Food and Drug Administration's Research and Evaluation Survey for the Public Education Campaign on Tobacco among LGBT (RESPECT)

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making Collection of Information Necessary

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing a young adult-targeted public education campaign to help prevent tobacco use among LGBT young adults and thereby reduce the public health burden of tobacco. The campaign will feature events, advertisements on television, radio and in print, digital communications including videos and social media, and other forms of media. For the purpose of this OMB package, each of these campaign elements will be referred to as "advertisements" or "ads."

The objective of the evaluation is to measure the effectiveness of FDA's [LGBT Campaign] designed to reduce tobacco use among LGBT young adults aged 18 to 24. The goal of the proposed information collection is to evaluate the effectiveness of these efforts in affecting specific cognitive outcomes related to tobacco use that are targeted by the campaign.

This study is designed to capture exposure to FDA's [LGBT Campaign] young adult tobacco-focused public education campaign and evaluate whether campaign exposure is associated with changes in outcome variables of interest. A small pilot study to test the screening process will be conducted in late 2015, and baseline data collection is scheduled to begin in January 2016. Three follow-up surveys will be conducted among those young adults who participated previously, with new cross-sectional participants being recruited to make up for attrition. The post-campaign data collection will begin approximately 6 months following the launch of the campaign with new participants being recruited on an ongoing basis. The data collection will end approximately 18 months after the launch of the campaign. This design will facilitate analysis of relationships between individuals' exposure to campaign activities and baseline to follow-up changes in outcomes of interest between campaign and comparison cities.

To complement this data collection, we will conduct cross-sectional media tracking surveys of LGBT 18 to 24-year-olds in the periods in between the primary outcome evaluation survey waves. The purpose of these surveys is to capture self-reported data on the target audience's awareness of and receptivity to campaign activities. This media tracking survey effort is important to inform the campaign on a regular basis as research has shown that receptivity to campaign messages is causally antecedent to actual ad effectiveness (e.g., Davis et al., 2013; Davis, Uhrig, et al., 2011; Dillard, Shen, & Vail, 2007; Dillard, Webber, & Vail, 2007). We hypothesize that if the campaign is effective, the baseline to follow-up changes in outcomes should be larger among individuals in campaign cities compared to individuals in comparison cities. Furthermore, the differences should be more pronounced for young adults in campaign cities exposed to the campaign more frequently (i.e., dose-response effects).

The primary method to recruit young adults for the outcome evaluation will be via intercept screenings in LGBT venues (e.g., bars, nightclubs). However, given that the target audience represents a relatively small proportion of young adults, we are complementing this approach by recruiting LGBT young adults through social media. Media tracking surveys will also be conducted by recruiting LGBT young adults via social media. The baseline survey will include measures of tobacco-related beliefs, attitudes, intentions, and behaviors. The outcome follow-up surveys will include measures of audience awareness of and exposure to the campaign advertisements as well as the aforementioned outcome variables of interest. The baseline and follow-up questionnaires are presented in Attachments 1 and 2. A brief screener that will be used to identify LGBT young adults recruited in person and via social media for both the outcome baseline and follow-up surveys is presented as Attachment 3.

2. Purpose and Use of the Information Collection

The information obtained from the proposed data collection activities is collected from individuals and will be used to inform FDA, policy makers in the United States, prevention practitioners, and researchers about the extent of LGBT young adults' exposure to the campaign's activities and the extent to which exposure to these activities is associated with changes in targeted outcomes. While not exhaustive, the list below illustrates a range of purposes and uses for the proposed information collection:

- Provide critical data on the reach of the campaign among LGBT young adults in targeted cities, particularly with estimates of the proportion of the population that was exposed to the campaign.
- Understand the influence of the campaign on targeted beliefs and attitudes among those evaluated in this study.
- Inform FDA, policy makers, and other stakeholders on the impact of the campaign among evaluated cities.
- Inform the public about the impact of the campaign in the evaluated cities.
- Inform future programs that may be designed for similar purposes.

To achieve these goals, data collection will consist of a baseline survey and three follow-up surveys with young adults as the target audience. The follow-up surveys will be conducted among those young adults who participated previously, with new cross-sectional participants being recruited to make up for attrition. By re-contacting study participants from previous waves, we can reduce the costs of data collection and allow for the possibility of examining changes in study outcomes within individuals over time. However, we anticipate that it will be difficult to retain a sufficiently large proportion of the baseline sample to rely exclusively on a longitudinal design. Young adults are more mobile than older adults (Benetsky et al., 2015) and may move out of the selected study markets or simply be difficult to re-contact. As a result, our goal is to recruit additional LGBT young adults at each wave to ensure the same overall sample size remains constant.

Eligible respondents will be young adults who are 18 to 24 years old and who self-identify as LGBT. The sample will include young adults who self-identify as LGBT, as well as young adults who self-identify as being queer, trisexual, omnisexual, transsexual, gender variant or pansexual (definition from National Health Interview Survey (NHIS) (http://www.cdc.gov/nchs/nhis.htm). The [LGBT Campaign] will target up to 15 cities. The outcome evaluation data collection will occur in 12 campaign-targeted cities and 12 similar ("comparison") cities. The embedded longitudinal cohort will also reduce cost, as well as respondent burden. By re-contacting participants from previous waves of data collection, we will reduce the amount of screening of the population required to reach our target sample compared to collecting an entirely new sample at each wave. The reduced screening, reduces overall burden on the population and thus reduces costs.

