have found that cessation before age 30 is a preventive factor to avoiding tobacco-related mortality (Doll, Peto, Boreham, & Sutherland, 2004, 2005; Villanti et al., 2010).

As mobile phones become more popular and widespread, they are being used in a variety of ways, including health-based interventions and social marketing campaigns. A review of mobile phone-based interventions for smoking cessation indicates that there are short-term benefits to such an approach, though currently the long-term benefits are less clear (Whittaker et al., 2009). Studies focusing exclusively on text messaging programs have had mixed results. On one hand, Free et al. (Free et al., 2011) found that users who received motivational and behavior-change texts had significantly higher abstinence rates at 6 months, compared with the control group users who received text messages unrelated to quitting (10.7% vs. 4.9%, $p<.0001$, respectively). Conversely, Rogers et al. (Rodgers et al., 2005) found a statistically significant

difference in 6-week abstinence rates between intervention and control groups (28% vs. 13%, p<.0001, respectively), but 6-month quit rates were hard to compare because of differential loss to follow-up. Although most of the existing research in mobile-based interventions for smoking cessation focuses on adolescents and adults, a systematic review of text-messaging interventions to promote healthy behaviors in adolescents and young adults suggests that these studies can have positive outcomes for young people (Militello, Kelly, & Melnyk, 2012).

As mobile phone use continues to grow, especially among the young adult population, it is becoming increasingly appropriate to develop mobile-based health interventions to reach this population. There have been a limited number of studies published to date, but they show promising results. More research and evaluation is needed to fully understand the impact that mobile phone-based interventions can have on health issues, such as smoking cessation, especially among young adult populations. This randomized clinical trial of the SmokefreeTXT Study will add unique value to the existing mHealth smoking cessation literature and aide in the development of future cessation programs by assessing potentially important components of a smoking cessation mobile-based program.

A.2 Purpose and Use of the Information

Arm 1	Assessment-only Messages	Brief, periodic messages prior to participants' quit date and weekly assessment messages
Arm 2	Assessment + Countdown Messages	Weekly countdown messages prior to participants' quit date, and weekly assessment
Arm 3	Daily messages	The full Smokefree TXT program including daily messages comprised of countdown messages, assessment messages, tips and motivational messages.

A major focus of the planned evaluation study is to assess the impact of advanced text messaging strategies relative to the standard practice of using text messaging simply to assess participants' progress in quitting. The evaluation assesses three intervention arms which include:

In addition, the evaluation will explore whether engagement with the text messaging features (beyond mere exposure) results in cessation-related outcomes.

The SmokefreeTXT (SFTXT) Evaluation was developed to assess the potential effectiveness of this intervention in helping young adults ages 18 to 29 quit smoking. The evaluation plan (**Attachment 1**) is based on a review of the existing literature and consideration of several relevant behavior change theories, including Social Cognitive Theory, the Theory of Planned Behavior, and Prime Theory of Motivation.

A.2.1 Research Questions

The proposed study will provide the only source of data available to answer the following research questions:

- How do Arm 1, Arm 2, and Arm 3 differ in smoking prevalence at 1 week, 6 week, 12 week and 24 week follow-up?
- Are differences in quit attempts and sustained cessation at the follow-up assessment points (one week post quit date; end of active cessation treatment; 12 week post-treatment; 24 weeks post-treatment) predicted by demographic, smoking behavior, motivational, and cognitive factors among smokers?
- Do demographic, smoking behavior, motivational, and cognitive factors predict treatment engagement?
- Are changes in motivational and cognitive factors associated with changes in smoking behavior at various follow-up intervals?
- Among participants in the full SFTXT condition, how do they perceive the usefulness of various elements of the intervention?

A.2.2 Research Instruments

Specific measures will include smoking status and smoking behavior during the intervention, and engagement with the text messaging and outcomes, including smoking cessation, reduction in number of cigarettes, self-efficacy regarding smoking, skills building, and other proximal outcomes.

