Supporting Statement Part A:

Justification

Comparing the Effectiveness of Traditional Evidence-Based Tobacco Cessation Interventions to Newer and Innovative Interventions Used by Comprehensive Cancer Control Programs

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Abstract

The Centers for Disease Control and Prevention (CDC) requests OMB approval to collect information for the project entitled Comparing the Effectiveness of Traditional Evidence-Based Tobacco Cessation Interventions to Newer and Innovative Interventions Used by Comprehensive Cancer Control Programs. This is a new Information Collection Request that will allow CDC to obtain and disseminate information on current promotion activities related to tobacco control that are undertaken throughout the United States. This project will also describe the client population and compare the effectiveness of telephone versus Web-based tobacco cessation interventions. Information will be collected over a 24-month period. Clearance is requested for two and one-half years to provide flexibility in start and end dates for data collection.

The promotion/cessation components are part of a larger Comparative Effectiveness Research (CER) study that also includes a companion study titled "Study of Comprehensive Cancer Control and Tobacco Control Program Partnerships." The partnership study has been described in a separate Information Collection Request.

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

Background

This is a new Information Collection Request. The Centers for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC), requests approval from the Office of Management and Budget (OMB) to collect information to address an important gap in the evidence base for administrative, policy, and funding decisions regarding the effectiveness of traditional versus innovative cessation activities undertaken by state-based Tobacco Control Programs (TCPs) throughout the United States. CDC's authority to conduct the study is established by Section 301 of the Public Health Service Act (see **Appendix 1a**). These activities are funded by the American Recovery and Reinvestment Act (ARRA) of 2009 (see **Appendix 1b**), which provided $1.1 billion for comparative effectiveness research (CER). The Act allocated nearly $400 million to the Department of Health and Human Services (HHS). HHS's overall goal for the investment in CER is to promote high quality care through availability of information that helps clinicians and patients match the best

science to individual needs and preferences. CER is the synthesis of research comparing the benefits and harms of different interventions to prevent, diagnose, treat and monitor health conditions in real-world settings. The purpose of CER is to improve health outcomes by developing and disseminating evidence based information to patients, and other decision makers, about which interventions are most effective.

The study's promotion component compares the effectiveness of traditional versus innovative interventions used in promoting the use of tobacco quitlines (QL) and will determine which types of interventions result in higher quitline enrollments. The study's cessation component examines the comparative effectiveness of innovative Web-based interventions and traditional telephonic cessation interventions in increasing tobacco cessation.

State TCPs have attempted to improve the promotion of smoking cessation services by shifting some of their advertising focus from traditional paid media (e.g., television, radio, print) to new, innovative forms of advertising (e.g., online banner ads, social media, etc.). In addition, TCPs have also expanded services from traditional telephone-based counseling (aka "quitlines") into Web-based cessation intervention programs. Understanding the effect of promotional activities on service usage and the comparative effectiveness of population-based smoking cessation activities across multiple states is essential to establishing an evidence base that can be used to inform decisions made by TCPs, policy makers, and CDC.

Tobacco quitlines are effective, population-based interventions that increase successful quitting (Task Force on Community Preventive Services, 2001). The *U.S. Public Health Services Clinical Practice Guideline: Treating Tobacco Use and Dependence – 2008 Update*, identified quitline counseling (telephone counseling that includes counselor-initiated calls or proactive counseling) as an evidence-based treatment that increased the odds of abstinence by approximately 60% (Fiore et al., 2008; Ossip-Klein & McIntosh, 2003). Although all states currently provide a quitline, only 0.05% to 7.25% of adult smokers in the United States receive smoking cessation services via state quitlines each year (Fiore et al., 2008; Saul et al., 2011). According to CDC's Best Practices for Comprehensive Tobacco Control, approximately 6 to 8 percent of tobacco users potentially can be reached by quitlines (CDC, 2007); however, primarily due to lack of resources, overall, only 1 to 2 percent of tobacco users are currently using quitlines. Studies have shown that mass media has been the most important and consistent

driver of call volume to quitlines in some localities (Cowling et al., 2010; Zhu et al., 2000). Sustaining a high level of promotion through traditional mass media (e.g., television, radio, print) is resource intensive and many states have had limited budgets for tobacco control and/or media promotions. To date there are no comprehensive studies that indicate what TCP promotional strategies exist throughout the US, what population is impacted by these strategies, and how they affect cessation program usage.

As an emerging modality of smoking cessation services, Web-based programs have a more limited evidence base as compared to telephonic counseling interventions. However, several randomized trials of individually tailored Web-based smoking cessation programs have reported quit rates of 7% to 26% at 6 months (Cobb et al., 2005; Pike et al., 2007; Rabius et al., 2008; Saul et al., 2007; Walters et al., 2006). Studies of Web-based cessation programs consistently show a dose-response relationship such that greater website utilization (e.g., number of log-ins and features used) is linked to improved cessation outcomes (Ette, 2005; Graham et al., 2006; Japuntich et al., 2006; Rabius et al., 2008). As of March 2011, 45 TCPs have smoking cessation websites and 25 offer interactive counseling online. (http://map.naquitline.org/reports/web/)

Despite the promise and availability of Web-based cessation programs, most users engage only minimally. A recent randomized trial of several cessation sites indicated that the majority of participants did not visit the sites more than two times and less than 13% of participants visited the site more than five times (Rabius et al., 2008). Two recent studies comparing the relative effectiveness of these two interventions have shown promise in clarifying the impact of each intervention, but one only compared usage in a proactive smoking cessation program where participants were actively recruited and followed-up with personalized counseling (Zbikowski et al., 2008), and one focused solely on one state (An et al., 2010). These studies highlight a clear gap in the understanding of how telephone-based cessation programs compare to typical Web-based programs in regard to user population, effectiveness, and impact.