The outcome study will rely primarily on participants intercepted and invited to complete the screening in LGBT venues to identify eligible young adults, followed by web-based data collection for eligible participants. We will supplement this approach by recruiting young adults through social media. We will advertise in social media and invite young adults aged 18 to 24-years-old to complete the screening survey online. We will then ask eligible young adults to continue on to complete the same web survey completed by participants recruited and screened in person.

The campaign's target audience consists of young adults who participate in the LGBT community. To determine LGBT status, we will use a series of questions used by the National Health Interview Survey (NHIS) (http://www.cdc.gov/nchs/nhis.htm) to identify individuals as being LGBT. Survey participants will be categorized as LGBT if they self-identify as one or more of the following: lesbian, gay, bisexual, transgender, transsexual, gender variant, queer or pansexual (also referred to as trisexual or omnisexual). Eligible young adults intercepted in person will receive a link by email or text message to complete the web survey. Eligible young adults recruited via social media will continue immediately to the survey from the screener.

This survey will be self-administered online (via the participant's personal computer or mobile device). The baseline survey will have a sample size of 3,150, with half of the sample (N=1,575) from 12 campaign-targeted cities and half (N=1,575) from comparison cities. The total sample for the follow-up surveys will be approximately 9,450, with an equal number of surveys in campaign and comparison cities. We will estimate the proportion of baseline participants expected to complete successive follow-up surveys and supplement that longitudinal sample with new cross-sectional participants to meet our target total sample size. This design permits an analysis of trends in outcomes between young adults in targeted and comparison cities. Compared to a purely cross-sectional design with independent samples, the inclusion of participants from previous waves requires accounting for the over-time correlation in responses from the embedded longitudinal sample. To account for the non-independence of these observations over time, we create unique identifiers for participants and use these to cluster the multiple observations per participant (Wooldridge, 2010; Wears, 2002).

Schedule permitting, 80 young adult respondents will be screened in person at LGBT bars as part of a pilot test of procedures. Of the total 12,600 baseline and follow-up surveys, approximately 3,150 (25%) will be completed by young adults recruited through social media. In addition to the baseline and follow-up surveys, we will recruit 1,500 young adults to complete media tracking surveys using social media advertisements. Media tracking surveys will be conducted in the three periods between waves of the outcome survey, with 500 surveys per wave.

Information collected in this campaign evaluation will not be generalized to broader or national LGBT populations.

3. Use of Improved Information Technology and Burden Reduction

Use of an embedded longitudinal cohort will markedly reduce burden relative to a design consisting solely of cross-sectional surveys. In addition, this outcome study will rely on a partially in-person computer-based screener, social media screener and web surveys for baseline and follow-up data collection. The proposed approach of screening eligible young adults via intercept screeners in LGBT venues and via social media provides a number of methodological advantages, including efficiency in identifying this hard-to-reach population, increased accuracy in measurement of key variables of interest, and reduced burden on study participants. Computerized administration permits the instrument designer to incorporate into the questionnaire routings that might be overly complex or not possible using a paper-based survey. The tablet and web surveys, which will be used to collect intercept screener data and baseline and follow-up surveys, can be programmed to implement complex skip patterns and fill specific wordings based on the respondent's previous answers. Interviewer and respondent errors caused by faulty implementation of skip instructions are virtually eliminated. Second, computerized and web-based administration increases the consistency of the data. The computerized version of the screener and web-based versions of screener and surveys can be programmed to

identify inconsistent responses and attempt to resolve them through respondent prompts. This approach reduces the need for most manual and machine editing, thus saving time and money. In addition, it is likely that respondent-resolved inconsistencies will result in data that are more accurate than when inconsistencies are resolved using editing rules. FDA estimates that 100% of the respondents will use electronic means (either via computerized screeners using a tablet, or web-based screeners and surveys) to fulfill the agency's request.

Respondents who are screened in bars will be screened with a self-administered questionnaire programmed on a tablet. All screener data collected in person will be transmitted via secure encrypted data transmission to RTI's offices, after which survey item response data will be automatically wiped from all field data collection devices. Respondents will be distinguished in the data only by a unique identifier linking individual screenings and interviews. Identifiers (email address and first name) will be stored, transmitted, and maintained in a data file separate from responses to questions. The computer-assisted self-interview technology for the screener survey permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry, will be minimized). Data are transmitted electronically at the end of the day. These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis. Finally, this technology permits respondents to complete the interview in privacy. Providing the respondent with a methodology that improves privacy makes reporting of potentially embarrassing or stigmatizing behaviors (e.g., tobacco use, gender identity) less threatening and enhances response validity and response rates.

The in-person computerized sample will be supplemented by a sample of respondents who are recruited through social media. These respondents will be recruited through social media platforms Facebook and Twitter, and led to an online screener for the study (see Attachment 3). Respondents will be invited to complete the screener using a web survey programmed and hosted on RTI's servers. This web survey will have the advantage of immediately notifying respondents if they are eligible for the full study. In addition, use of social media as a recruitment tool will cast a wider net to identify additional, eligible study respondents who are members of this hard-to-reach population.

In an effort to prevent individual participants from completing surveys multiple times to receive additional incentives and reduce the number of poor quality surveys, we have implemented the following 4-step procedure to identify duplicates and poor quality surveys for removal:

1) Prevent all exact email matches from moving past the screening instrument (an individual email can only enter the baseline survey one time).
2) After a participant completes the survey, identify exact/almost exact name matches (80%+ name matches for names longer than 5 characters) between email addresses provided during screening (e.g. jamieguillory1@gmail.com,

jamieguillory2@gmail.com, jamieguillory1@yahoo.com, jamieguillory43@hotmail.com, etc.). These email addresses are flagged and reviewed by the project analyst to determine whether the names are similar enough to warrant coding these as suspicious and removed. Surveys that are not deemed as suspicious then go on to Step 3. Duplicate email addresses are then provided to the survey provider as individuals who should not automatically receive additional incentives beyond any they have already received. If a participant labeled as duplicate contacts us for their incentive, we will inform them that only one incentive is allowed per respondent.

