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Application Information

Full Study Title: Exploring Reactions to Health Warnings on Waterpipe Tobacco Ads
Short Title: Reactions to Warnings on Hookah Ads
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Summary:

Waterpipe tobacco smoking (WTS) is increasing in the U.S. among young adults exposing them to its many health risks. This increase is partly to due to waterpipe tobacco product and social allure ads that manufacturers, waterpipe bars and cafés use to portray WTS as a fun, social activity while masking its harmful effects. The positive feelings these ads likely elicit may reduce worry and perceived health risks and increase the appeal of WTS. Ad appeal may be curbed by placing health warnings. Thus, we address the extent to which the addition of text only and text + graphic (i.e., pictorial) health warnings influence reactions to waterpipe tobacco ads as well as risk appraisals, attitudes toward WTS, and intention to engage in WTS.

Purpose of the Project:

We propose to explore the efficacy of varied health warnings (text only vs. text plus graphic warnings) to decrease ad appeal on desire to engage in WTS and examine potential cognitive and emotional mediators, such as perceived risks of WTS and attitudes toward WTS.

Study Design:

This research will be done in three phases involving young adults, ages 18-34, susceptible to WTS (i.e., nonusers who do not oppose trying WTS)[27] or engage in WTS at least monthly. Phase 1 concerns selecting text and graphic health warnings that can strongly influence beliefs and feelings about personal risk and intention to quit or try WTS. We will create, refine, and select text and graphic health warnings in four domains: 1) longer-term health effects, 2) shorter-term health effects, 3) addictiveness, and 4) types and levels of toxicant exposures. We will also select the most appealing waterpipe product and social allure ads themes that entice young adults to engage in WTS. The top two text and graphic health warnings in each domain and the top two product and social allure ads within each theme will be used for Phase 2. In Phase 2, using the online consumer crowdsourcing platform Turkprime[28], susceptible nonsmokers and smokers (N=1000 per group) will be randomized to review ads with: 1) no health warnings, 2) text only health warnings, or 3) text + graphic health warnings. Nested within Arms 2 and 3 is health warning domain and ad theme. Reactions to ads will include ability to grab attention, cognitive and affective beliefs and attitudes toward each ad and ad appeal to engage in WTS. Main outcomes will include perceived risk and worry about harms (i.e., risk appraisal), attitudes

toward WTS, and intention to try or quit WTS. At a two-week follow-up, we will reassess these main outcomes, WTS, and recall of ad content. In Phase 3, using a new sample of susceptible nonsmokers and waterpipe tobacco smokers (N=100 per group), we will conduct an eye-tracking laboratory study to examine whether warnings evoke changes in attention that mediate changes in risk attitudes. The *primary aims* are to:

AIM 1 (Phase 1): Develop, pilot test, and select text and graphic health warnings in four domains (i.e., long/short-term health effects, addiction, type and level of toxicant exposures) that most dissuade WTS as well as select waterpipe tobacco product ads (themes of flavored tobacco, waterpipe apparatus) and social allure ads (four themes of eroticism, exoticism, social acceptance, and occasion appropriate) that most entice WTS.

AIM 2 (**Phase 2**): Using a RCT, examine how waterpipe tobacco product and social allure ads with or without text/graphic health warnings influence: 1) reactions to ads (e.g., beliefs and attitudes, ad appeal to engage in WTS); and 2) risk appraisals, cognitive and affective beliefs and attitudes about WTS, and intention to quit or try WTS. We explore how domain of health warning, ad theme, and population influence these outcomes.

AIM 3 (Phase 2): Explore whether health warnings' effects on risk appraisals, cognitive and affective beliefs and attitudes about WTS, and intentions to quit or try WTS are mediated by *reactions to ads.*

AIM 4 (Phase 3): Using eye-tracking measures, examine how attentional outcomes mediate reactions to ads (e.g., beliefs and attitudes, ad appeal to engage in WTS) with and without health warnings.