This study will focus on state TCPs and their user populations with two primary aims: (1) The Quitline Promotional Activities Component will examine the impact of traditional (e.g., television, radio, and print) activities compared with new, innovative efforts (e.g., online banner ads, social media, mobile phone applications) in increasing calls to state quitlines

among targeted populations; and (2) the Cessation Intervention Component will seek to describe the characteristics, utilization patterns, and cessation success of smokers who enroll in telephone smoking cessation programs versus Web-based programs. Due to low percentages of users who seek help quitting other tobacco products this study will focus on smokers only. Key research goals for each component are presented in Exhibits 1 and 2.

Exhibit 1. Key Evaluation Questions—Promotional Activities Component

1. What innovative promotional and educational activities are states implementing for the quitline, cessation, and related-cessation interventions?
2. Who is exposed to states' online promotional ads? How do audiences reached via innovative media platforms compare with audiences reached via traditional media platforms?
3. Is exposure to promotional ads associated with quitline awareness and cessation-seeking behavior as assessed by reach and utilization of states' quitline?

Exhibit 2. Key Evaluation Questions—Cessation Intervention Component

1. Do demographic characteristics of participants who enroll in telephone-based counseling differ from those of participants who enroll in a Web-based cessation program?
2. Do baseline smoking and quitting behaviors of participants who enroll in telephone-based counseling differ from those of participants who enroll in a Web-based cessation program?
3. What are the predictors of successful quitting (e.g., 30-day point prevalence abstinence rates) for each intervention?
4. Does quitting success differ significantly among participants who enroll in telephone-based counseling as compared to those who enroll in a Web-based cessation program?

The promotion and cessation components complement and extend the usefulness of results to be obtained in a companion study titled "Study of Comprehensive Cancer Control and

Tobacco Control Program Partnerships." See **Appendix 3** for an overview of these studies and their components. Information will be collected for CDC by a contractor, RTI.

Overview of the Data Collection System

Quitline Promotional Activities Component

The Centers for Disease Control and Prevention (CDC) and its contractor, RTI, will recruit up to 50 state TCPs to participate in the Quitline Promotional Activities Component. Investigators will monitor, describe, and report ongoing activities from all participating states to promote their quitline, as well as the associated quitline call volume for the duration of the study period (up to 24 months). The goal of including up to 50 states is to get a comprehensive view of state-based TCP promotional activities in terms of: 1) level of advertising, 2) types of advertising used, and 3) other contextual factors such as tobacco control policies.

Media purchase and placement data, as well as quitline call volume data, are typically monitored by TCP staff and/or their contractors (e.g., media vendors and service providers) as part of their regular monitoring and evaluation activities. If states are not currently monitoring online activity, investigators will assist the TCP in linking free analytic tools that can measure the reach and utilization of websites and social media without collecting personally-identifiable information. In addition, investigators will work with each individual state to customize the most efficient mechanism and timeline for sharing all promotional activity data (e.g., quarterly automated Web traffic reports) – thus creating minimal burden on the TCP staff (see **Appendix 4).** Information will be stored on a secure server using existing RTI protocols. This is a request to compile and analyze already-existing data; no new/original data collection will be conducted as part of the Quitline Promotional Activities Component.

Cessation Intervention Component

The primary aim of this component is to compare the user characteristics and effectiveness of traditional telephone versus Web-based cessation programs administered by TCPs. Investigators seek to recruit a total of 8,000 participants aged 18 years or older, 4,000 users of each modality (telephone or Web-based), in approximately 4 states. States eligible to participate are required to currently be participating in the National Comprehensive Cancer