Respondents will complete the following 5 web-based surveys:

1) Pre-treatment baseline survey;
2) 1 week post quit date questionnaire;
3) 6 week post-quit date questionnaire;
4) 12 week post-treatment questionnaire;
5) 24 weeks post-treatment questionnaire.

A.2.3 Conceptual Framework

A conceptual framework (**Attachment 2**) developed by Research Triangle Institute International (RTI) in collaboration with the NCI and Matthews Media Group (MMG), identifies key constructs and pathways through which the intervention is presumed to lead to cessation. Key strategies used in the intervention include skills training, motivational interviewing, cognitive behavioral techniques, and efficacy-building messages. Key outcome variables include cessation initiation, cessation maintenance, relapse, reduction in cigarette smoking, and period of abstinence from smoking.

A.3 Use of Improved Information Technology and Burden Reduction

The five surveys are all web-based and accessed to the respondent through a link sent to respondents in an email. A contractor for NCI, will develop, host, and support a secure content management system (portal) to be used for all aspects of the study. The portal will serve as the central location for information dissemination, project administration, and survey administration and monitoring. The website will be built with a two-tiered security approach. The first layer of security, Secure Socket Layer (SSL), will ensure that only encrypted data flow over the Internet. As the second layer of security, staff and other authorized users will have role-based authentication for reports and other secure areas of the website.

A Privacy Impact Assessment (PIA) for the Smokefree.gov, which includes the SmokefreeTXT program has been completed and approved by NIH on December 18, 2012. The IT system name is, "NIH NCI Smokefree QuitTXT Evaluation Study (Survey)" (**Attachment 17**).

Antifraud

Because surveys will be web-based and incentives will be offered for the study, the possibility of having a significant number of fraudulent respondents who may be completing the survey simply for the incentive money exists. Thus, we must take steps to reduce the likelihood of that happening. We have developed a plan for numerous options for dealing with fraudulent respondents, including use of available technology to eliminate fraud, ensure unique IP addresses, and other rigorous security measures (**Attachment 3**).

Survey Control System

The Survey Control System (SCS) is a comprehensive tool for monitoring and processing project activities, such as multiple waves and mailings/e-mails and generating routine and ad hoc reports. The SCS will be the primary tool that integrates data collection and processing, allowing project staff to monitor the flow of data from the start of data collection through the creation of data files for analysis and delivery. The SCS is critical to the successful management of day-to-day activities and is used routinely to schedule project tasks, alert staff to potential operational delays, and identify problem situations that require immediate attention.

A.4 Efforts to Identify Duplication and Use of Similar Information

Data exists related to current usages patterns of participants in the national ongoing SFTXT program, and is currently reported to the Tobacco Control Research Branch on a

monthly basis. This data includes length of time in the program, drop out from the program (if the user did so), messages received, and self-reported quit status. However, no comparison data collected in a controlled fashion exists which would allow for assessment of the potential impact of varying treatment intervention length and intensity. In addition, no detailed data is available from users of the program regarding demographics, smoking behavior, level of nicotine dependence, motivation and cognitive factors known to be associated with treatment outcomes. Collection of this data within the context of a controlled research trial is crucial for both an evaluation of the intervention and identification of evidence-based means to improve the effectiveness of the program.

An examination of the existing literature related to young adult smoking and cessation with a focus on reasons young adults smoke, a look at existing cessation programs for young adults, the use of mobile technology for health interventions, approaches to recruiting young adults to cessation interventions, and the use of incentives and outcome measures in young adult cessation interventions (**Attachment 4**) was conducted. There are many ways in which to implement smoking cessation interventions, and although there are a variety of approaches, recent reviews have noted that a combination of approaches may be most effective. As mobile phones become more popular and widespread, they are being used in a variety of ways, including health-based interventions and social marketing campaigns. Using mobile phone-based interventions for smoking cessation may be particularly appropriate because of the ability to tailor messages to user characteristics, send time-sensitive messages to distract users from cravings, and reach a large group of people at any time and in any location.