Phase 1 (In-Person Panel) Activities:

We will recruit two panels of 10 waterpipe tobacco smokers and 10 susceptible nonsmokers (5 men, 20% minority for both), respectively. Panels will help refine health warnings and identify product and social allure ads to be tested further. Panel input should enhance relevance and impact of warnings. Panel members will be recruited from central North Carolina using varied approaches (newspapers, flyers, Facebook) during the first two months of the Year 1. They will be asked to meet every two weeks for up to four sessions, led by Drs. Lipkus (PI) and Griffiths (Co-I), lasting about one hour. Participants will receive $50/session. We will also recruit 5-10 more members to each panel as back-up; they will attend a session if, upon reminder calls, original panel members cannot attend a session or drop-out.

After reviewing the purpose of the panel and learning about harms of WTS, the panels will engage in two main guided activities:

- *Review product and social allure ads*: Each panel will select through discussion four ads that exemplify best product and social allure themes (6 total, see B.2., D.3.3). Ads will include those we piloted and from WTS entities (bars, cafés, manufacturers/distributers) accessible via social media, websites, and distribution sources (e.g., yelp.com, Divine Hookah, iHookah). Conversations will also cover *placement* of warnings.

- *Help create, refine and select health warnings*. We will introduce WTS health warnings from prior studies including our WTS harm messages. Cigarette text and graphic warnings will be shown that could be adapted to WTS. Warnings will be grouped into four domains with illustrations. Using a protocol to evaluate health warnings, the panel will discuss strengths and weaknesses of each text and graphic warning (e.g., credibility, effects of perceived harm, desire to quit), what to keep and change (e.g., wording, content, graphics). Their goal will be to select the best four examples of persuasive text and graphic warnings for each health domain (16 examples total for text and 16 examples for graphic). As with the FDA's proposed use of graphic cigarettes warnings, WTS warnings will cover at least 20% of ad space.

All panel sessions will be recorded which will be explained to participants prior to obtaining their consent to participate in the panel sessions. Participants will be asked not to use names or identifiers during discussions but if these do occur during the panel sessions, the identifying information will be stripped from the recordings. The recordings will only be reviewed by team members, and once the necessary information regarding the ads is extracted, the recordings will be destroyed.

Phase 1 (Pilot) Procedures:

Pilot testing of warnings. Using Turkprime, we will pilot test warnings online using 400 waterpipe tobacco smokers and 400 susceptible nonsmokers ($2.00 payments). *The text and graphic warnings will be pilot tested separately* (*N* = 200 for each from each population). As a between-subjects design, participants will be randomized to one of the four warning domains and then asked to review – either text or graphic – the four warnings within the domain chosen by each panel counterbalanced in a Latin-square design. As suggested by Hammond and Reid [71], each warning will be rated on such outcomes as: grabbing attention[96], clarity, credibility[97], relevance, fear appeal (e.g., not fearful at all/fearful)[98], graphicity[99], extent warning influenced cognitions and affective beliefs (e.g., harmful/beneficial, safe/unsafe, nice/nasty)100and global attitude about warning (negative/positive)[99] and efficacy to deter WTS (average of 3-item measure, e.g., "Overall, how effective is the warning?" $\alpha > .90$)[97]. They will rate the extent each warning represents each health domain (1=not at all to 7= a great deal). The main outcome among both populations is warning efficacy to deter WTS, a rating shown to influence quit intentions and cessation[101]. Responses will be averaged for each warning and within each domain. *The top two text and graphic warnings within each domain (8 for text and 8 for graphic total) with the highest mean score on warning efficacy by smoking status (smoker or susceptible) will be chosen for testing in Phase 2.* All text and graphic warnings will be used as stimuli in Phase 3.