Control Program (NCCCP) under cooperative agreement (DP07-703), have existing relationships with the TCP in their state, have both telephone and Web-based smoking cessation programs, be willing and capable of participating in the study in terms of staff capacity, and already be collecting quitline intake data that conforms to the North American Quitline Consortium (NAQC) Minimum Data Set (MDS) requirements. All intake data will be obtained from existing MDS-compliant datasets already being collected by states so duplication of data collection efforts and burden on TCPs and cessation program participants will be minimized. Using information directly from the National Quitline Data Warehouse (NQDW) is not feasible because identifiers necessary to complete the follow-up study are not collected by NQDW. Investigators examined the feasibility of using CDC's National Quitline Data Warehouse (NQDW) for this project. Investigators will use the MDS-compliant intake data already being collected by TCPs for transmission to NQDW for this project. However, investigators cannot use NQDW seven-month follow-up data because only a select sample of callers who received a service have follow-up information collected per year. Therefore, it is unlikely that all of the persons selected for this study at intake would have follow-up information that would enable investigators sufficient information to compare quit rates of persons participating in the telephone component to quit rates of persons participating in the Web-based component. Also, investigators will ask some additional questions on user experiences with the Web-based interventions as well as additional demographic information that are not included as part of the TCPs transmission to NQDW. In summary, this data collection will utilize MDS-compliant intake data already being collected by TCPs for transmission to NQDW, it will collect contact information for participants, and it will collect seven month follow-up data for participants. Investigators will work with TCPs and NQDW to send linked intake and follow-up data to NQDW. Each person in this study will receive only one intake questionnaire (as part of the already existing TCP program to collect information for transmission to NQDW), and one follow-up questionnaire (as part of the current study which will contain all of the MDS-compliant questions and some additional questions as described below) thereby eliminating any duplication of data collection efforts between this study and the NQDW (i.e., they will not receive a NQDW follow-up questionnaire).

For this study, investigators will ensure that the TCPs are obtaining proper informed consent and follow-up contact information as part of their regular intake protocol. The follow-up

sample will be drawn from smokers who complete the intake process for either the quitline or Web-based intervention offered in each state. Investigators will work with TCPs to implement a participant follow-up data collection process to meet study goals.

The number of clients for each modality in each state will determine whether a census (all participants) or random sample method will be used to identify sufficient numbers of participants of quitline and Web-based services from each state to obtain a sufficient sample size. Census methods will be used when the number of study participants expected to be obtained from a state is estimated to approximate the state's quitline call volume and/or registrations for Web-based services during the study time period. Random sample methods will be used when the state's quitline call volume and/or registrations for Web-based services during the study time period exceeds the requisite number of study participants in that state. If participation rates are lower than expected for a state, investigators will determine the best method of increasing the sample size in other states to meet the total sample requirements.

Investigators and the TCPs will collaboratively determine the best way to transfer data collected by investigators to the respective TCP and NQDW so they may also access it at a later date. As this study involves a follow-up component it will be requisite that investigators work with TCPs to collect personally identifiable information at intake to facilitate follow-up and maintain a link to intake information. This identifiable information will be collected, stored, and appropriately destroyed as described in Supporting Statement B, Section B.2.

Privacy Impact Assessment

Items of Information to be Collected

Quitline Promotional Activities Component

Investigators will compile existing data related to quitline promotional activities and quitline call volume for the analyses necessary for the Quitline Promotional Activities Component (see **Appendix 4**). These data are typically monitored as part of the TCPs' regular evaluation efforts. Investigators anticipate that no sensitive data with privacy concerns will be compiled. Investigators will request the following types of data from TCPs:

- **Media Purchase/Placement Data**. Investigators will compile information related to the type of promotional activities implemented during the study period. These activities will be coded by investigators to identify the mode (e.g., traditional vs. innovative) and other qualitative characteristics such as type of message, theme, and target audience. These data will be used to compare how different types of promotional efforts impact quitline call volume in terms of overall intensity and caller characteristics. Reach and utilization measures will vary by promotional effort. For instance, level of exposure of television advertising is typically measured by gross rating points (GRPs), whereas traditional print advertising is measured in number of impressions and online banner ads is measured by Click-Through Rates (CTRs). These measures are typically summarized in a media placement report for the TCPs by their media vendor on a regular basis following the media purchase period (typically on a quarterly basis). These reports can be forwarded to the investigators in their existing formats (i.e. PDF, excel, etc).

- **Quitline Call Volume and Online Activity**. Quitline call volume will be obtained from the TCPs and pre-existing, de-identified, quitline intake data obtained from quitline users who receive services from TCPs, will be obtained from the National Quitline Data Warehouse (NQDW, OMB control no. 0920-0856, exp. 7/31/2012, see **Appendix 3**). NQDW began collection of quitline intake data on Jan. 1, 2011 and OMB approval for data collection expires 7/31/2012. This use of pre-existing data that is readily accessible to RTI from the NQDW repository will eliminate the need for any additional original data collection and respondent burden. Measures from the NQDW will include number of calls per quarter and de-identified information including the following: demographics and smoking characteristics of callers, and self-reported referral sources. Call volume and self-reported referral sources will be used to estimate the impact of each promotional component on the study.

  For states that support a website to promote the quitline, Web analytics will be obtained to measure the reach and utilization of the site. Aggregate traffic metrics such as number of weekly visits, number of unique visitors, average time spent on site, and geographic region of visitors, can be obtained from each state's preferred Web analytic platform, in most cases Google Analytics. Google Analytics is a free

platform that relies on JavaScript code that is inserted into each webpage and first-person cookies that allows unique visitors to be anonymously tracked on a website. Google Analytics also allows administrators to design reports in CSV or PDF format that can be automated to compile information at regular intervals and sent to the investigators. Additionally, investigators can be given user access to accounts on Google Analytics to access data in these formats directly.

