**FDA CTP E-Blast Survey Audience Analysis Study**

**0910-0810**

**B. Statistical Methods**

**1. Respondent Universe and Sampling Methods**

The FDA Center for Tobacco Products (CTP) maintains an email subscriber list of approximately 40,000 members. These members have opted in, voluntarily, to be included in the database by registering through either the CTP website page, “Sign Up for Email Updates from CTP” (http://www.fda.gov/TobaccoProducts/AboutCTP/ucm176164.htm), or the GovDelivery network. Once registered, members receive complimentary copies of CTP newsletters and announcements via email. The approximately 40,000 subscribers are registered to at least one of the CTP newsletters or announcements, including:

1. CTP Connect
2. CTP News
3. Spotlight on Science

Subscribers have the ability to read and write in English as the subscriber base receives all the emails in English. Although subscribers may not all be from the United States, they do have the opportunity to participate in the survey.

The CTP research team will send an email blast (E-blast) to the entire database of approximately 40,000 CTP email subscribers, inviting them to participate in the online survey.

To avoid the potential of one individual completing the survey more than one time, IQ Solutions (CTP’s contractor) will program the survey completion to limit one survey per device.

*Sample Size*

The primary outcome of this study will be based on a convenience sample derived from the CTP email communications database of approximately 40,000 subscribers. The goal is to receive completed surveys from up to 1,200 CTP email subscribers from 1,500 who open up the email. For a previous Substance Abuse and Mental Health Services Administration (SAMHSA) survey, sent to GovDelivery subscribers, whose focus was to understand the information seeking behaviors of the current SAMHSA audience base (inclusive of collecting demographic information), IQ Solutions received a 1.5 percent response rate. Moreover, the successful average delivery rate of the CTP E-blast is 97 percent, the average CTP E-blast open rate is 13.9 percent, and the average CTP E-blast click rate is 2.9 percent. We therefore expect to receive between 400 and 1,200 completed surveys—that is, between one percent and three percent of the approximately 40,000 current CTP email subscribers. For the purposes of this submission, we will assume that we will receive no more than 1,500 completed surveys.

Online survey respondents will receive an invitation to complete the survey via a CTP E-blast emailed to the current E-blast subscriber base. If a recipient of the invitation is interested in taking the survey, they will click on a link URL provided to them in the electronic invitation.

To be eligible to participate in the online survey for the CTP E-blast Survey Audience Analysis Study, each respondent must:

* Subscribe to at least one of the following: CTP Connect, CTP News, Spotlight on Science (IQ Solutions will be using the database of subscribers to these resources to send an email inviting each subscriber to take the E-blast survey);
* Be 18 years of age or older (as determined by a screener question on the survey); and
* Have access to the Internet. *Note*: The online survey will be mobile-friendly.

This method is not intended to generate a nationally representative sample or a precise estimate of population parameters. The sample drawn here is designed primarily to provide information on CTP’s email subscribers.

The one-time actual burden figures are listed in Tables 1, 2 & 3, Part A.

**2. Procedures for the Collection of Information**

This section describes the procedures for the survey data collection.

The data will be collected via a web-based anonymous survey disseminated by IQ Solutions. The CTP research team will send an email to all CTP email subscribers inviting them to complete an online survey (Attachment A).

The survey begins with initial information that provides potential respondents with informed consent information, including the purpose of the study, the benefits and risks of the study, and informs participants about the anonymous nature of the study. The survey is classified as anonymous as no personally identifiable information (PII) is asked of participants. The item immediately following the informed consent information invites potential respondents to click “Start survey now” or “Exit survey” to assure that those respondents who complete the survey are doing so voluntarily. In line with the anonymous nature of this survey, no IP addresses or other forms of PII will be recorded. The survey first asks respondents four demographic questions (i.e., age cohort, country of residence, the state of employment [if in the United States], and education level). If the respondent indicates that they are 17 years of age or younger from an initial survey screener item, the survey program will terminate this respondent’s survey.

The survey instrument (Attachment C) includes contact information for the study’s Principal Investigator who will be available to respond to questions posed by respondents. The survey will be hosted on IQ Solution’s cloud-based servers. All surveys will be conducted using a self-administered, online questionnaire.

***Summary of Protocol***

The list of study procedures is as follows:

1. Adult (18 years or older) survey respondents are recruited via an E-blast sent to every individual in CTP’s email subscriber database. This email invitation will state the length of the survey (14 questions, including three multi-part questions), the approximate amount of time it will take to complete the survey (approximately 5 minutes), and confidentiality standards.
2. If the email recipient decides they would like to take the survey, they will click on the survey link provided in the email.
3. The survey begins with informed consent information and then invites the potential respondent to click “Start survey now” or “Exit survey” to assure that those respondents who complete the survey are doing so voluntarily.
4. Also, if the respondent indicates that they are 17 years of age or younger, the survey program will terminate this respondent’s survey.
5. If the respondent does not qualify for the survey, he or she will receive text thanking them for their time and explaining that they do not qualify for the survey.
6. If the respondent does qualify for the survey, they will continue to answer the 14 questions, including the three multi-part questions.

***Unusual Problems Requiring Specialized Sampling Procedures***

No specialized sampling procedures are involved.

***Use of Periodic Data Collection Cycles to Reduce Burden***

This is a one-time survey data collection effort.

#### 3. Methods to Maximize Response Rates

The ability to obtain the cooperation of potential respondents in the survey will be important to the success of this study. IQ Solutions will maintain the survey link live for three weeks and send two reminder emails (See Attachment A) to encourage response rates during this period.

Since engagement in the study is minimal, no respondents will be paid an incentive to participate in the online survey. All participation in this study is voluntary.

**4**. **Tests of Procedures or Methods**

The evaluation contractor IQ Solutions will conduct rigorous internal testing of the online survey instrument prior to its fielding. Evaluators will review the online test version of the instrument that to verify that instrument skip patterns are functioning properly and that all survey questions are worded correctly and are in accordance with the instrument approved by OMB.

**5. Individuals Involved in Statistical Consultation and Information Collection**

The following individuals inside the agency have been consulted on the design of survey:

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