Pilot testing of ads. Using Turkprime, we will pilot test ads online using 400 waterpipe tobacco smokers as well as 400 susceptible nonusers ($2.00 payment). *The social allure and product ads will be tested separately* (*N* = 200 for each). As a between-subjects design, participants will be randomized to one of the four social allure ad themes and asked to review the top four ads per

theme selected by each panel. Ads will be counterbalanced in a Latin-square design. For waterpipe product ads, participants will be randomized to review either the four tobacco- or four waterpipe apparatus-themed ads counterbalanced in a Latin-square design. Reactions to the social allure and waterpipe product ads will mirror those of the warnings. These will include: extent ad grabbed attention[96], credibility, relevance, fear appeal, extent ad influenced cognitive and affective beliefs about WTS[100], global attitude about ad[99], effort reviewing the ad, and extent ad *enticed* them to want to smoke (average of 2 items about ad making WTS more appealing and making them want to smoke 1=none at all, to 7=a great deal). They will rate extent each ad captured the social allure/product themes. Responses will be averaged for each ad within theme. *The top two ads within each social allure theme (8 total), and the top two within each product ad theme (4 total), with the highest mean score on enticing them to "want to smoke" waterpipe will be chosen for Phase 2.* All 24 ads will be used as stimuli for Phase 3.

Phase 2 Procedures:

Tests of ads with or without health warnings. Using Turkprime, we will recruit online 1000 waterpipe tobacco smokers and 1000 susceptible nonsmokers ($2.00 payment). After screening and collecting baseline demographic and tobacco use data (e.g., cigarettes), participants will be stratified and randomized to review ads with or without health warnings. After obtaining participants' reactions to ads, we will assess key study constructs. All participants will complete a two-week follow-up.

Interventions. Participants will be stratified by sex and use of other tobacco products (no/yes) and then randomized in a 1:2:2 ratio to one of three arms: 1) no health warnings (i.e., review ads only – control); 2) text health warnings only; or 3) text + graphic health warnings. Nested within Arm 2 and 3 will be both ad themes (six total) and health warning domains (four total). Each arm is discussed below.

- *Control arm (*N = 200*)*. Participants will be randomized with equal probability to one of the six ad themes (2 from product, 4 from social allure). They will view in counterbalanced order the two ads chosen for that theme from Phase 1 – no order effects are expected. They will not receive any warnings. (N ≈ 33 per cell).
- *Text only health warnings (*N = 400*)*. Ad theme selection will occur as with the control arm. Nested also as a between-subjects factor will be warning domain. Participants will see two text warnings from the same domain randomly assigned to the two ads within the same theme with ad order counterbalanced. Hence, this arm is primarily a 4 (warning domain: long-/short-term health effects, addiction, toxins) X 6 (ad theme: eroticism, exoticism, social acceptance, occasion appropriate, (flavored) tobacco, waterpipe apparatus) X 2 (ad order: A1A2 vs A2A1) between-subjects factorial design. Expecting no order effects, there are 24 main cells (N ≈ 32 per cell combining populations).
- *Text plus graphic health warnings (*N = 400*)*. This arm is procedurally identical to the text only arm. The exception is that the two graphic warnings would be randomly added to the text warning in the same domain; thus, graphs are matched to the text warnings by health domain. (N ≈ 32 per cell combining populations).

Post intervention assessments. We will assess participants' reactions to each ad. *We will not assess reactions to warnings specifically; doing so may unduly bring attention to them.* Reactions to warnings will have been obtained from Phase 1 and 3. After responding to the last ad, and aligned with the Message Impact Framework[72], we will assess participants' knowledge of harms[102], risk appraisals16*,* cognitive and affective beliefs and attitudes about WTS100, and intentions to quit/willingness to try WTS (4-item scale)[14]. We've used versions of these measures with αs > .70.