For states that utilize social media to promote the quitline, activity on the social media platforms (e.g., YouTube, Facebook, Twitter) will be tracked using free public programs, such as Facebook Insights. Facebook Insights allows groups or organizations to create a user-friendly dashboard of metrics including number of posts on a wall, number of comments, and number of fans/friends for particular time periods. States can choose to provide administrator access to these social media accounts directly to investigators to obtain the necessary metrics. Data from Facebook Insights can also be quickly exported in CSV format by the TCPs and forwarded to the investigators. The majority of metrics for YouTube and Twitter can be obtained by investigators directly by viewing the TCPs pages on these social media sites.

Cessation Intervention Component

Intake (baseline) data and 7-month follow-up data will be used to analyze the outcomes of interest. All intake measures will come from existing data collected by TCPs from quitline or Web-based program users. Standard MDS measures for the telephone and similar Web-administered items will include demographics, current smoking status, smoking history, current smoking behaviors, previous quit history, self-reported source of referral to the program, and services requested from the program. These data are collected by the states as part of their regular quitline monitoring and evaluation activities; therefore, no new original intake data will be collected (see **Appendix 3**). These are standard components that meet MDS requirements, which have already been approved by OMB for the NQDW.

Follow-up information will be collected using the existing TCP format while ensuring study-specific questions are included. For the 7-month follow-up survey, participants will be asked about their satisfaction with the cessation intervention, current smoking status, quit

attempts made since their enrollment, duration of quit (if applicable), use of nicotine replacement therapies and/or medication to help quit, use of various behavioral smoking cessation strategies, and use of technology and various forms of media. The majority of this instrument is consistent with NAQC recommendations for the MDS; however a small number of items will be added to further describe users in terms of their use of technology and media. Investigators will work with states to ensure that necessary contact information is collected at the time of intake so that contact can be made for follow-up. Information in Identifiable Form (IFF), including name, mailing address, phone numbers, and e-mail addresses, will be collected for the purposes of contacting participants for follow-up data collection and mailing an honorarium upon study completion.

In addition, service utilization data will be obtained from the quitline and website service providers. For participants who undergo telephone-based counseling these metrics will include number and length of telephone calls, receipt of mailed materials, and services received. Among participants who use the Web-based interventions utilization data will be obtained that measure number of site log-ins, time spent on the site, time spent on different features of the site, and interaction with specific site content (see **Appendices 5–8** for consent forms and data collection instruments to be used).

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

All participants in either arm of the cessation component will be 18 years of age or older. None of the intervention websites have content directed to children younger than age 13. In addition, the Web-based version of the follow-up survey will only be accessible to participants of the study.

A.2 Purpose and Use of the Information Collection

Collectively, these interventions support the smoking cessation goals of multiple agencies under the US Department of Health and Human Services, including the National Institutes of Health and CDC with its Winnable Battle goal of decreasing overall tobacco use. These interventions also address the National Comprehensive Cancer Control Program's goal of emphasizing the primary prevention of cancer.

Quitline Promotional Activities Component

The purpose of the Quitline Promotional Activities component is to compare and contrast the impact of traditional efforts (e.g., television, radio, print advertising) versus new, innovative efforts (e.g., online banner ads, social media presence, websites, mobile phone applications) in promoting quitlines. This comprehensive review will provide federal, state, city, and local tobacco control programs with information regarding the variety of promotional programs currently in use, their anticipated target populations, and the impact of interventions on cessation program recruitment. Investigators will identify the types of promotional efforts being implemented by TCPs; assess their reach and utilization, as well as their impact on quitline call volume (e.g., intensity of call volume and caller characteristics).

Cessation Intervention Component

The purpose of the Cessation Intervention component is to describe the utilization and comparative effectiveness of traditional telephone-based counseling to Web-based interventions in improving smoking quit rates. The results of this study will provide state TCPs, CCCs , CDC, and other agencies with an evidence basis to inform administrative, policy, and funding decisions. This will help these programs collectively improve smoking cessation rates and reduce tobacco-related morbidity and mortality by supporting effective programs aimed at increasing smoking cessation. The primary outcome of interest for this component will be 30-day point prevalence at 7-month follow-up that complies with the recommended length of follow-up for the MDS and approximates the Society for Research on Nicotine and Tobacco (SRNT) workgroup recommendations (NAQC 2009b).

Investigators will disseminate results through a variety of strategies, including (1) conference presentations, (2) final evaluation reports, (3) peer-reviewed journal articles, and (4) meetings with key stakeholder groups.

Privacy Impact Assessment Information

The proposed study components will entail collection of data from multiple sources, some of which will be individuals and will require the collection and temporary retention of individually identifiable information for the purposes of obtaining follow-up information. All identifying information will be stored securely and destroyed upon completion of data collection.

Quitline Promotional Activities Component

Respondents to this component will be state TCPs and their vendors, not individuals. Respondents are acting in their capacity as an employee of the TCP or vendor and they are not requested to provide any personal information. Investigators will collect the name and contact information of the TCP representative to whom the survey will be mailed so that RTI can follow up with non-respondents. This will be the only individually identifiable information collected for this study component.

