DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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To: Office of Management and Budget (OMB)

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Subject: Generic Sub-study, **Alternative Tobacco Products Study** under "A Generic Submission for Theory Development and Validation (NCI)," (OMB No. 0925-0645, Expiry Date 12/31/2014)

Background/ Need and Use for Information

The National Cancer Institute's (NCI) Behavioral Research Program (BRP) is within the Division of Cancer Control and Population Sciences (DCCPS). The goal of BRP is to increase the breadth, depth, and quality of behavioral research in cancer prevention and control. BRP conducts varying programs of formative research to develop and validate cancer-related behavioral theories. This project will serve to examine health perceptions in the context of smokeless tobacco, which is an emerging scientific priority not only in DCCPS, but also in the Food and Drug Administration (FDA)'s Center for Tobacco Products. This NCI office is requesting that OMB review this sub-study, which describes a voluntary, low-burden, non-controversial, formative behavioral research project related to theory development and validation. Data collection for this project is authorized under 42 USC *§* 285 and 285a-1 (Section 410 and 412 of the Public Health Service Act).

This proposed sub-study request involves formative research to refine and preliminarily validate a theory regarding implicit claims associated with lower risk and reduced addictiveness, and will enable researchers to identify stimuli to be used in future rigorous empirical research. Companies producing and marketing alternative tobacco products such as Snus (a type of smokeless tobacco), have been prohibited from making claims that these products pose less risk than traditional tobacco products such as cigarettes. Additional prohibitions specify that these products should not be advertised as being less addictive than cigarettes. However, implicit claims of addictiveness and risk are difficult to assess. The extent to which claims of reduced addictiveness or harm can be conveyed implicitly is an empirical question. However, a theoretically rich social psychological literature on implicit cognition and emotional appeals suggests that such crafting such implicit claims is possible. This mixed methods study aims to

identify the types of advertisements that are most likely to convey such claims, by using traditional eye-tracking methodology to determine which images may be associated with participant perceptions of reduced addictiveness and harm. Once such advertisements are identified, these can be used as stimuli in more rigorous empirical examination of theories concerning implicit claims associated with lower risk and reduced addictiveness.

This research will help to refine a theory concerning implicit claims of reduced harm and addictiveness, leading to further theory validation by identifying stimuli to use in future rigorous empirical research. Preliminary results from a pilot study of six males (three 18-29 years of age; three 30-50 years of age) and three females (18-29 years of age) revealed that the Snus product in the Emissions advertisement (**Attachment C**) was the one that individuals were most willing to try, and perceived the least harmful and least addictive. For this same advertisement, eye tracking results showed that the more harmful participants rated it, the less total fixation duration on the graphic ($r=-.849$, $p=.016$), and the more time participants spent fixated on the text, the more harmful they rated the Snus product in that advertisement. Interesting eye tracking results also emerged for the other advertisements and differences emerged in black vs. white backgrounds of the warning labels. However, due to the low sample size, the variability of the results limits our interpretation and more data must be collected. Focus group discussion themes were extracted and include topics such as mouth cancer (e.g. severity of cancer, mention of the warning label, mouth cancer as compared to lung cancer), use of Snus in places where one can't smoke, flavoring, packaging, no need to spit, and potential harm to children. Young males were the only group that had heard of and used snus. Prior research has found that males are more likely to use smokeless tobacco than females and are particularly targeted by snus advertising (see last page for References). For this project, recruitment will target young males.

This data will be collected in the Cognitive Testing Laboratory, within the Office of Communications and Education (OCE), at NCI. Recruitment and incentives for the project will be funded through the Smokefree contract with Mathews Media Group (MMG), Inc., which supports (among other types of projects) new data collections. Labor for data collection will also be provided through this contract.

Participants, Methodology, and Research Instrument

A convenience sample ($N = 48$) of young adult males (age 18-29 years) will be recruited by the contractor through their database of potential respondents, newspaper advertisements, postings on online patient database portals (e.g., Clinical Connection), local flyers in Rockville area establishments, and through social media outreach (**Attachment F**). An estimated 144 potential participants will be screened (**Attachment G)** in order to achieve a mix of ages, education statuses, and race/ethnicities, and to screen out participants who cannot be calibrated in the eye tracker (e.g., those with trifocal contact lenses).