Two-week follow-up. Using Turkprime, all participants will be asked to take an online survey two weeks later ($2.00 payment). As *secondary aims*, the goal of the follow-up is to assess WTS and recall of ad content, both reactions to warnings[72], and sustainability of earlier effects. A two-week time frame aligns with other studies on recall of warning labels[57]. Participants will be asked first about their risk appraisals, cognitive and affective beliefs and attitudes about WTS, intention to quit/willingness to try WTS, and among smokers, frequency of WTS during the last two weeks. If a participant has not quit, they will be asked why. If a susceptible engaged in WTS, we will ask why. We will ask all if they saw and responded to WTS ads during the last two weeks (if yes, where), attended social events involving WTS or bought any WTS products – all no/yes. All will be asked to recall content of the two ads they viewed earlier. Analyses of recall will follow the steps by Strasser et al. on cigarette warnings[103]. Based on an MTurk study that used similar methods as proposed[104], we expect 60% - 70% of participants will complete follow-up. We predict stronger sustainability of earlier effects and a higher percent of recall accuracy for warnings in the text + graphic arm than text only arm.

Phase 3 Procedures:

Participants will be stratified by sex and use of other tobacco products (no/yes) and then randomized in a 1:2:2 ratio to the three arms as Phase 2 (control, ads with text warnings, ads with text + graphic warnings). Tasks will be presented (and eye position sampled) using a Tobii T60XL eye tracker, which uses an unobtrusive infrared camera system to sample gaze position at 60 Hz (and with resolution <1 degree of visual angle) while allowing participants free head movement. Each image will be displayed for a fixed time of 10 seconds, during which participants move their head and eyes naturally while looking at the image. The images will consist of the 24 ads, 16 text and 16 graphic warnings from Phase 1. Details of each arm follows.

- *Control arm*: Participants will view the 24 ads from Phase 1 twice in random order without warnings. Further, 16 control non-tobacco ads matched for graphical content, presence of text, people, and other factors will be randomly distributed among these ads.
- *Text only*: Participants will view at random the 24 ads twice. Each ad will have a different text warning chosen at random from the 16 from Phase 1 with the caveat that each text warning would be seen three times. The 16 control ads will have text disclaimers to control for physical features of the ads.
- *Text + graphic*: This arm is identical to the text only arm except that a graphic from Phase 1 will be added to a text warning. Thus, each ad will be seen twice; the text +

graphic warnings will be seen three times. The 16 control ads will have text disclaimers and logos or other images to control for physical features of ads.

Rationale and Justification:

In the United States, WTS among young adults is not trivial. For example, during 2013-2014 among 18-24-year-olds prevalence of daily, weekly, and usually monthly use was about 18% nationally[17,18]. Many young adults face health risks due to WTS. The amount of smoke inhaled by a single one-hour waterpipe session lasting 30-60 minutes can equal that produced by > 100 cigarettes[32]. Waterpipe smoke contains heavy metals (arsenic, lead), carcinogenic polycyclic aromatic hydrocarbons[33], pulmonary disease-causing volatile aldehydes[34], carbon monoxide[35-38], and nicotine[38,39]. Inhaling these toxins is likely why WTS is associated with cancers, poor pulmonary function, and heart disease[29,40-44]. WTS is also addictive[45], with data suggesting nicotine dependence occurs faster than from cigarettes[46]. *WTS is not safe*.

Waterpipe product manufacturers and waterpipe cafés often fail to mention harms of WTS[22,23]. Rather, they entice WTS in young adults via appealing *product* (e.g., flavored tobacco, aesthetically pleasing waterpipes) and *social allure* ads portraying WTS as a pleasant, relaxing and sociable activity. Social allure ads capture themes of eroticism, exoticism, social acceptance, and holiday gatherings[20] to persuade the audience to partake in WTS. This strategy is working based on the growing use and spread of waterpipe cafés.[47-50] Waterpipe product and social allure ads may mislead young adults to believe that WTS is safe, a common belief that can encourage WTS in this age group[19,24].

Inclusion Criteria:

Eligible participants will be young adults ages 18 to 34 years old who are susceptible to, or who are current hookah tobacco smokers (defined as using hookah tobacco at least once in the past month and now using hookah tobacco on at least a monthly basis). Participants in Phases 1 and 2 must have Internet access and a TurkPrime account.