Cessation Intervention Component

Respondents to this component will be individuals participating in telephone or Web-based cessation programs. While most of the intake and a random sample of the 7-month follow-up information needed to meet the goals of this study is already collected (and linked to each other) by state TCPs, some of the follow-up information may not be collected to the extent required to meet the study goals. In instances where follow-up information is not collected in a sufficient manner, investigators will need to undertake follow-up data collection with individuals identified by their intake information. This identifiable information will be securely stored and maintained using technical, physical, and administrative controls already in-place. During intake, potential candidates will be informed of the nature and intent of this study and administered a standard informed consent that includes their willingness to be re-contacted in 7-months to collect follow-up information. This procedure will ensure that participants are fully aware that descriptive information given in the intake will be used to guide follow-up and minimize any perceived impact on the privacy of the individual.

A.3 Use of Improved Information Technology and Burden Reduction

Quitline Promotional Activities Component

All data for the Quitline Promotional Activities Component will be compiled from existing resources. Investigators will work with the TCPs and/or their contractors (e.g., media vendors and service providers) to establish the most efficient mechanisms for data sharing. In most cases, automated reports can be set up through Google Analytics (or other Web analytic platform) and programmed to be e-mailed to the investigators at regular intervals or TCPs will forward reports to investigators that have already been compiled by their vendors as part of their contractual services. All reports or data files can be shared with the investigators in their current

format, typically PDF or Excel files for media placement reports or CSV files for Web analytic and social media data.

Cessation Intervention Component

All intake data will be obtained from existing datasets. For participants in the "phone only" study arm, the intake questionnaire primarily will be administered by state TCP quitline vendors using Computer Assisted Telephone Interviews (CATI). However, an increasing number of states are implementing online referral and intake data collection for their quitlines that collect measures similar to the MDS collected via telephone (NAQC, 2011). CATI and Web-based data collection have been shown to improve accuracy of data collection, as well as interviewer and respondent burden (Groves et al., 2009). Participants in the "Web-only" study arm will complete an online intake questionnaire when they enroll in the Web-based intervention. All online data collection will be self-administered on the participants' personal computers.

Investigators will work with TCPs to determine whether already-available information will be sufficient to answer the follow-up study questions. If additional follow-up data needs to be collected or the study timeline cannot accommodate the TCPs protocol for follow-up data collection, investigators will work with TCPs to implement a pre-established follow-up procedure that minimizes burden on the TCP or its vendor and ensures smooth transfer of information between investigators and the TCP vendor. If needed, this follow-up procedure will maximize the potential for the highest follow-up survey response rates by allowing respondents the option to complete the follow-up survey by either Web or telephone. Web surveys will allow participants to complete the survey at their convenience with 24-hour accessibility and minimize the complexity of survey instructions due to electronically-programmed skip patterns. Thus, Web-based data collection offers flexibility and minimizes respondent burden. A copy of the data collection instruments and consent forms are provided in **Appendices 6a, 6b and 7**.

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

Quitline Promotional Activities Component

This study will minimize the duplication of data collection efforts by using existing data for this project as much as possible. No new, primary data will be collected in this component. All call volume data will be obtained from TCPs and deidentified demographic and self-reported

referral source information from NQDW (OMB Control No: 0920-0856, expires 7/31/2012), the CDC repository of state quitline data.

Cessation Intervention Component

In designing the proposed data collection activities investigators have taken several steps to ensure that this effort does not duplicate ongoing efforts. Investigators will reduce the amount of new or original data collection by using MDS-compliant intake data that are already collected by the state programs. In addition, intake data for the Web-based program users will be obtained following a data sharing protocol established between investigators, the state TCPs, and/or their service providers. Essentially, data obtained from the intake questionnaires are comparable to a "record review."

Investigators have examined all other existing data sources for 7-month follow-up data on participants who use cessation services. While CDC currently asks states to conduct 7-month follow-up surveys among a proportion of randomly selected quitline users and report this information to the NQDW, many states do not currently conduct a follow-up effort on every participant as is required to meet the sample size requirements for this study. Also, CDC has indicated that during the study time frame the 7-month follow-up data may no longer be available from NQDW due to the expiration date of the current approval. While investigators will make their best effort to minimize burden on TCPs by utilizing existing follow-up data that is consistent with the study needs, the type of data, sample size requirements, and timeline of the study may require investigators to work with TCPs to collect more complete follow-up information than currently exists.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

Quitline Promotional Activities Component

Because all data for the Quitline Promotional Activities Component will be obtained from existing resources, investigators are not requesting the collection of new information for this study. Investigators will work with the TCPs and/or their contractors (e.g., media vendors and service providers) to establish the most efficient mechanisms for data sharing. Most existing

reports can be shared in their current PDF or Excel format. Automated reports from Web analytic platforms can be exported or e-mailed by the platform in CSV or PDF formats as well.

Cessation Intervention Component

The present study only includes two data collection timepoints: an intake (baseline) questionnaire and a 7-month follow-up questionnaire. The follow-up information is critical for any type of effectiveness analysis. A 7-month follow-up is a standard timepoint in the evaluation and monitoring of quitline programs (NAQC, 2009b). In order to maintain data that will be comparable to other studies it will be important to maintain this standard timeline for data collection.