As mobile phone use continues to grow, especially among young adult populations, it is becoming increasingly appropriate to develop mobile-based health interventions to reach this

population. There have been a limited number of studies published to date, but they show promising results. More research and evaluation is needed to fully understand the impact that mobile phone-based interventions can have on health issues, such as smoking cessation, especially among young adult populations.

To our knowledge, this study is the only smoking cessation text-messaging evaluation to-date designed to distill the effective components of a text-messaging intervention, including the impact on message type, frequency, and program duration, on cessation rates.

A.5 Impact on Small Businesses or Other Small Entities

No small entities will be involved in this survey. All respondents will be individuals who participate voluntarily.

A.6 Consequences of Collecting the Information Less Frequently

The outcome measures and assessment intervals used in this study conform to those identified within the field of tobacco control/smoking cessation as "gold standard" self-report outcomes (**Attachment 4**). To identify appropriate measures, a review of the Youth Risk Behavior Survey (YRBS), Youth Tobacco Survey (YTS), and Tobacco Use Special Cessation Supplement to the Current Population Survey (TUS-CPS) was conducted to identify tobacco use and cessation-related measures. NCI's Measures Guide for Youth Tobacco Research provided access to non-national tobacco survey measures and scales, and the Health Information National Trends Survey (HINTS) and the Pew Internet and American Life Survey allowed us to identify survey questions related to Internet, social media, and mobile phone use.

Participants will be randomized to one of the three arms, as described in Section A.2. They will then complete the baseline survey, which will include information to enroll them in the appropriate version of SFTXT; participants will be assigned a quit date approximately two weeks from the day they complete the baseline questionnaire. After a participant's quit date they will receive four follow-up surveys at different time intervals. The data collection plan, including response intervals are included (**Attachment 5).** Collecting information less frequently would not answer the research questions of this study.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This study does involve special circumstances requiring the respondent to report information more often than quarterly. Depending on when the participant is assigned a "quit date," a participant may need to respond to the pre-treatment baseline, one week post quit date, and end of active cessation treatment questionnaires all within three months. The assessment intervals conform to those identified within the field of tobacco control/smoking cessation as "gold standard" self-report outcomes.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on January 14, 2013 (Volume 78, Page 2678). 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 regarding funding. The comments were responded to with the requested information.

The SFTXT evaluation was developed through NCI's Tobacco Control Research Branch collaboration with: MMG, Inc. and RTI, International. Feedback on the methodology and instruments was sought and received from a panel of four smoking cessation research experts, including two who have previously designed and evaluated text-based smoking cessation interventions. In addition, researchers from University of Illinois at Chicago's Institute for Health Research and Policy (IHRP) and the George Washington University School of Public Health were consulted to discuss recruitment barriers for a young adult smoking population and provide advice to the project. A full list of collaborators can be found in **Attachment 6**.

A.9 Explanation of Any Payment or Gift to Respondents

Nonresponse and high attrition rates are known challenges to performing research related to eHealth and mHealth interventions and the use of incentives is standard to field as a proven strategy to improve data collection with this type of research. To reduce nonresponse and attrition, particularly for the follow-up surveys, participants will receive an incentive for completing each of the five surveys. Research shows that effective incentive amounts can reduce both item nonresponse and attrition (Castiglioni et al., 2008; Jackle & Lynn, 2008). The incentive will be in the form of a gift card from either Amazon.com or itunes.com (whichever the respondent chooses). The gift card can be delivered electronically to participants upon completion of the survey, via e-mail or a pop-up. The amount of the gift card (incentive) for each survey as well as the follow-up effort that would be used for participants is as follows:

Incentive Amounts and Nonresponse Follow-up Methods					
	Interview Waves (5)				
	Baseline	**1 week Post Quit Date**	**6 Weeks Post Quit**	**12 Weeks Post Treatment**	**24 Weeks Post Treatment**
Incentive	$20	$15	$15	$20	$30
Follow-up	7 e-mails[1]	7 e-mails	3 e-mails	3 e-mails	3 e-mails
	1 phone call	1 phone call	1 phone call	1 phone call	1 phone call

Our budget for incentives is based on the anticipated attrition rates.