Exclusion Criteria:

Study exclusion criteria include people who are younger than 18 and older than 34, those who are not susceptible to WTS or who are not current hookah smokers, those who do not have a TurkPrime account who are thus unable to complete assessments (for Phases 1 and 2), and those who are unable to complete the entirety of the study in English.

Recruitment & Enrollment:

Individuals in Phase 1 and 2 will be recruited online using Turkprime[28], a research platform that supports behavioral sciences data collection through the Internet crowdsourcing platform Amazon Mechanical Turk (MTurk), and uses MTurk workers. MTurk workers, are individuals from the public who volunteer to participate in online studies with payment. Overall, Turkprime enhances the efficiency of implementation of experimental tasks that are difficult to conduct with MTurk (e.g., ability to conduct prospective studies). The investigative team will follow all the conditions required to use this platform for data collection. For example, the research team

will post key words and title for the various phases of the study, indicate amount of time needed to complete study tasks, and amount of payment. Those interested will then be linked to the study consent form and study materials.

We will obtain active informed consent online, with the approval of the Duke University Medical Center Institutional Review Board (DUMC IRB). The online consent will inform about the research, including confidentiality, voluntary nature of participation, and potential risks and benefits. It will also emphasize that no personally identifying information will be available to, or collected by, the investigators conducting this research. The online consent form will contain contact information for the DUMC IRB if participants have questions about the study or their rights as a research participant or experience any issues or problems participating in the study (see "Data Safety and Monitoring" for additional details). The voluntary and confidential nature of the research will be emphasized again at the beginning of the study surveys. Note that all studies using this platform to study waterpipe tobacco under Dr. Lipkus as the PI have been designated by the DUMC IRB as exempt.

During Phase 1, we will create two 10-member panels, one for smokers and one for susceptible nonsmokers, as well as a backup panel of 5 to 10 members for each. Phase 2 will involve a sample of 1000 waterpipe tobacco smokers and 1000 susceptible nonsmokers who match the study eligibility criteria. For Phase 3, 100 waterpipe tobacco smokers and 100 susceptible nonsmokers ages 18-34 will be recruited from the subject pools managed by the Social Science Research Institute and Duke's Department of Psychology and Neuroscience. Information about the study will be made available to the subject pools. Individuals who express interest will be asked to contact the study project coordinator. In the event we cannot readily obtain eligible study participants from these subject pools, we will advertise the study in central North Carolina using newspaper, flyers, and social media outlets (e.g., Facebook). In person written consent will be obtained for Phase 3. Participants who will form the first advisory panels will be recruited through newspapers in Central North Carolina, Craigslist, advertisements in college newspapers and through social media. They will be asked to review and sign a written consent form, of which they will receive a copy, during the first panel visit at the Duke University School of Nursing. The consent form will emphasize the basic elements described above (e.g., confidentiality, benefits, risks, etc.).

Setting:

Study procedures will take place at Duke University.

Multicenter:

No

Total Participant Accrual:

3,000

Duration of Accrual:

6 months

Duration of Study:

16 months

Sample Size (power calculations) and statistical considerations:

Power calculations were conducted on factorial MANOVAs for H2A and H2B, and general linear models for H3 (mediation). There are no established programs to calculate required sample size for multiple mediations; however, general linear models are the core procedures for multiple mediations. As stated, the factorial design is incomplete; to be conservative, this power analysis was based on a complete 3 (study arms) x 4 (health domains) x 6 (ad themes) X 2 (populations) design. Using G*Power[109] the required total *N* for detecting an effect size (small: $f = 0.10$ or $f2 = 0.02$; medium: $f = 0.25$ or $f2 = 0.15$; large: $f = 0.40$ or $f2 = 0.35$) with 90% power, two-tailed, with $\alpha = .01$ for all main and interaction effects is 3934 for small, 657 for medium, and 289 for large effects. We are well-powered to detect moderate effect sizes.