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

There are no other special circumstances that require the data collection to be conducted in a manner inconsistent with 5 CRF 1320.5(d)(2). This data collection request fully complies with the regulation.

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

Federal Register Announcement

A Notice was published in the *Federal Register* on June 15, 2011 (Volume 76, Number 115, pages 34995–34996) (see **Appendix 2a**). One public comment was received and acknowledged (see **Appendix 2b)**.

Consultations

A list of key evaluation consultants for this project is provided in ***Exhibit 3***. Investigators consulted with public health scientists considered to be subject matter experts on the study design and evaluation instruments. The intake questionnaire and the majority of the items on the 7-month follow-up questionnaire are based on NAQC's MDS, which was created through a collaboration of experts in smoking cessation and quitline interventions. In addition, RTI has worked closely with CDC throughout the development of the protocol and the identification/recruitment of appropriate TCPs.

Exhibit 3. Evaluation Consultants

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A.9 Explanation of Any Payment or Gift to Respondents

Quitline Promotional Activities Component

No gift or payment will be made to states for their participation.

Cessation Intervention Component

Participants will be offered an honorarium of $40 for completing the follow-up survey. The honorarium is intended to recognize the time burden placed on the participants, encourage

their cooperation, and convey appreciation for contributing to this important study. Numerous empirical studies have shown that honoraria can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999). The amount of the honoraria was budgeted for and determined through discussions with staff with expertise in conducting adult surveys about smokers.

A.10 Assurance of Confidentiality Provided to Respondents

Privacy Impact Assessment Information

Quitline Promotional Activities Component

There is no risk to states for participating in this study and only minimal risk of identifying individual users of the cessation programs included in this component. Participating states can play a critical role in making this project informative to the tobacco control community by sharing, aggregating, and analyzing information about quitline call volume and website traffic to promotional activities across multiple states. All quitline data in the NQDW are de-identified; therefore, there is no risk of sharing sensitive information on quitline callers. In addition, this is a mutually beneficial opportunity that will help to inform state promotional strategies.

Cessation Intervention Component

This component entails the measurement of minimally sensitive information. Respondents will be assured via the computer script or by the telephone interviewer that their individual responses will not be shared with anyone outside the research team and that their names will not be reported with responses provided. Respondents will be told that the information obtained from all of the surveys will be combined into a summary report so that details of individual questionnaires cannot be linked to a specific participant.

To maintain privacy, each respondent has a personal password to open the Web-based survey. No mention of the survey topic will be made in the initial e-mail introduction or before the potential respondent has entered his or her password and been given the opportunity to ensure that he or she has adequate privacy to complete the survey.

Privacy Act Determination

Respondents for the promotional activities component of the study are tobacco control programs. No personal information will be collected, and the Privacy Act does not apply.

Identifiable client intake and follow-up information will be collected for the cessation intervention component of the proposed study. The Privacy Act applies to these data collections. The applicable System of Records Notice is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems.

Safeguards

Quitline Promotional Activities Component

Investigators maintain restricted access to all data preparation areas (e.g., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a "need-to-know" basis only. Investigators take multiple security measures to ensure separation between respondents' identities and their survey data.

Cessation Intervention Component

To maintain privacy, each respondent has a personal password to open the Web-based survey. No mention of the survey topic will be made in the initial e-mail introduction or before the potential respondent has entered his or her password and been given the opportunity to ensure that he or she has adequate privacy to complete the survey.

Investigators maintain restricted access to all data preparation areas (e.g., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a "need-to-know" basis only. Investigators take multiple security measures to ensure separation between respondents' identities and their survey data.

Consent

Quitline Promotional Activities Component

No consent is required as this is a secondary data analysis with de-identified data.

Cessation Intervention Component

All respondents will be assured that the information will be used only for the purpose of this research and will be kept private to the extent allowable by law, as detailed in a study consent form (see **Appendix 7**).

A copy of the IRB documentation is provided in **Appendix 11**.

A.10.D Nature of Response

Quitline Promotional Activities Component

Participation is voluntary. Investigators anticipate that all 50 state-based TCPs will agree to participate.

Cessation Intervention Component

Participation is a condition of award for the four state-based TCPs that agree to participate in this study component; however, participation is voluntary for quitline clients and Web clients. Access to quitline or Web services will not be affected for individuals who choose not to participate in the study.

A.11 Justification for Sensitive Questions

Quitline Promotional Activities Component

No sensitive information will be collected in this component.

Cessation Intervention Component

The purpose of this study is to examine the comparative effectiveness of two types of cessation interventions that differ by way of service modality (e.g., telephone-based vs. Web-based). Many of the questions on the intake and follow-up questionnaires are smoking-related. While an individual may feel some discomfort in discussing their smoking behaviors due to the decreased social desirability of smoking behaviors or due to their difficulty quitting, the items on these surveys are generally considered to be minimally sensitive in nature and expected in a cessation intervention. All of the intake items and the majority of the follow-up items are

standard items that conform to the MDS which has been implemented by all state quitlines to varying degrees and reviewed by OMB (NQDW, OMB control no. 0920-0856, exp. 07/31/2012). Furthermore, the study participants are seeking help to quit smoking; therefore, they are showing a willingness to think about and/or discuss their smoking behaviors.

