# FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF PRETESTING COMMUNICATIONS ON TOBACCO PRODUCTS (0910-0674)

**TITLE OF INFORMATION COLLECTION:** Online Quantitative Study of Youth Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use among General Market Youth (Wave 2); OMB Control Number 0910-0674.

## DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) is seeking OMB approval under generic clearance OMB No. 0910-0674 to conduct online quantitative research (i.e., copy testing[1]) with youth aged 13–17 in the United States who have experimented with cigarettes (i.e., have reported smoking fewer than 100 cigarettes in lifetime) and youth aged 13–17 who are at risk of initiating (e.g., would smoke if a friend offered them a cigarette).

   The research will be fielded for the purpose of assessing FDA's second wave of draft (or "rough-cut") advertisements for its General Market At-Risk Youth Tobacco Prevention Campaign ("The Real Cost") prior to launch. Research results will be used to assess whether rough-cut advertisements provide an understandable and engaging message about the harms of tobacco use without potential unintended adverse or counterproductive effects.

2. **Intended use of information:**
   This study is the last phase of primary formative research that will inform the development of FDA's second wave of advertisements for "The Real Cost" campaign. This study follows a series of focus groups that assessed youth experimenters' perceptions of advertising concepts designed to reduce youth tobacco use.

   The study will consist of showing nine (9) rough-cut campaign advertisements to a sample of the campaign target audience. Copy testing results for each rough-cut advertisement will be assessed individually, as well as compared across all nine (9) tested rough-cut advertisements to answer the following questions:
   - Does the rough-cut advertisement provide an understandable message about the harms of tobacco use?
   - Does the rough-cut advertisement provide an engaging message about the harms of tobacco use?
   - Does the rough-cut advertisement have any potential unintended adverse or counterproductive effects related to beliefs around the harms of tobacco use?

3. **Description of respondents:**
   The study participants will consist of 900 youth aged 13–17 who report having smoked fewer than 100 cigarettes in their lifetime ("experimenters") and 900 youth aged 13–17 who indicate they have never smoked but are open to trying cigarettes in the future ("at-risk non-

[1] "Copy testing" is a marketing term synonymous with "communications check" that involves showing draft versions of TV ads (i.e., "rough-cuts") to a small sample of the target audience to assure understanding of messages and assess any potential unintended consequences as part of the message development and testing phase.

trier"). Each audience will represent a diverse population in terms of age, race, and gender. Each rough-cut advertisement will be viewed by 75 participants from each target group for a total of 150 participant views per advertisement and 675 participants per target group. Additionally, another 225 participants per target group will not view a rough-cut advertisement. The total sample size will be 1,800. Approximately 5,400 participants will be screened in order to obtain a sample size of 1,800.

| | **Ad View Group** | **No Ad View Group** | **Total** |
|---|---|---|---|
| Youth Experimenters | 675 | 225 | 900 |
| Youth At-risk Non-triers | 675 | 225 | 900 |
| **Total Respondents** | | | **1,800** |

**4. Date(s) to be conducted:**

The study is projected to occur between August 4, 2014 and February 1, 2015.[2]

**5. How the information is being collected:**

The information is being collected by a contractor using an online self-administered survey with youth aged 13–17. Qualified participants will be randomly assigned to view one (1) to two (2) rough-cut advertisements or no advertisement.

Participants selected to view advertisements (Ad View Group) will first be provided with three (3) questions about their exposure to tobacco use and past 30 day tobacco use. Following these questions, participants will view a rough-cut advertisement and will then be prompted to complete a questionnaire designed to assess whether the advertisement provides an understandable and engaging message about the harms of tobacco use. If applicable, following completion of the questionnaire, participants will view a second randomly selected advertisement and will then be prompted to complete the same questionnaire provided after viewing the first advertisement.

The rough-cut advertisement will average thirty (30) seconds in length. Following completion of the advertisement questionnaire(s), participants will be provided with general questions about their attitudes and beliefs about the harms of tobacco use as well as additional demographic questions. The questions targeting general attitudes and beliefs about the harms of tobacco use are being collected to assess potential unintended consequences.

Participants selected not to view any advertisements (No Ad View Group) will only be provided with questions about attitudes and beliefs around the harms of tobacco use, followed by additional demographic questions. Participants who do not view any advertisements are primarily being included to measure for unintended consequences.

**6. Confidentiality of respondents:**

[2] Depending on approval dates and recruitment time.

All data will be collected with an assurance that the respondents' responses will remain private to the extent allowable by law.

The assent form will contain a statement that no one will be able to link the respondent's identity to his/her responses, and each participant will only be identified by a tag generated by the online survey operator. Additionally, survey questions will not ask participants to provide identifying information as part of their responses, and no identifying information will be included in the data files delivered by contractors to the agency.