We will use 90% power at .01 level of significance (two-tailed) for univariate tests and contrasts. Possible covariates obtained within the survey will include: race, sex, education, use of other tobacco products and among smokers, WTS frequency and level of addiction to WTS. Missing data will multiply imputed[105] as appropriate after checking missing randomness106. For H2A and H2B, factorial MANOVAs will be conducted using SAS Proc GLM for all outcomes simultaneously. For H2A, if the omnibus multivariate test is significant at a .05 level, rather than .01, for the primary outcomes (risk appraisals, beliefs/feelings about WTS, global attitude about WTS, and intention to quit/willingness to try WTS), we will perform post-hoc univariate tests for each outcome at a .01 level for comparisons among: (a) ads without health warnings (control arm), with text warning only, and with both text + graphic health warnings; (b) four health warning domains; (c) six ad themes; d) two study populations; and interactions of a-d. Noteworthy, the interactions will be incomplete due to lack of health warnings in the control arm. Thus, Type IV sum of squares will be used to address empty cells. For H2B, the same statistical methods will be conducted as with H2A, using reactions to ads as the main outcomes. For H3, we have several mediators (reactions to ads). We will use the SAS Macro by Preacher and Hayes[107] to test multiple mediation effects in each study population. This approach address both multiple mediators simultaneously as well as multi-categorical variables108 such as warning domains as proposed herein.

Importance / Value:

Waterpipe tobacco smoking (WTS) is becoming widespread in the United States among young adults[17,18]. Increases in WTS are partly due to advertisements (ads) that entice young adults to engage in WTS[19,20]. Often devoid of health warnings[22,23], waterpipe product and social allure ads likely mislead young adults to believe WTS is safe, promoting experimentation with WTS and reducing the desire to quit among users[19,24]. Thus, as shown with cigarette health

warnings[1], designing effective text and graphic (i.e., pictorial) warnings is vital to curbing the effects of these ads.

Risks / Benefits:

We consider this study to involve very minimal risk. Some participants may become alarmed of learning the potential health implications of waterpipe tobacco smoking and the potential for addiction. This may be especially alarming among smokers of other tobacco products (e.g., the perception of the compounding of health risks and potential for addiction using several products). For others, learning of these issues may reinforce existing knowledge.

The benefits of participation, other than the fiscal compensation for completing the entire study (see below), are that participants gain a better understanding of health effects of WTS. The ultimate study goal, and hence benefit to study participants, is to equip them with knowledge that they can use to curb the persuasive appeal of WTS ads, prevent further experimentation with waterpipe tobacco, and achieve cessation to avoid future harm. The benefits of this study also include findings that may lead to policy changes in the regulation of WTS ads from commercial establishments, such as those posed by the FDA.

Data Safety and Monitoring:

This study neither involves the testing of pharmacologic agents nor therapeutic treatments. The primary goal of this study is to examine how the provision of text only or text + graphic health warnings, or lack therefore, on social allure and waterpipe tobacco product ads influence risk appraisals, cognitive and affective beliefs and attitudes about waterpipe tobacco smoking (WTS) and intentions to quit/willingness to try WTS among waterpipe tobacco smokers and susceptible nonsmokers, respectively. This study also examines whether any effects are mediated by reactions to the ads, with a subcomponent to study in more detail attentional factors as potential mediators through use of eye-tracking. Thus, it is classified as a Type 3 Study (Non-therapeutic, non-physical intervention), a minimal risk level study that dictates annual review by the Duke Cancer Center Scientific Monitoring Subcommittee for scientific progress and IRB compliance *(The overall Duke DSMB plan follows the specific details regarding DSMB procedures that will be followed by the research team).*