The intake questionnaire also includes several demographic items (e.g., gender, year of birth, zip code, educational attainment, race, ethnicity). The follow-up questionnaire includes a few additional demographic items not collected in NQDW (e.g., current employment status, marital status). All of these characteristics can be predictive of smoking cessation outcomes; therefore, they are important contextual factors to include in analyses.

OMB considers questions regarding race and ethnicity to be sensitive. These items on the intake surveys follow all of the standards set forth by the MDS and the OMB Directive No. 15 on Race and Ethnic Standards for Federal Statistics and Administrative Reporting (available from: http://wonder.cdc.gov/wonder/help/populations/bridged-race/Directive15.html). All questions on the surveys are necessary to achieve study goals and allow investigators to conduct a thorough analysis of the findings.

A.12 Estimates of Burden Hours and Costs

For the Promotion Activities component of this study, the burden for TCPs and/or their vendors for providing data to investigators is estimated at 10 minutes per response per state. The Quitline Promotion Activities Data (**Appendix 4**) will be reported on a quarterly schedule for approximately 50 TCPs per year (over the period of up to 24 months).

For the Cessation Activities component of the study, participating TCPs will transmit existing client intake and utilization data for both quitline clients (**Appendix 5a**) and clients who use Web-based services (**Appendix 5b**). Transmissions will be scheduled on a quarterly basis. The burden for each batch transmission of existing data is estimated to be 15 minutes per response.

TCPs participating in the Cessation Activities component of the study will also report client follow-up information to CDC. Because the seven-month follow-up surveys are being conducted specifically for study purposes, the burden estimate is based on the total time commitment for collecting information about each quitline client or Web-based services client

(15 minutes per client). On an annualized basis, seven month follow-up data collection will be conducted among 2,000 QL clients (**Appendix 6a**) each and 2,000 Web-based services clients (**Appendix 6b)** each. Follow-up information will be collected once per client, from a total of 2,000 clients per group (QL or Web), per year.

All information for this study will be transmitted to CDC's data collection contractor, RTI, over approximately 24 months, and all estimates are annualized over two years. OMB clearance is requested for two and one-half years, to provide flexibility in start and end dates for the 24-month data collection period. The total estimated annualized burden to respondents is 1,037 hours.

A.12-1 Estimated Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)
Tobacco Control Programs	Quitline Promotion Activities Data	50	4	10/60	33
	Intake Data for Quitline Clients	2	4	15/60	2
	Intake Data for Web Services Clients	2	4	15/60	2
Quitline Clients	Follow-up Survey for Quitline Clients	2,000	1	15/60	500
Web Services Clients	Follow-up Survey for Web Clients	2,000	1	15/60	500
				Total	1,037

To estimate the cost to respondents, we used $23.00/hour as the average hourly wage for TCP staff members, and $7.37/hour (the current Federal minimum wage) as the average hourly wage for clients seeking quitline cessation services or Web services. The total estimated annualized cost to respondents is $8,221.

A.12-2 Total Cost to Respondents

Type of Respondent	Form Name	Number of Respondents	Total Burden (in hr)	Average Hourly Wage	Total Cost
Tobacco Control Programs	Quitline Promotion Activities Data	50	33	$23.00	$759
	Intake Data for Quitline Clients	2	2	$23.00	$46
	Intake Data for Web Services Clients	2	2	$23.00	$46
Quitline Clients	Follow-up Survey for Quitline Clients	2,000	500	$7.37	$3685
Web Services Clients	Follow-up Survey for Web Clients	2,000	500	$7.37	$3685
				Total	$8,221

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

Respondents are subject to no direct costs other than their time to participate; there are no start-up or maintenance costs. Utilization data and intake data are collected as part of state TCPs' regular evaluation and monitoring activities of their programs; however, if TCPs incur additional costs for obtaining this information for the study, investigators will reimburse the costs. Investigators will be financially responsible for any additional follow-up data collection that

must occur beyond what states currently conduct for regular evaluation purposes to meet specific study goals and sample size requirements. Similarly, if TCPs incur additional costs for obtaining follow-up data, investigators will also reimburse the TCPs for these costs.

A.14 Annualized Cost to the Federal Government

The contractual costs to RTI include costs for scientific staff who have responsibilities for project management, study design and data analysis; the personnel costs associated with recruiting and collaborating with TCPs; distributing and tracking follow-up surveys if necessary; managing data; and reporting results. Other contractual costs include costs for survey production and distribution, the cost of computing equipment, study incentives, and other administrative costs. The total estimated cost of the contract is $2,200,269 over a 3-year period, however, data collection will occur over two to two and one-half years. The estimated annualized cost to the government of $1,128,804 represents total project costs annualized over two years. The contractor's costs are based on estimates provided by the contractor who will carry out the data collection activities. The CDC oversight costs include personnel costs of Federal employees involved in oversight and are estimated at $38,400 annually. This estimate includes one project director and one technical monitor at the GS-13 level (15% FTE each), and one consulting medical epidemiologist at the GS-13 level (10% FTE). The 2011 Department of Labor GS-13 base pay of $71,674 was used in calculating these amounts.