3) Check questions with Likert-type scales. If simple straight-lining or other pattern is found then these surveys will be removed. The remaining surveys will go on to Step 4.
4) Identify low engagement behavior by reviewing the speed of answers. Respondents who exceed four or five standard deviations from the mean completion time will be marked as speeders and their surveys will be removed from the sample.

In addition, to prevent fraudulent cases, we will be implementing the following procedures for the Follow-Up 2 survey:

- Require Facebook authentication for social media participants in the contact information survey.
- For social media participants, add a referrer field into the screener and screen out if it does not contain facebook.com (indicating that the participant has been recruited via Facebook or Instagram).
- For social media participants, add CAPTCHA at the screener and screen out if CAPTCHA is failed.
- For social media participants, screen out immediately if the country code of the IP address at the screener is not US-based.
- Have all respondents (intercept and social media in all cohorts) answer questions in the survey that are asked in the screener, and screen out if those answers do not match.

Eligible respondents will be routed to the full web survey, and given a unique ID to use to enter the survey. Respondents will be able to quit the survey at any time and resume where they left off upon reentry. Respondents will also be emailed a link to resume the survey if they do not complete the survey in one sitting, contact information to ask questions, receive reminders to complete the survey, and receive a virtual gift card upon completion.

Administration of the survey using web methods will help to contain costs, allowing for a sample that is geographically diverse without driving up interviewer costs for travel during data collection.

4. Efforts to Identify Duplication and Use of Similar Information

FDA's Research and Evaluation Survey for the Public Education Campaign on Tobacco among LGBT (RESPECT) is new. To date, there has been no in-depth evaluation of this campaign in a real-world setting, and there are no existing data sources that contain measures on awareness of and exposure to the campaign. This proposed information collection therefore does not duplicate previous efforts. In designing the proposed data collection activities, we have taken several steps to ensure that this effort does not duplicate ongoing efforts and that no existing data sets would address the proposed study questions. We have carefully reviewed existing data sets to determine whether any of them are sufficiently similar or could be modified to address FDA's need for information on the effectiveness of the campaign with respect to reducing young adult tobacco-related outcomes. We investigated the possibility of using existing data to examine our research questions, such as data collected as part of ongoing national surveillance systems, evaluations of current or past surveys including LGBT young adults, including the National Adult Tobacco Survey (NATS) and the National Health Interview Survey (NHIS). Due to the timing of the campaign, the limited geographic reach of the campaign, and specificity of the target population, none of these existing data sources will be able to provide the necessary data collection needs of the campaign, none will include the necessary in-depth survey questions on awareness of individual ads and other campaign materials, and none contain all of the necessary outcome variables specific to the campaign's messages.

5. Impact on Small Businesses or Other Small Entities

Respondents in this study will be members of the general public and specific subpopulations, not business entities. No impact on small businesses or other small entities is anticipated.

6. Consequences of Collecting the Information Less Frequently

Respondents to this collection of information will be invited to answer up to three surveys. While there are no legal obstacles to reduce burden, any lack of information needed to evaluate the [LGBT Campaign] may impede the federal government's efforts to improve public health. Without the information collection requested for this evaluation study, it would be difficult to determine the value or impact of the campaign on the lives of the people they are intended to serve—LGBT young adults. Failure to collect these data could reduce effective use of FDA's program resources to benefit young adults in the United States. Careful consideration has been given to how frequently the campaign's intended audience should be surveyed for evaluation purposes. We believe that the proposed outcome study design will provide sufficient data to evaluate the campaign effectively.

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

There are no special circumstances for this collection of information that require the data collection to be conducted in a manner inconsistent with 5 CRF 1320.5(d)(2). The message testing activities fully comply with the guidelines in 5 CFR 1320.5.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* on June 30, 2015 (80 FR 37270). FDA received 1 comment:

Comment: The commenter did not believe the amount of hours was justified for learning about the LGBT population. Additionally, the commenter did not see an explanation of the value of collecting this information.

Response: FDA disagrees with this comment. The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) authorized the FDA to develop and implement several public health education campaigns about the dangers of using tobacco products. Through literature reviews and analysis of national survey data, FDA identified groups that are uniquely at-risk of tobacco initiation due to a variety of factors, and who would benefit from an innovative education campaign designed to prevent tobacco use. One such group is young adults who identify as LGBT, who according to recent data smoke at approximately 2 times the rate of the general adult population.