Adverse Event Reporting: The study consent form presented on will have a study-related email address and a study toll-free number. In the event a participant emails or calls the toll-free study number, the project manager will record all reported events in the adverse event log (including the subject's name, date, and event description). The project manager will inform the principal investigator, Isaac Lipkus, Ph.D., who will consult with co-investigators as needed on the action that should be taken. This action and date of implementation also will be recorded in the adverse event log. The entire investigative team will participate in classifying events as "serious" or "non-serious (see listing below)," as well as "non-attributable," "possibly attributable" or "attributable" to the intervention (unlike a pharmaceutical trial where known side effects exist, the classification of "expected" vs. "unexpected" is inappropriate for this intervention). *Serious*—any event or condition that is life threatening, results in a

hospitalization, cancer or a physical or cardiac event serious enough to require medical attention. A brief listing follows:
Fatal
Life threatening
Permanently disabling
Required or prolonged hospitalization (Admission—not ER visit)
Overdose
Significant hazard to patient
Non-Serious—all other events.
All adverse events will be reported on an annual basis to the Duke Cancer Center Scientific Monitoring Subcommittee. In keeping with NIH guidelines, minority status and gender also will be included in these reports to allow for detection of differential effects.

Monitoring Safety of Participants

There will be several ongoing mechanisms for monitoring non-medical adverse events. The project coordinator will oversee day-to-day monitoring of the study activities. This monitoring will be facilitated by an email address and a toll-free number provided to participants to report concerns related to study participation. These ongoing progress reports will enable monitoring of the number of participants involved in the intervention groups, attrition rates, and other relevant data.

Mechanisms for Reporting Mon-medical Adverse Events to the Study Principal Investigator and Institutional Review Board (IRB)

The project coordinator or Principal Investigator will follow up with participants within 48 hours to ensure that the event has been resolved and will document actions taken. Participants will be able to call directly to the study's toll-free number to report non-medical AEs. All non-medical AEs will be reported to the Principal Investigator and to the IRB via annual progress reports.

Mechanisms for Monitoring and Reporting Medical Adverse Events

There are no foreseeable medical adverse events linked to this study. All research projects conducted at or originating from the Duke University School of Nursing are required to have yearly departmental and Institutional Review Board (IRB) review. Reports of AEs are required as part of these progress reports. Additionally, any changes to the project between review periods must be approved by the IRB prior to fielding.

Plans for Assuring Compliance with Adverse Event Reporting

Participants will be instructed to email or call a 24-hour toll-free number if they experience an AE. As mentioned previously, the project coordinator will then inform the Principal Investigator and the IRB as detailed above. All adverse events will be reported to NIDA within 3 weeks of occurrence. Because this study does not include the use of an investigational drug, there is no requirement that the AE be reported to NIDA in real-time. All AEs are reported as part of the progress reports in the non-competitive and competitive renewals.

Plans for Assuring that Action Resulting in Suspension of Trial is Reported

The Principal Investigator will be responsible for contacting NIDA grant program director if any action resulting in temporary or permanent suspension of the trial occurs. Because this trial does not involve any investigational medication, the action would be limited to an IRB- or investigator- initiated suspension.

Plans for Assuring Data Accuracy and Protocol Compliance Assurance of data accuracy
All surveys will use standardized language and procedures which will be pretested. The project coordinator will produce reports of recruitment and survey completion rates for study investigators. All programming and subsequent checking of data quality and accuracy will take place by project staff at Duke. To enhance the quality of these data, we will implement several safeguards as stipulated in section D.9. in the research plan on data quality. In addition, our statistician will perform a quality data check to make sure all the variables and codes are appropriate.

Assurance of Protocol Compliance
The PI and the clinical coordinator will monitor protocol compliance throughout the project. The investigative team will review all procedures, including methods to protect participants' confidentiality and quality control of data.

Action to protect patient confidentiality
Before participants start to complete the online tasks (Phase 1 and Phase 2) or the eye-tracking laboratory component (Phase 3), they will be reminded that all their data will be confidential and that the research only uses study-related IDs that are not linked to any identifying information.