A.10 Assurance of Confidentiality Provided to Respondent

Participants in this study will be subject to assurances and safeguards as provided by the Privacy Act of 1974 (5 USC 552a), which requires the safeguarding of individuals against invasion of privacy. The Privacy Act also provides for the private treatment of records maintained by a Federal agency according to either the individual's name or some other identifier. This information collection is covered by NIH Privacy Act Systems of Record 09-25-0156, "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD" (**Attachment 18)**. All persons working with the study will adhere to the provisions stipulated within that announcement. In accordance with the Privacy Act of 1974, the privacy of individual respondents will be protected. The following describes the measures taken to protect the privacy of the participants, to the fullest extent provided by law.

[1] Emails are different from the text messages they will also be receiving.

All survey data will be collected and stored at RTI. RTI will hold the master list of survey data and contact information on the project share folder (including first name, if provided, phone numbers and email addresses). In addition, a limited amount of data will be exchanged throughout the study between RTI and Mobile Commons, the text messaging provider. This exchange of data is required in order to activate Mobile Commons (1) to send participants a phone verification text message and (2) to start participants on their cessation treatment text messaging program (and which study arm to use). RTI will also receive text messaging data from Mobile Commons, which will be appended to the overall survey database stored at RTI.

During the course of data collection some of the key data items need to be exchanged between RTI and Mobile Commons. To accomplish this task RTI will program and use secure SSL (Secure Socket Layer) enabled ASP.Net-based RESTful web services to send and receive data from Mobile Commons. An application programming interface (API) is a specification intended to be used as an interface by software components to communicate with each other. The data flow exchange is provided as an attachment (**Attachment 5**).

The following data will be exchanged between the two entities:

- RTI will collect contact information, enrollment data, and make study group assignments. The following data will be sent to Mobile Commons by invoking their Web Application Programming Interface (API).
    - Participant Unique ID
    - Mobile phone number
    - Phone verification code (for phone verification only)
    - Phone verification status
    - Study arm assignment
    - Quit Date
- Mobile Commons will send RTI the following data: 1) smoking status check-in response from participant, 2) text message sent to participant, 3) texts back from participants, and

4) reports of successful/failed message deliveries. These data will go through the Application Programming Interface to RTI. MMG will also provide aggregate data on ads and clicks on the ads to RTI.

Eligible young adults will review information about the study and asked to read an online consent form (**Attachment 7**). This study obtained IRB approval (**Attachment 8**). RTI, International is committed to protecting the rights, welfare, and privacy of individuals who participate in their research studies, as well as the security of the data during these studies. RTI, International staff submitted the study plan and accompanying protocol to the RTI, International IRB's Office of Research Protection.

Data Exchange Methods

During the course of data collection some of the key data items need to be exchanged between RTI and Mobile Commons. To accomplish this task RTI will program and consume secure SSL (Secure Socket Layer) enabled ASP.Net-based RESTful web services to send and receive data from Mobile Commons. An application programming interface (API) is a specification intended to be used as an interface by software components to communicate with each other.

The following will describe the two-way data exchange:

1) RTI will invoke Mobile Commons APIs and send phone number, gender, quit date, and other variables as soon as participant completes the baseline interview.
2) RTI will invoke Mobile Commons APIs nightly to receive data regarding the text messages sent and received from each participant.

Authorization for the APIs at Mobile Commons are done using HTTP Authentication via RTI specific log in and password, and access to these servers is kept under a strict access control list. All interactions use 128-bit SSL.