The following individuals inside the agency have been consulted on the design of the campaign evaluation plan, audience questionnaire development, or intra-agency coordination of information collection efforts:

Tesfa Alexander
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-796-9335
E-mail: Tesfa.Alexander@fda.hhs.gov

Lucinda Miner
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-796-9181
E-mail: Lucinda.Miner@fda.hhs.gov

Gem Benoza
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-0088
E-mail: Maria.Benoza@fda.hhs.gov

David Portnoy
Office of Science
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-796-9298
E-mail: David.Portnoy@fda.hhs.gov

Leah Hoffman
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-7134
E-mail: Leah.Hoffman@fda.hhs.gov

Janine Delahanty
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-9705
E-mail: Janine.Delahanty@fda.hhs.gov

Matthew Walker
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-3824
E-mail: Matthew.Walker@fda.hhs.gov

The following individuals outside of the agency have been consulted on questionnaire development. Additionally, input has been solicited and received from FDA on the design of this study, including participation by FDA in meetings with OMB:

Matthew Farrelly
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-541-6852
E-mail: mcf@rti.org

Jennifer Duke
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-485-2269
E-mail: jduke@rti.org

Jamie Guillory
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-316-3725
E-mail: jguillory@rti.org

Kristine Fahrney-Wiant
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-485-5531
E-mail: fahrney@rti.org

Jane Allen
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-597-5115
E-mail: Janeallen@rti.org

Youn Lee
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-485-5536
E-mail: Younlee@rti.org

Amy Henes
RTI International
701 13th Street, NW
Washington, DC, 20005
Phone: 202-974-7821
E-mail: ahenes@rti.org

Patricia LeBaron
RTI International
230 W Monroe Avenue, Suite 2100
Chicago, IL 60606
Phone: 312-777-5204
E-mail: plebaron@rti.org

Pamela Rao
Akira Technologies, Inc.
1747 Pennsylvania Ave NW Suite 600
Washington, DC 20002
Phone: (202) 517-7187
Email: prao@akira-tech.com

Xiaoquan Zhao
Department of Communication
George Mason University
Robinson Hall A, Room 307B
4400 University Drive, 3D6
Fairfax, VA 22030
Phone: 703-993-4008
E-mail: xzhao3@gmu.edu

Joseph Lee
East Carolina University
Belk Building
Greenville, NC
Phone: 919-966-2807
E-mail: leejose14@ecu.edu

Jeff Jordan
Rescue Social Change Group
2437 Morena Blvd.
San Diego, CA 92110
Phone: 619-231-7555 x 150
Email: jeff@rescuescg.com

Mayo Djakaria
Rescue Social Change Group

660 Pennsylvania Avenue SE, Suite 400
Washington, DC 20003
Phone: 619-231-7555 x 120
Email: mayo@rescuescg.com

Dana Wagner
Rescue Social Change Group
660 Pennsylvania Ave SE, Suite 400
Washington, DC 20003
Phone: 619-231-7555 x 331
Email: dana@rescuescg.com

Brandon Tate
Rescue Social Change Group
6463 Sunset Boulevard, Suite 504
Hollywood, CA 90028
Phone: 619-231-7555 x 152
Email: brandon@rescuescg.com

9. Explanation of Any Payment or Gift to Respondents

Due to difficulty in recruiting intercept respondents, intercept respondents will be paid $10 in cash for completing the screener. Those who are eligible will receive an email invitation to complete the full survey. If they choose to complete the full survey they will receive an online gift card of $20.00, with a $5 bonus (total of $25.00) if they complete the full survey within two days of invitation. Incentives are particularly important in intercept surveys. By definition, intercept respondents are busy doing something else at the time they are intercepted. In the case of this study, when intercepted, respondents will be entering a bar, leaving the bar to go elsewhere, or are likely to be otherwise engaged in interactions with others inside the bar. Unlike a mail or web survey that can be done at the respondent's leisure, or a telephone or in-person interview that can be scheduled at the respondent's convenience, in an intercept study the invitation to participate is a relatively immediate one, and respondents are likely to require motivation to stop what they are doing. While there is little published experimental research that examines the effectiveness of incentives vs. no incentives with intercept surveys, there are numerous examples of public health research that has used cash incentives when intercepting respondents at bars or other "party" venues. Incentives within this literature tend to range from $5-$10 for completing a brief survey when entering the venue (e.g. Bourdeau et al. 2015, Guillory et al. 2015, Miller et al. 2003, and Voas et al. 2013) and were typically $20 when both survey data and biological measures were collected upon leaving the venue data (e.g. Bourdeau et al. 2015, Miller et al. 2003, and Voas et al. 2013). A meta-analysis of incentive use during intercept studies in the transportation field suggests that incentives that are paid at the time of completion have a larger impact on response rates than promised incentives (Schaller, 2005).

Respondents who are recruited through social media (Facebook, Twitter) will receive a link to a virtual gift card via email, such as from Visa or Amazon, with a value of $20 upon completion of the survey. Respondents recruited via social media will not receive separate compensation for completing screener instruments. The incentive procedures and amounts for new cross-sectional sample at follow-up waves will be identical to the baseline survey. For the longitudinal sample, participants will receive $20 for completing the follow-up survey and an additional $5 if they complete the survey within 48 hours of the invitation to participate.