Selection of Subjects:

Age range: 18 – 34
Sex: All sexes
Source of subjects: Recruited locally from Durham, NC, Duke University, and from Turkprime which recruits people, who get paid for completing online surveys and studies, from anywhere in the United States.

Advertisements:

Individuals in Phase 1 and 2 will be recruited online using Turkprime[28], a research platform that supports behavioral sciences data collection through the Internet crowdsourcing platform Amazon Mechanical Turk (MTurk), and uses MTurk workers. MTurk workers, are individuals from the public who volunteer to participate in online studies with payment. For Phase 3, the 100 waterpipe tobacco smokers and the 100 susceptible nonsmokers ages 18-34 will be recruited from the subject pools managed by the Social Science Research Institute and Duke's Department of Psychology and Neuroscience. In the event we cannot readily obtain eligible study participants from these subject pools, we will advertise the study in central North Carolina using newspaper, flyers, and social media outlets (e.g., Facebook).

Informed Consent Process:

Phases 1 and 2: We will obtain active informed consent online, with the approval of the Duke University Medical Center Institutional Review Board (DUMC IRB). The online consent will inform about the research, including confidentiality, voluntary nature of participation, and potential risks and benefits. It will also emphasize that no personally identifying information will be available to, or collected by, the investigators conducting this research. The online consent form will contain contact information for the DUMC IRB if participants have questions about

the study or their rights as a research participant or experience any issues or problems participating in the study. The voluntary and confidential nature of the research will be emphasized again at the beginning of the study surveys. Note that all studies using this platform to study waterpipe tobacco under Dr. Lipkus as the PI have been designated by the DUMC IRB as exempt.

Phase 3: In person written consent will be obtained. Participants who will form the first advisory panels will be recruited through newspapers in Central North Carolina, Craigslist, advertisements in college newspapers and through social media. They will be asked to review and sign a written consent form, of which they will receive a copy, during the first panel visit at the Duke University School of Nursing. The consent form will emphasize the basic elements described above (e.g., confidentiality, benefits, risks, etc.).

Subject Compensation:

Fiscal compensation will vary by study phase and tasks. Among panel members, they will receive $50 for each session they attend, with each session expected to last about an hour. For Phase 1 participants who review either the ads or the health warnings, they will be compensated with a payment of $2.00 for tasks that are expected to take 15 to 20 minutes. For Phase 2 participants, they will get a total of $4.00 for both reviewing the intervention materials and for completing the two-week post-intervention assessments. Each is expected to take about 15 minutes. Participants in Phase 3 will receive $25.00 for their in-person participation.

Privacy and Confidentiality of Study Records:

Data collected online will be anonymous with each participant having a unique Turkprime ID with no identifying information. With respect to data, all will be stored at the Duke University School of Nursing. Assessment completion will be monitored in Qualtrics by study personnel as Survey data will be downloaded by authorized personnel and stored in a password protected database behind Duke's server. User-level restrictions will be in place to ensure only authorized, fully trained study staff have access to these data. All study related databases will be password-protected and accessed only by study personnel. All computerized data will be stored and protected as part of the Duke University School of Nursing's data storage protocols.

Will Protected Health Information (PHI) be used or accessed in this study?

Yes

PHI Sources:

Questionnaires

Will the study team need to collect PHI prior to consent (Does the study team need a HIPAA waiver)?

No

Privacy and Confidentiality of HIPAA Waiver:

Data collected online will be anonymous with each participant having a unique Turkprime ID with no identifying information. With respect to data, all will be stored at the Duke University School of Nursing. Assessment completion will be monitored in Qualtrics by study personnel as Survey data will be downloaded by authorized personnel and stored in a password protected database behind Duke's server. User-level restrictions will be in place to ensure only authorized, fully trained study staff have access to these data. All study related databases will be password-protected and accessed only by study personnel. All computerized data will be stored and protected as part of the Duke University School of Nursing's data storage protocols.

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