A.11 Justification for Sensitive Questions

Sensitive questions are defined as those whose answers, if made public, could cause physical, mental, emotional, economic, or other harm to an individual. Participants will be asked to provide their year of birth, gender, and race/ethnicity information as part of the enrollment process. Additionally, there are questions on the Screener and Baseline Questionnaire (**Attachments 9 and 10**) that are considered sensitive as they relate to use of alcohol, cigarettes, and income. Personally identifiable information (PII) is collected in the form of the respondent's name, phone number, and email which is needed to contact potential respondents. Participation in the study is voluntary and participants have the right not to answer any questions without consequences; they are given this information in the consent form. Section A.10 discusses the steps taken to safeguard this information.

A.12 Estimates of Annualized Burden Hours and Costs

Table A12-1 presents the calculations for the annualized burden hours for this study. Data collection activities for all participants involve completion of an online screener/recruitment questionnaire. Participants who complete the screener and are eligible and interested in the study will be asked to complete a baseline survey. Those who complete the baseline survey and enroll in the full study will have 4 additional surveys. The first will be conducted at 1 week after their assigned quit date. Participants will be asked to complete another questionnaire at 6 weeks after their assigned quit date, at 12 weeks post-treatment and 24 weeks post treatment. We have assumed that 20% of individuals screened will be eligible and interested in the study. We then estimate an 80% response rate at each wave of data collection. The estimated annualized burden is 4,250 hours, and over the course of two years amounts to 8,500 hours.

A.12 - 1 Estimates of Annualized Burden Hours

Type of Respondents	Survey Instrument	Number of Respondents	Number of Responses Per Respondent	Average Time per Response (in hours)	Total Burde Hours
Adults Ages 18 to 29	Screener/recruitment (Attachment 9)	10,620	1	5/60	885
	Baseline (Attachment 10)	2,124	1	30/60	1,062
	Follow-up: 1 week post-quit date (Attachment 14)	1,700	1	15/60	425
	Follow-up: 6 weeks post quit date (Attachment 15)	1,360	1	30/60	680
	Follow-up: 12 weeks post-treatment (Attachment 19)	1,088	1	15/60	272
	Follow-up: 24 weeks post treatment (Attachment 20)	870	1	15/60	218

	Ineligible Script/Survey (Attachment 13)	8,496	1	5/60	708
	Total				**4,250**

Table A12-2 presents the calculations for cost of annualized burden hours. The cost burden to respondents represents the time required to participate in the study. The total annualized cost to respondents is $92,395 calculated at $21.74 per hour. Over the course of two years, this amounts to an estimated cost of $184,790. This data is Based upon the average wages, "May 2011 National Occupational Employment and Wage Estimates - United States," U.S. Department of Labor, Bureau of Labor Statistics. http://www.bls.gov/oes/current/oes_nat.htm#b29-0000. The participants' wages are unknown and may vary significantly depending on respondent employment status and the state, tribe, or territory in which they reside. Therefore, the average hourly wage data below are based on estimated data.

A.12 - 2 ESTIMATED ANNUALIZED COST TO RESPONDENTS

Type of Information Collection	Number of Respondents	Total Burden Hours	Average Hourly Wage Rate	Total Cost
Adults Ages 18 to 29				
Screener/recruitment	10,620	885	$21.74	$19,239.90
Baseline	2,124	1,062	$21.74	$23,087.88
Follow-up: 1 week post-quit date	1,700	425	$21.74	$9,239.50
Follow-up: 6 weeks post quit date	1,360	680	$21.74	$14,783.20
Follow-up: 12 weeks post-treatment	1,088	272	$21.74	$5,913.28
Follow-up: 24 weeks post treatment	870	218	$21.74	$4,739.32
Ineligible Script/Survey	8,496	708	$21.74	$15,391.92

Totals		**4,250**		$92,395.00

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no operating, maintenance or capital costs associated with the completion of online assessments and the cessation text messaging intervention other than the costs presented in A.12.