A more detailed justification for the use of incentives is provided in Attachment 4. The use of modest incentives is expected to enhance survey response rates without biasing responses. A smaller incentive would not appear sufficiently attractive to participants. We also believe that the incentives will result in higher data validity as participants will become more engaged in the survey process. This will also enhance overall response to the baseline and follow-up surveys and reduce attrition at follow-up within the embedded longitudinal cohort. The use of incentives will help ensure that baseline data collection is completed in a timely manner and potentially reduce the number of additional intercept recruitment time in LGBT venues. Use of incentives within the embedded longitudinal cohort will reduce attrition, which in turn will reduce respondent burden and the cost of follow-up surveys. The specific amount of the proposed incentive is similar to the incentives used in several federally-funded projects, including the National Health and Nutrition Examination Survey (NHANES) (incentives range from $20 to $125 depending on the survey and physical exam components in which respondents agree to participate), and the National Survey on Drug Use and Health (NSDUH) ($30 for 60 minute interview). RTI has also used similar incentives for previous FDA campaign evaluations, including the Evaluation of the Public Education Campaign on Teen Tobacco (ExPECTT, Food and Drug Administration), which employs a $20 promised incentive for 30 and 45 minute in-person or web surveys, and the Evaluation of the Fresh Empire Campaign on Tobacco (EFECT, Food and Drug Administration), which employs a $25 promised incentive for 30 and 45 minute in-person or web surveys. Additional research studies have used similar incentives to effectively recruit members of the LGBT community, noting that members of the LGBT community are a particularly difficult-to-reach population and that incentives for participating in research are an important component of recruiting LGBT research participants (Meyer & Wilson, 2009). Jones et al. (2008) provided 18 to 30 year old black men who have sex with men $20 gift card incentives for participating in cross-sectional surveys. Silvestre et al. (2006) paid minority men who have sex with men $25 for an HIV epidemiological study. Remafedi and Carol (2005) offered LGBT youth $20 incentives and smoking cessation referrals for participating in interviews for designing tobacco prevention campaigns.

10. Assurance of Privacy Provided to Respondents

RTI's Institutional Review Board (IRB) will review and approve the informed consent content (Attachments 5 and 6) for the evaluation survey. The IRB's primary

concern is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law.

All data collection activities will be conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents and to protect the rights and welfare of human research subjects as contained in their regulations. Respondents will receive information about privacy protections as part of the informed consent process. All those who handle or analyze data will be required to adhere to the standard data security policies of RTI.

Respondents who are screened in bars will be screened with a self-administered questionnaire on a tablet, which affords more privacy than interviewer-administered or a self-administered paper and pencil instrument. Respondents who participate in the full web-survey will be encouraged to do so in private to reduce the likelihood of household members viewing their responses. Respondents are given the choice to skip any question they choose. All screener data collected in person will be transmitted via secure encrypted data transmission to RTI's offices, after which survey item response data will be automatically wiped from all field data collection devices. Respondents will be distinguished in the data only by a unique identifier linking individual screenings and interviews. Identifiers (email address and first name) will be stored, transmitted, and maintained in a data file separate from responses to questions.

At this time, for the Web survey we plan to use the Acuity4Survey platform, which is run by a company called Voxco (http://www.acuity4survey.com/). Data will be housed in RTI's Enhanced Security Network. We confirmed that Voxco uses SSL encryption. RTI Information Technology Services (ITS) has reviewed Voxco's data security approaches and has approved RTI staff to use the infrastructure on projects.

ITS also maintains a Voxco administrative login so that it can audit project data security procedures. Only RTI project team members will have access to survey response data, and only a couple of RTI staff members will actually be able to download survey response data onto a project share drive. This tight access control of the survey response data is a further step to mitigate risk.

No personally identifying information about respondents (first name, email, or cell phone number) will be linked with the survey response file exported from Voxco. The Survey Start Code and Case Identification Number will be in both the contact information file and the survey data file and are the only link between the two files. However, by themselves, neither the Survey Access Code nor the Case Identification Number is personally identifiable information. It is necessary to be able to use the Case Identification Number to link the contact data with the survey data for the following reasons: 1) to ensure that access to the survey is restricted to those who have already screened as eligible (i.e., valid Survey Access Codes from the contact data file will be preloaded into the survey website so that they can automatically be validated when the intercept respondents enter them on the survey access page in

Voxco) and that each respondent only completes the survey one time, 2) to allow respondents to complete the survey in more than one setting if needed (i.e., they can stop and restart the survey if needed, which is not possible if respondents do not enter a Survey Access Code), and 3) to allow us to identify non-respondents (to follow-up with non-respondents with Survey Access Codes that have not yet been entered on the survey website).

All those who handle or analyze data will be required to adhere to the standard data security policies of RTI.

Implementation of data security systems and processes will occur as part of the survey data collection. Data security provisions will involve the following:

- All data collection activities will be conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents and to protect the rights and welfare of human research subjects as contained in their regulations. Respondents will receive information about privacy protections as part of the informed consent process.
- All data collectors will be trained on privacy procedures and be prepared to describe them in full detail, if necessary, or to answer any related questions raised by respondents. Training will include procedures for safeguarding sample member information in the field, including securing hardcopy case materials and laptops in the field, while traveling, and in respondent homes, and protecting the identity of sample members.
- All project employees will sign a privacy agreement that emphasizes the importance of respondent privacy and describes their obligations.
- All field staff tablet computers will be equipped with encryption software so that only the user or RTI administrators can access any data on the hard drive even if the hard drive is removed and linked to another computer.
- All data transferred to RTI servers from field staff tablets will be encrypted and transferred via a secure (SSL) broadband connection or optionally a secure telephone (land) line. Similarly, all data entered via the Web-based survey system will be encrypted as the responses will be on a Web site with an SSL certificate applied. Data will be passed through a firewall at RTI and then collected and stored on a protected network share on the RTI Network. Only authorized RTI project staff members will have access to the data on the secure network share.
- Respondents recruited through social media (Facebook and Twitter) will also access the survey with a unique ID and will complete the survey on a secure server. The result is that no information about the respondent's identity (with the exception of an email address and cell phone number) will be downloaded to or housed on RTI's server.

All respondents will be assured that the information they provide will be maintained in a secure manner and will be used only for the purpose of this research. Respondents will be assured that their answers will not be shared with others 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.

Respondents will participate on a voluntary basis. The voluntary nature of the information collection is described in the introductory section of the Consent Process for both the screener consent (Attachment 5) and the main instrument consent (Attachment 6).