Identifying information will not be included in the reports delivered to the agency. All data received by FDA will remain in a secured area or on a password-protected computer. No data will contain identifying information.

Neither the contractor nor the online survey provider will share personal information regarding research participants with any third party without the participants' permission unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or another legal process.

**7. Amount and justification for any proposed incentive:**

The amount of the incentive as a token of appreciation is $20 eGift card.

As participants often have competing demands for their time, incentives are used to encourage participation in research. The use of incentives treats participants justly and with respect by recognizing, and acknowledging the effort they expend to participate. In this particular research we are asking respondents to provide thought-intensive open-ended feedback on concepts that require a high level of participation. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation.[3]

Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation,[4] as well as provide enough motivation for them to participate in the study rather than another activity. If the incentive is not adequate, participants may agree to participate and then not show up or drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with facility rental and moderator and observer time.[5]

Additionally, this can cause a difficult and lengthy recruitment process that, in turn, can cause delays in launching the research both of which lead to increased costs. Incentives are also necessary to ensure adequate representation among harder-to-recruit populations such as youth, low socio-economic groups and high-risk populations (current or former tobacco users and those susceptible to tobacco use).[6]

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[3] Halpern, SD., Karlawish, JH., Casarett, D., Berlin, JA., Asch, DA. Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine.* 2004; 164(7), 80l-803.

[4] Russell, ML., Moralejo, DG., Burgess, ED. Paying research subjects: Participants' perspectives. *Journal of Medical Ethics.* 2000;26(2), 126-130.

[5] Morgan, DL, Scannell, AU..Planning Focus Groups. Thousand Oaks, CA: Sage, 1998.

[6] Groth, SW. Honorarium or coercion: use of incentives for participants in clinical research. *Journal of the New York State Nurses Association*. 2010.

In the context of this study, the target population is considered a harder-to-recruit population on multiple accounts (youth aged 13–17 who are also at-risk of or currently experimenting with tobacco use). The study also requires respondents to comment on an activity that is a sensitive subject matter and could cause them to be reluctant to participate. Thus, it is critical to provide adequate incentives to encourage and retain participation among the limited number of potential youth respondents.

**8. Questions of a sensitive nature:**

Some studies require the inclusion of people who match selected characteristics of the target audience that the FDA is trying to reach. This may require asking questions about race/ethnicity, income, education, health behaviors and/or health status on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that the FDA speaks with the kinds of people for whom its messages are intended. Respondents are assured that the information is voluntary and will be treated as private to the extent allowable by law. All information on race/ethnicity will fully comply with the standards of OMB Statistical Policy Directive No. 15, October 1997 (http://www.whitehouse.gov/omb/fedreg/1997standards.html).

FDA tobacco use communications may be concerned with the prevention of premature mortality from heart disease and oral and respiratory cancers, and some projects may involve asking questions about (or discussing) how one perceives his/her own personal risk for serious illness. This information is needed to gain a better understanding of the target audience so that the messages, strategies and materials designed will be appropriate and sensitive. Questions of this nature, while not as personal as those about sexual behavior or religious beliefs, for instance, still require some sensitivity in how they are worded and approached. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation.

FDA tobacco communications may also be concerned with discouraging tobacco use by youth before they start. The FDA acknowledges the sensitivity of questions about the purchase and use of tobacco, which is illegal for minors in most states.

Raw data from data collections that include sensitive information (e.g., screening questionnaires and audiotapes) are not retained once the data have been extracted and aggregated. The information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

**9. Description of statistical methods:**

This research relies on quantitative methods and will use convenience samples rather than probability samples. This research is not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

Youth participants will be directly identified using standard mall intercept recruitment procedures that employ screening questions about age; current, past, and intended tobacco use; race and ethnicity; and gender. Recruitment will continue until a representative sample of the required number of participants for each category (900 youth cigarette experimenters and 900 youth at-risk non-triers) is obtained.

**BURDEN HOUR COMPUTATION** *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

| Type/Category of Respondent | No. of Respondents | Participation Time (minutes) | Burden (hours) |
|---|---|---|---|
| Youth Screening Questionnaire and Assent | 5,400 | 5 | 450 |
| Parental Opt-out | 5,400 | 5 | 450 |
| Youth At-risk Non-triers Copy Testing Participation | 900 | 10 | 150 |
| Youth Experimenters Copy Testing Participation | 900 | 10 | 150 |
| **Total** | **12,600** | | **1,200** |

**REQUESTED APPROVAL DATE:** June 2, 2014

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