A.14-1 Annualized Government Costs

Type of Cost	Total Cost	Annualized Cost
RTI Contract Costs		
Labor	$597,137	$298,569
Materials and services	$864,718	$432,359
Indirect costs	$738,414	$369,207
Subtotal, Contract Costs	$2,200,269	$1,100,135
CDC Oversight Costs		

2 GS-13, $71,674/year @ 15%		$21,502
1 GS-13, $71,674/year @ 10%		$7,167
Subtotal, CDC Oversight Costs		$28,669
Total Cost to Federal Government		$**1,128,804**

CDC = Centers for Disease Control and Prevention

A.15 Explanation for Program Changes or Adjustments

This is a new information request.

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

Tabulation Plans

Quitline Promotional Activities Component

Data will be tabulated to meet the objectives and research questions described in Section A.2. The planned analyses are briefly described below:

1. By type of self-reported referral source (e.g., traditional vs. innovative), describe the users who called the quitline (e.g., sample characteristics in terms of demographics, baseline smoking and quitting behaviors, and intention to quit). Analyses will include review of absolute numbers, proportions, cross tabulations, and chi-square analyses.
2. By type of promotional activity, summarize overall reach and utilization. Analyses will include review of absolute numbers, proportions, cross tabulations, and chi-square analyses.
3. By type of promotional activity (e.g., traditional vs. innovative), estimate number of weekly quitline callers.
4. Develop preliminary models that assess the association between type of promotional activity and quitline call volume. Analyses will include conducting linear regressions with type of promotional activity as the independent variable and quitline call volume as the dependent variable. These models will also include

covariates for level of exposure, well as other important contextual factors, such as cigarette taxes and smoke-free air laws.

Cessation Intervention Component

Data will be tabulated to meet the objectives and research questions described in Section A.2. The planned analyses are briefly described below:

1. By mode of intervention, describe the users who were enrolled in the program (e.g., sample characteristics in terms of demographics, baseline smoking and quitting behaviors, and intention to quit). Analyses will include review of absolute numbers, proportions, cross tabulations, and chi-square analyses.
2. By mode of intervention and sample characteristics, estimate the number and proportion of users who reported high levels of program satisfaction. Analyses will include review of absolute numbers, proportions, cross tabulations, and chi-square analyses.
3. By mode of intervention and sample characteristics, estimate the number and proportion of users with high utilization rates (e.g., number of log-ins, number of calls, use of program features). Analyses will include review of absolute numbers, proportions, cross tabulations, and chi-square analyses.
4. By mode of intervention and sample characteristics, estimate the number and proportion of users who successfully quit (e.g., 30-day point-prevalence abstinence rate). Analyses will include review of absolute numbers, proportions, cross tabulations, and chi-square analyses.
5. Develop preliminary models that assess the association between mode of intervention and successful quitting. Analyses will include logistic regressions with mode of intervention as the independent variable and dichotomous past 30-day smoking status as the dependent variable. These models will also include covariates for a number of demographic and baseline smoking characteristics as well as other important contextual factors, such as cigarette taxes and smoke-free air laws.

Publication Plans

For this study, we expect the findings to be disseminated to a number of audiences. Investigators will provide each participating state with a customized quarterly report that includes a benchmark metric comparing the state's activity with an aggregate measure of all the other participating states. Therefore, the evaluation reports will be written in a way that emphasizes scientific rigor for more technical audiences but are also intuitive, easily understood, and relevant to less technical audiences. The reporting and dissemination mechanism will consist of four primary components: (1) final evaluation reports, (2) peer-reviewed journal articles, (3) meetings with key stakeholder groups (e.g., North American Quitline Consortium; annual Program Director's meeting for NCCCP), and (4) conference presentations (e.g., the American Public Health Association's Cancer Forum, Society for Research on Nicotine and Tobacco).

The results of our study also will be used to develop at least one peer-reviewed journal article (e.g., Nicotine and Tobacco Research, Tobacco Control, Preventing Chronic Disease, American Journal of Public Health, American Journal of Health Promotion, American Journal of Preventive Medicine, Cancer Epidemiology, Biomarkers and Prevention, Cancer Prevention Research) that summarizes findings on the comparative effectiveness of traditional versus innovative cessation interventions.

The key events and reports to be prepared are listed in ***Exhibit 7.***

A.16-1 Project Time Schedule

Project Activity	**Time Schedule**
Initiation of TCP promotional activity monitoring	As soon as possible after OMB approval
Initiation of intake questionnaires	As soon as possible after OMB approval
Initiation of 7-month follow-up questionnaires	7 months after initiation of intake questionnaires
Data cleaning and analysis	3 months after completing data collection
Submit final report	Within 3 months after completing data collection
Submit at least one manuscript	Within 1 year after completing data collection

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

We do not seek approval to eliminate the expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.