11. Justification for Sensitive Questions

The majority of questions asked will not be sensitive in nature. There will be no requests for a respondent's Social Security Number (SSN). However, it will be necessary to ask some questions that may be considered to be sensitive in nature in order to assess specific health behaviors, such as cigarette smoking, marijuana and alcohol use. While this may be a sensitive question, we feel that it is important to ask respondents about marijuana use because it is a common risk factor that may influence receptivity to the campaign. We have also included questions asking participants about their alcohol use. While these also may be sensitive questions, non-daily smoking while drinking alcohol is a common behavior among young adults and it is important to understand how co-use of alcohol and cigarettes is influenced by the campaign. These questions are essential to the objectives of this information collection. Questions about messages concerning lifestyle (e.g., smoking, current smoking behavior, attempts to quit smoking) and some demographic information, such as race, ethnicity, gender, sexual identity and income, could be considered sensitive, but not highly sensitive. Questions about gender and sexual identity are necessary to determine whether participants identify as LGBT so that we can screen them as eligible participants for the baseline, follow-up and media tracking surveys. To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The informed consent (see Attachments 5 and 6) will apprise respondents that these topics will be covered during the survey. This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.
- Web surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses.
- Participants will be provided with a specific toll-free phone number (linking directly to the RTI IRB Office) to call in case they have a question or concern about the sensitive issue.

Finally, as with all information collected, these data will be presented with all identifiers removed.

12. Estimates of Annualized Burden Hours and Costs

12.1. Annualized Hour Burden Estimate

FDA's burden estimate is based on prior experience with in-person studies similar to the Agency's plan presented in this document, as well as previous research using social media advertising to recruit young adult participants. To reduce overall burden hours, participants who screen and complete the baseline outcome evaluation questionnaire will be re-contacted to complete the first follow-up campaign evaluation questionnaire, those who complete the first follow-up campaign evaluation questionnaire will be re-contacted to complete the second follow-up campaign evaluation questionnaire, and so on. Re-contacted individuals will not need to complete the screener again. We expect a 65 percent eligibility rate and 50 percent response rate for individuals recruited in person and a combined eligibility and response rate of 30 percent for individuals recruited via social media. In each successive round of data collection, we expect 50 percent of re-contacted individuals to complete the follow-up questionnaire, therefore, additional screenings will be conducted for each follow-up in order to maintain the target sample size for each follow-up questionnaire.

The target number of completed questionnaires ("completes") for the outcome evaluation study is 12,612, or 4,204 annually over the 3-year approval period ("annualized"). The annualized sample sizes and burden hours are presented in Exhibit 1 below, and provided in parentheses following the study totals in the following paragraphs.

In-person recruitment will take place in a variety of LGBT venues (e.g., bars, nightclubs). The owners or managers of potential recruitment sites will be asked a series of questions to determine the appropriateness of its clientele for participation in the study. Approximately 1,920 venues (640 annualized) will be assessed at 5 minutes per assessment for a total of 159 hours (53 annualized).

To obtain the target number of completed questionnaires ("completes") for the outcome evaluation study, 24,744 (8,248 annualized, or annually over the 3-year approval period) young adults (18,177 [6,059 annualized] recruited in person and 6,567 [2,189 annualized] recruited via social media) will participate in a screening process ("screener"). The estimated burden per screener is 5 minutes (0.083 hour), for a total of 2,055 hours [685 annualized] (1,512 hours [504 annualized] for participants recruited in person and 543 hours [181 annualized] for persons recruited via social media). Before the beginning of data collection, the 5-minute screener will be tested in a small pilot study of 81 young adults (27 annualized) for a total of 6 hours (2 hours annualized).

A total of 12,612 (4,204 annualized) LGBT young adults (9,456 [3,152 annualized] of those screened in person and 3,156 [1,052 annualized] of those screened through social media) will complete questionnaires in 4 rounds of data collection (baseline

and three post-campaign rounds). The estimated burden per complete is 30 minutes (0.5 hour) for the baseline questionnaire and 40 minutes (0.667 hour) for each follow-up complete, for a total of 7,884 hours (2,628 annualized) (5,916 hours [1,972 annualized] for those recruited in person and 1,968 hours [656 annualized] for those recruited via social media).

To obtain the target number of completes (1,503 completes [501 annualized]) for the media tracking survey, 5,004 (1,668 annualized) young adults will be recruited via social media ads to complete a screener for all three waves of the media tracking survey. The estimated burden per screener response is 5 minutes (0.083 hour), for a total of 415 [138 annualized] hours for all waves of media tracking screener. An estimated 501 (167 annualized) LGBT young adults will complete each of the three waves of the media tracking survey (assuming a 30 percent combined eligibility and response rate to screeners via social media). The estimated burden per completed media tracking questionnaire is 40 minutes (0.667 hour), for a total of 999 (333 annualized) hours for the three waves. The total burden for the media tracking survey (screeners and completes) is 1,413 hours (471 annualized).

The target number of completed campaign questionnaires (i.e., screeners and questionnaires for both the outcome evaluation and media tracking survey) for all respondents is 45,864 (15,288 annualized). The total estimated burden is 11,517 (3,839 annualized).