First, participants will be consented (**Attachment A**) and fill out a baseline questionnaire with items about Snus and demographics (**Attachments B-** word document and web based screen shots). Participants will view advertisements in counterbalanced order (**Attachment C**), and eye movements will be monitored during the viewing process. Participants will answer a series of questions about the advertisements, including those that assess perceptions of reduced harm and addictiveness (**Attachment D-** word document and web based screen shots). Finally, participants

will either engage in a discussion with a small focus group or a brief one-on-one interview with the moderator; the protocol for both of these scenarios can be found in **Attachments E1** and **E2.**

The 12 participants recruited for the focus groups will have a little down time during the first part of the study (eye tracking). This time is kept at a minimum because they will be able to complete the baseline questionnaire during that time. This saves these participants from having to return to the lab at a different date/time for the focus group.

The study will be completed in the Office of Market Research and Evaluation Lab, Office of Communications and Education, NCI. Participation will take approximately 1-2 hours (based on pretests described above). Trained research staff will facilitate the session for each participant. Participants will be reminded of their appointment via phone **(Attachment F)** and email **(Attachment F).** Participants will be consented for the study **(Attachments A1 and A2).**

The Tobii Eye Tracker will record eye movements while the participants read the consent form. Eye tracking is an unobtrusive way to gather information about the online attentional deployment of the participant. The advantages of eye tracking over other means of assessing attention is 1) that the measure of gaze is taken while the participant is engaged in the task (i.e., online), rather than just after completing the task, and 2) eye tracking is a more direct measure of attention compared to other measures (e.g., dot probe tasks).

Participants will be placed into one of two groups: 1) Eye tracking and focus groups, with a $75 incentive for participation; 2) Eye tracking and Individual Interview, with a $50 incentive for participation. All participants will be debriefed following their participation (**Attachment H).** The goal is to include 12 participants in group one (Eye tracking and focus groups) and 36 in group two (Eye tracking and Interview).

Analyses will involve examining correlations among advertisement features, questionnaire responses, and eye tracking information (e.g., scanning vs. systematic engagement). Findings will be disseminated to relevant audiences –health psychologists/ public health researchers who capitalize on basic psychological science advances to understand real world phenomena such as clinical trial informed consent.

Other Considerations

Personally identifying information (PII) will be collected by the contractor during the recruitment process; specifically, name, address, and telephone number will be collected in order to facilitate recruitment and reminders. PII will be stored on a password protected file on a password protected computer in a locked office. PII will be destroyed after completion of the study.

The NIH Office of Human Subjects Research Protections determined this research was Exempt from IRB review under 45 CFR 46.101(b)(2) for the interview and survey procedures for this project (**Attachment I**).

Burden

Approximately 144 potential participants will be asked to complete a 5 minute screener in an attempt to identify a total of 48 participants who will complete the study, which has an anticipated length of no more than two hours for group one (n=12) and one hour for group two (n=36); thus, the total hour burden is 72 (See table below). To date, a total of 684 burden hours have been used of the 6,000 hours that were requested. Estimated cost to the Federal Government is $4,720; for staff (estimated based on 3 FTE hours per week for 6 weeks), $2,020 for recruitment, and $3,000 for survey incentives.

Estimates of Burden Hours						
Category of Participants	Group	Instrument	Number of Participants	Frequency of Response	Average Time Per Response (Hours)	Total Hour Burden
Individuals	Group 1: Eye Tracking + Focus Group	Screener (Attachment G)	36	1	05/60	3
	Group 1: Eye Tracking + Focus Group	Questionnaire (Attachments B, D and E1)	12	1	2	24
	Group 2: Eye Tracking + Individual Interview	Screener (Attachment G)	108	1	05/60	9
	Group 2: Eye Tracking + Individual Interview	Questionnaire (Attachments B, D and E2)	36	1	1	36
Total						72

List of Attachments

A: Consent forms –
- Group 1: Eye Tracking and Focus Group, and
- Group 2: Eye Tracking and Individual Interview

B: Baseline Questionnaire (Word and PDF Versions)

C: Snus Advertisements

D: Eye Tracking Questionnaire (Word and PDF Versions)

E: Moderator's Guide
- E1: Eye Tracking and Focus Group
- E2: Eye Tracking and Individual Interview

F: Recruitment Materials – Advertisements, Phone Reminder Scripts, Email Reminders, and Directions to Study Location

G: Screeners
- Group 1: Eye Tracking and Focus Group, and
- Group 2: Eye Tracking and Individual Interview

H: Debriefing Information

I. OHSRP Exemption

References

Nelson et al., 2006 Am J. Public Health, 96(5), 897-905; Trends in Smokeless Tobacco Use Among Adults and Adolescents in the United States

Mejia & Ling, 2010, Am. J. Public Health, 100(1), 78-87; Tobacco Industry Consumer Research on Smokeless Tobacco Users and Product Development

Choi et al., 1995; Tobacco Control, 4(suppl1): S57-63, Does advertising promote smokeless tobacco use among adolescent boys? Evidence from California