A.14 Annualized Cost to the Federal Government

NCI costs are based on labor and incentive costs for study participant retention. Two GS-14 Level scientists will commit 25% of their salaried time to survey completion amounting to $97,500 per year. Contracting employees will provide project management support and recruitment for an estimated annual cost of $77,499. Additionally, the cost of advertising amounts to $75,000 per year. Additional project management related activities to the research, development, and day-to-day data management will add $655,290 per year. The total annualized cost is estimated to be $905,289, and over the course of two years to be $1,810,578.

Staffing	**Task**	**Total Cost over 2 Years**	**Annualized Cost**
NCI	NCI GS-14 Scientists (25% time)	$195,000	$97,500
Contractor	Project Management Support & Recruitment	$154,998	$77,499
	Advertisement Buy	$150,000	$75,000
	R&D, Development of Database, Collecting Data, Cleaning Data, Sending Email, Running Reports, and Managing Data Tables	$1,310,580	$655,290
		$1,810,578	$905,289

A.15 Explanation for Program Changes or Adjustments

This is new information collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Once data editing has been completed, RTI will use summary statistics to describe the study population (means, counts, and proportions) using key variables and the main outcome (smoking status). Summary tables will be created that show the relationship between main outcomes and key variables. Because of our three condition design, we will use Analysis of Variance with planned comparisons to determine whether there are differences in outcomes (cessation, abstinence, reduction in number of cigarettes, relapse) for the three conditions.

We also will assess the effects of engagement with the intervention components to determine whether those who were more engaged were more likely to quit smoking. Beyond these analyses, there are additional analyses that will be worthwhile. Understanding the potential impact of nonresponse bias will be important. Understanding the potential impact of nonresponse bias is important for correctly interpreting the study results.

The SFTXT Evaluation recruitment will begin immediately after obtaining OMB approval. The contract period will include recruiting, fielding, analyzing, and disseminating findings from these studies. The contractors will be responsible for preparing the data sets and final report for the study. The timetable for the data collection for the SFTXT Evaluation is shown below, in Table A.16-A.

Table A.16-A. Data Collection Timetable	
Study activity	**Months after OMB approval**
SFTXT Evaluation	

Pre-test	Months 0 – 0.5
Recruitment	Months 0 – 6
Data collection	Months 0 – 15
Data cleaning	Months 16 – 21
Data analysis	Months 16 – 21
Draft data tables	Months 16 – 21
Finalize data tables	Months 21 –22
Draft report and presentation	Months 23 –25
Finalize report and presentation	Months 25 – 26

Following completion of the intervention study and analysis, a final report will include details on the methods used in the evaluation, including sample recruitment, data collection, and measures and data analysis. A slide deck will also be prepared describing the study and can be used by NCI for future presentations.

The NCI staff will work within NCI and with other federal agencies (e.g., Department of Veterans Affairs; Department of Defense) to disseminate the results. Results will be presented at national conferences and published in peer-reviewed journals.via conferences and publications. Some conferences under consideration include, but are not limited to: mHealth, Summit American Public Health Association, Society for Research on Nicotine and Tobacco, National Conference on Tobacco or Health, Society of Behavioral Medicine, and College on Problems of Drug Dependence.

Peer-reviewed journals that may be interested in a publication based on this intervention study include, but are not limited to: Addictive Behaviors, American Journal of Health Promotion, Annals of Behavioral Medicine, Drug Alcohol Review, Health Communication, Journal of Health Communication, Journal of Internet Medical Research, Nicotine & Tobacco Research: Official Journal of the Society for Research on Tobacco and Nicotine, Preventing

Chronic Diseases, Journal of the American Medical Informatics Association, and Tobacco Control.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The SFTXT evaluation will not require exemption from displaying the expiration date of OMB approval. Any reproduction of the data collection instrument will prominently display the OMB approval number and expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

The NCI SFTXT Program Evaluation does not require any exceptions to the Certificate for Paperwork Reduction Act (5 CFR 1320.9).