Exhibit 1. Estimated Annual Burden Hours[a]

Type of Respondent	Activity	Number of Respondents Annually	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Annual Hours
Venue owners and managers	Venue recruitment assessment	640	1	640	.083	53
Total Venue Recruitment		**640**	**1**	**640**		**53**
General Population: Pilot test of procedures in bars	Screener – Pilot study	27	1	27	0.083	2
Total Screener Pilot		**27**	**1**	**27**		**2**
Screener: General population – Recruited in person (65% screen as eligible)	Screener – Baseline, outcome study	2,423	1	2,423	0.083	201
	Screener – First follow up, outcome study	1,212	1	1,212	0.083	101
	Screener – Second follow up, outcome study	1,212	1	1,212	0.083	101
	Screener – Third follow up, outcome study	1,212	1	1,212	0.083	101
Screeners: In person		**6,059**		**6,059**		**504**
Screener: General population	Screener – Baseline, outcome study	875	1	875	0.083	73
	Screener – First	438	1	438	0.083	36

– Recruited via social media	follow up, outcome study					
	Screener – Second follow up, outcome study	438	1	438	0.083	36
	Screener – Third follow up, outcome study	438	1	438	0.083	36
Screeners: Social media		**2,189**		**2,189**		**181**
Total screeners		**8,248**		**8,248**		**685**
Outcome Study LGBT young adults aged 18-24 in select media markets – Recruited in person (50% response rate)	Questionnaire – Baseline outcome study	788	1	788	0.5	394
	Questionnaire – First follow up, outcome study	788	1	788	0.667	526
	Questionnaire – Second follow up, outcome study	788	1	788	0.667	526
	Questionnaire – Third follow up, outcome study	788	1	788	0.667	526
Completes: Screened in person		**3,152**		**3,152**		**1,972**
Outcome Evaluation: LGBT young adults aged 18-24 in select media markets - Recruited via social media (30% combined eligibility and response rate)	Questionnaire – Baseline outcome study	263	1	263	0.5	131
	Questionnaire – First follow up, outcome study	263	1	263	0.667	175
	Questionnaire – Second follow up, outcome study	263	1	263	0.667	175
	Questionnaire – Third follow up, outcome study	263	1	263	0.667	175
Completes: recruited online		**1,052**		**1,052**		**656**
Total completes (recruited in person and recruited online)		**4,204**		**4,204**		**2,628**
LGBT young adults aged 18-24 in the select media markets - Recruited via social media (30% combined eligibility and response rate)	Screener – First media tracking	556	1	556	0.083	46
	Screener – Second media tracking	556	1	556	0.083	46
	Screener – Third media tracking	556	1	556	0.083	46
Media tracking screeners		**1,668**		**1,668**		**138**
LGBT young adults aged 18-24 in the select media markets - Recruited via social media (30% combined eligibility and response rate)	Questionnaire – First media tracking	167		167	0.667	111
	Questionnaire – Second media tracking	167	1	167	0.667	111
	Questionnaire – Third media tracking	167	1	167	0.667	111
Media tracking questionnaires		**501**		**501**		**333**

Total media tracking (screeners and questionnaires)	**2,169**		**2,169**		**471**
TOTALS ACROSS ALL STUDY COMPONENTS	**15,288**		**15,288**		**3,839**

[a]There are no capital costs or operating and maintenance costs associated with this collection of information.

12.2. Annualized Cost Burden Estimate

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than time to participate. There are also no start-up or maintenance costs. RTI has conducted many smoking-related surveys of similar length among young adults. We have examined diagnostic data from each of these prior surveys and estimate that data collection for this study will take approximately 30 minutes per respondent for the baseline outcome survey and 40 minutes for the follow-up surveys. We estimate that the media tracking surveys will also take 40 minutes. According to the U.S. Department of Labor (DOL) Bureau of Labor Statistics the average hourly wage in 2013 was $8.19 for adults over 18. Thus, assuming an average hourly wage for adults of $8.19, the estimated total cost to participants will be $93,047 (3 years of data collection). The estimated annual value of respondents' time for participating in the information collection is summarized in Exhibit 2.

Exhibit 2. Estimated Annual Cost[a]

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
Adults 18 and older in the United States	Venue Recruitment	53	$8.19	$434.07
	Pilot screening	2	$8.19	$16.38
	Screener for baseline survey	274	$8.19	$2,244.06
	Screener for follow-up surveys	411	$8.19	$3,366.09
	Screener for media tracking surveys	138	$8.19	$1,130.22
	Baseline survey	525	$8.19	$4,299.75
	Follow-up surveys	2103	$8.19	$17,223.57
	Media tracking survey	334	$8.19	$2,735.46
Total		3787		$0

[a]Numbers reflect cost for 1 year of data collection (total data collection period is 3 years).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

This information collection is funded through a contract with RTI. The total estimated costs attributable to this data collection are $8,037,087 (Exhibit 3). There are additional contract-funded activities occurring before and after this data collection that include project planning and data analysis. Other activities outside this data collection include coordination with FDA and its media contractor, evaluation plan development, instrument development, reporting, RTI IRB, and progress reporting and project management. This information collection will occur from 2016 through 2017.

Exhibit 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	25%	$90,823	$22,705
GS-14	15%	$110,902	$16,635
GS-15	5%	$126,245	$6,312
		Total Salary Costs	**$45,652**
		Contract Cost	**$7,991,435**
		Total	**$8,037,087**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data from this information collection will be used to estimate awareness of and exposure to the campaign among LGBT young adults. These estimates will take the form of self-reported ad recognition and recall that assess basic exposure as well as frequency of ad exposure. These estimates will also be calculated separately for each specific campaign advertisement.

