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

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TITLE OF INFORMATION COLLECTION: Online Qualitative Study of Youth Reactions to Strategic Concepts Designed to Prevent Youth Tobacco Use; 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 0910-0674 to conduct online qualitative research with youth aged 12–17 who have never tried tobacco products (i.e., non-triers) to understand their reactions to different youth tobacco use prevention campaign messaging strategies.

2. **Intended use of information:**
   The information will inform CTP's efforts to develop and implement public education campaign messaging related to preventing tobacco use initiation among youth aged 12–17, with a focus on those most susceptible to use.

   The project is designed to explore reactions to various strategic concepts intended to prevent youth tobacco use. The online qualitative research will consist of exposing youth non-triers to up to eight strategic messaging approaches and having them "blog" their responses. An online moderator will prompt youth to answer questions regarding understanding, relevance, appeal, and motivation of the concepts shared. The results will be ultimately converging on the most promising strategic concepts that will serve as the foundation for creative concept development.

3. **Description of respondents:**
   The study participants will consist of 60 youth aged 12–17 who have never tried tobacco products (i.e., non-triers) and who represent a diverse population in terms of age, race, and gender. To obtain the target number of participants for the study, 180 youth respondents will be contacted through a screening and consent process. Respondents will be separated into four online discussion groups of 15 respondents each based on their age (12-to-14 year olds and 15-to-17 year olds) and their self-reported "openness" to trying tobacco in the future (i.e., youth who respond during screening that they are "very likely or somewhat likely to try tobacco products within the next year" will be considered "open to tobacco use"; youth who respond that they are "very unlikely or unlikely to try tobacco products within the next year" will be considered "not open to tobacco use"). This segmentation will help assess potential differences in messaging strategies targeting youth who are open to tobacco use versus those who are not open to tobacco use.

4. **Date(s) to be Conducted:**
   The discussion groups will begin 8/20/2013 and will be completed by 8/22/2013[1]. The study will be conducted online.

[1] Depending on approval dates and recruitment time.

5. **How the Information is being collected:**
   The information is primarily being collected by a contractor who will host an online discussion forum with youth aged 12–17 over a period of three days. The online qualitative research tasks will include direct responses to strategic concept ideas, short writing assignments, and moderated discussions to obtain insights on key research questions. No group discussions will occur in real time; instead, participants will log in at their convenience at least twice a day but no more than four times a day for no less than 10 minutes per session to complete various individual activities as well as respond to posts on a moderated online group discussion. All activities, whether individual or group, are estimated to take 120 minutes and will have set time parameters to ensure participants do not exceed 120 minutes total during the study period. Finally, all participants will use an invented screen name that is not personally identifying to protect their identity.

6. **Confidentiality of Respondents:**
   There will be four online discussion forums of 15 youth each, for a total of 60 respondents representing a diverse population.

   All data will be collected with an assurance that the respondents' responses will remain private to the extent allowable by law. The assent and consent forms will contain a statement that no one will be able to link the respondent’s identity to his/her responses, and each participant will access the online forums using an invented screen name to protect his/her identity. Additionally, discussion forum questions will not ask participants to provide other identifying information as part of their responses, and no identifying information will be included in the data files delivered by contractors to the agency.

   Participant responses to discussion forum activities will be treated as discussion transcripts to assist in campaign development and to provide FDA with a written record of the sessions. Identifying information will not be included in the transcripts or reports delivered to the agency. All data received by FDA will remain in a secured area. No data will contain identifying information.

   Neither the contractor nor the recruitment facilities will share personal information regarding panel members with any third party without the participant’s permission unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or another legal process.

   A group leader will not know any information that may identify participants outside of the online forum but will monitor all of the information and posts on this website. This person will work with the research team and will make sure that no one shares any private, personally identifiable, or inappropriate information. Posts considered inappropriate will be removed from the forum by the group leader. All information will be stored on a password-protected computer.

7. **Amount and justification for any proposed incentive**
   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 written 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[2].

Incentives must be high enough to equalize the burden placed on respondents in respect to their time and cost of participation[3], 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[4]. 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 cost. 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).[5]

In the context of this study, the target population is considered a harder-to-recruit population on multiple accounts (youth aged 12-17 who are also susceptible to 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. Additionally, the nature of the study requires retaining participants online over a period of three days, during which participants must repeatedly log in to the site and complete different tasks. Keeping this level of engagement from a distance over a period of time is much more difficult than retaining participants for a one-time, finite research task. Thus, it is critical to provide adequate incentives to encourage and retain participation among the limited number of potential youth respondents.

Based on similar online groups conducted by our research partner in the past year, the requested incentive for this study is $20 per day for up to 3 days. The incentive will be provided to the parent or guardian of each youth participant at the conclusion of their participation.

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 OMB standards.

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

[2] Halpern, S.D., Karlawish, J.H., Casarett, D., Berlin, J.A., & Asch, D.A. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. Archives of Internal Medicine, 164(7), 80l-803.

[3] Russell, M.L., Moralejo, D.G., & Burgess, E.D. (2000). Paying research subjects: Participants' perspectives. Journal of Medical Ethics, 26(2), 126-130.

[4] Morgan, D.L. and Scannell, A.U.. Planning Focus Groups. Thousand Oaks, CA: Sage, 1998.

[5] Groth, S.W. (2010). Honorarium or coercion: use of incentives for participants in clinical research. Journal of the New York State Nurses Association.

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. In face-to-face data collections, questions of this kind are generally asked later in the interview or group discussion, when respondents are more comfortable with the interview situation and are more at ease with the interviewer/moderator. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation. The interviewer/moderator makes it clear that they do not have to respond to any question that makes them uncomfortable.

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. Because questions are being asked of youth aged 12–17, interviews will be conducted by moderators specifically trained for interactions with youth.

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 qualitative methods and is not intended to yield results that are statistically projectable. Participants will be identified using standard telephone 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 (15 non-trier youth aged 12–14 who are open to tobacco use, 15 non-trier youth aged 15–17 who are open to tobacco use, 15 non-trier youth aged 12–14 not open to tobacco use, 15 non-trier youth aged 15–17 not open to tobacco use) 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)
12–14 year old Non-Triers: Youth/Parent Screener	90	5	7.5
12–14 year old Non-Triers: Not Open to Use	15	120	30
12–14 year old Non-Triers: Open	15	120	30

to Use			
15–17 year old Non-Triers: Youth/Parent Screener	90	5	7.5
15–17 year old Non-Triers: Not Open to Use	15	120	30
15–17 year old Non-Triers: Open to Use	15	120	30
Total	**180**		**135**

REQUESTED APPROVAL DATE: August 9, 2013

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