Data from this information collection will also be used to examine statistical associations between exposure to the campaign and baseline to follow-up changes in specific outcomes of interest for campaign and comparison groups. We will conduct two primary types of analyses. The first will focus on aggregate changes in outcomes from the baseline to follow-up periods between the campaign and comparison cities. The second analytic approach will focus on individual changes in outcomes as a function of campaign exposure, which will vary within and across campaign and comparison cities. The embedded longitudinal cohort may also permit some longitudinal analysis. The primary outcomes of interest among young adults will be awareness of the campaign as well as tobacco-related beliefs, attitudes, intentions and

behaviors. We hypothesize that there should be larger changes in outcomes among individuals with more frequent campaign exposure (i.e., dose-response effects).

In addition to relying on self-reported exposure, we will also utilize measures of market-level campaign intensity, which will be constructed with available data on campaign activities, including traditional and digital advertising and local campaign events. These data will be merged to the survey to provide an additional measure of campaign exposure among study participants. This will allow us to analyze the relationship between the market-level delivery of the campaigns and actual levels of awareness in each sample that is collected. This will also facilitate further analyses of the relationship between exogenous market-level measures of campaign dose and changes in the aforementioned outcome variables of interest.

The reporting and dissemination mechanism will consist of three primary components: (1) summary statistics (in the form of PowerPoint presentations and other briefings) on individual awareness of and reactions to the campaign, (2) a comprehensive evaluation report summarizing findings from this information collection, and (3) at least two peer-reviewed journal articles that document the relationships between campaign exposure and changes in the aforementioned outcomes of interest. The key events and reports to be prepared are listed in Exhibit 4.

Baseline information collection must be completed before the launch of the campaign. OMB approval is requested as soon as possible.

Exhibit 4. Project Schedule

Project Activity	Date
Baseline data collection	January 2016 – May 2016
Wave 2 data collection	September 2016 – November 2016
Wave 3 data collection	April 2017 – June 2017
Wave 4 Data Collection	September 2017 – November 2017
Preparation of analytic data file	Approximately 4 weeks after completion of data collection
Data analysis	Approximately 5–12 weeks after completion of each analytic data file
Report writing and dissemination	Approximately 12-16 weeks after completion of each analytic data file

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

Not applicable. All data collection instruments will display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable. There are no exceptions to the certification statement.

References

Benetsky M.J., Burd C.A., Rapino M.A. (2015). *Young Adult Migration: 2007-2009 to 2010-2012.* United States Census Bureau, American Community Survey Reports, ACS-31. Washington, D.C.: United States Census Bureau.

Bourdeau, B., Miller, B., Johnson, M., Voas, R. (2015). Method of transportation and drinking among club patrons. Transportation Research Part F, 32, 11-22.

Davis K., Nonnemaker J., Duke J., Farrelly M.C. (2014). Perceived effectiveness of cessation advertisements: The importance of audience reactions and practical implications for media campaign planning. *Health Communication, 28*(5), 461-472.

Davis K., Uhrig J., Cann C., Rupert D., Fraze J. (2011). Exploring African American women's perceptions of a social marketing campaign to promote HIV testing. *Social Marketing Quarterly, 17*(3), 39-60.

Dillard, J.P., Shen, L.J., Vail, R.G. (2007). Does perceived message effectiveness cause persuasion or vice versa? 17 consistent answers. *Human Communication Research, 33*, 467–88.

Dillard J.P., Webber K.M., Vail R.G. (2007). The relationship between the perceived and actual effectiveness of persuasive messages: A meta-analysis with implications for formative campaign research. *Journal of Communication, 57*, 613-617.

Guillory, J., Johns, M., Farley, S., Ling, P. (2015). Loose Cigarette Purchasing and Nondaily Smoking Among Young Adult Bar Patrons In New York City. American Journal of Public Health. 105(8), e140-e147.

Jones, K.T., Gray, P., Whiteside, Y.O., Wang, T., Bost, D., Dunbar, E., Foust, E., Johnson, W.D. (2008). Evaluation of an HIV prevention intervention adapted for black men who have sex with men. *American Journal of Public Health, 98*(6), 1043-1050.

Meyer, I.H., Wilson, P.A. (2009). Sampling lesbian, gay, and bisexual populations. *Journal of Counseling Psychology, 56*(1), 23-31.

Miller, B., Byrnes, H., Branner, A., Johnson, M., Voas, R. (2003). Group Influences on Individuals' Drinking and Other Drug Use at Clubs. Journal of Study of Alcohol and Drugs, 74(2),280-287.

Remafedi, G., Carol, H. (2005). Preventing tobacco use among Lesbian, Gay, Bisexual, and Transgender Youths. *Nicotine & Tobacco Research, 7*(2), 249-256.

Schaller, B. (2005). On-Board and Intercept Transit Survey Techniques. Transit Cooperative Research Program (TCRP) Synthesis 63, published by Transportation Research Board, Washington.

Silvestre, A.J., Hylton, J.B., Johnson, L.M., Houston, C., Witt, M., Jacobson, L., Ostrow, D. (2006). Recruiting minority men who have sex with men for HIV research: Results from a 4-city campaign. *American Journal of Public Health, 96*(6), 1020-1027.

Voas, R., Johnson, M., Miller, B. (2013). Alcohol and drug use among young adults driving to a drinking location. Drug and Alcohol Dependence, 132, 69-73.

Wears RL. Advanced statistics: statistical methods for analyzing cluster and cluster-randomized data. Acad Emerg Med. 2002*;* 9*:*330–41.

Wooldridge JM. Econometric Analysis of Cross Section and Panel Data, Second Edition. 2010. MIT Press. Cambridge, MA.