Official Title: Optimizing risk messages for waterpipe tobacco cessation in young adults

NCT Number: NCT03595280

Study Protocol

Initial Approval: November 28, 2017

MedStar Health Research Institute-Georgetown University Oncology Institutional Review Board

Date:	12/1/2017
To:	Darren Mays
From:	Cindi Charles Institutional Review Board
IRB #:	2017-1378
Title:	Optimizing Risk Messages for Promoting Waterpipe Tobacco Cessation in Young Adults
Approval Date:	11/28/2017
Expiration Date:	11/27/2018
Action:	Initial Review - Expedited

Attachments being reviewed:

Document	Version
Mays Hookah R01 CRC Exemption.doc	0.01
ICF for Vanguard Pilot.doc	0.04
ResearchMatch Contact Message.docx	0.01
CDC - Fact Sheet - Hookahs - Smoking & Tobacco Use.pdf	0.01
Recruitment Flyer.pdf	0.01
Scientific Review Correspondence.pdf	0.01
References.docx	0.01
Sample Image Directory.docx	0.01
Follow-Up Surveys 10102017.doc	0.01
Mays CV.pdf	0.01
ICF for Randomized Trial.doc	0.04
Baseline Survey 10102017.doc	0.01
Facebook Ad.docx	0.01
Mays Hookah R01 CRC Exemption.doc	0.01
Craigslist Advertisemen Message.docx	0.01
Hookah Messaging Matrix	0.01
Vanguard Pilot Interview Outline.docx	0.01
Waterpipe R01 Final.docx	0.01

Stamped Documents:

Document	Version
ICF for Vanguard Pilot.doc.pdf	0.01
ICF for Randomized Trial.doc.pdf	0.01
2017-1378_Recruitment Flyer.pdf_IRB Stamped.pdf	0.01
2017-1378_Craigslist Advertisement Message.docx_IRB Stamped.pdf	0.01
2017-1378_Facebook Ad.docx_IRB Stamped.pdf	0.01
2017-1378_ResearchMatch Contact Message.docx_IRB Stamped.pdf	0.01

The above-referenced study and supporting documents were approved through expedited review by the IRB Chair or a designee on 11/28/2017. The IRB has determined that the research involves no greater than minimal risk and falls under the following expedited review category:

7. Research on:
(a) individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), **OR**
(b) research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

This is to inform you that you may commence your project. Please note that this approval is granted through 11/27/2018.

This study will automatically become inactive when its approval expires on 11/27/2018 *unless* a continuing review submission is approved by the IRB before that date. The IRB requires that you submit an application for continuing review at the end of each approval period and/or at study completion. ***It is the PI's responsibility to submit the application for continuing review and the appropriate IRB forms with adequate time for review and approval prior to the expiration date.***

Any investigator whose project is externally funded must submit the applicable sponsor grant or contract for review and approval by the appropriate sponsored research office of the recipient institution (GU or MHRI). The project cannot proceed without the approval of the sponsored research office.

The International Committee of Medical Journal Editors (ICMJE) has established a requirement for registration of clinical trials in a public registry prior to enrollment as a condition of consideration for publication. Georgetown University has established a central registration process through the National Library of Medicine's Clinical Trials Protocol Registration System (PRS) known as ClinicalTrials.gov. Please contact the GU PRS administrator, Patricia Mazar, by e-mail at mazarp@georgetown.edu to set up a PRS user account to register clinical trials. The e-mail should contain the principal investigator's full name, department, phone number, and e-mail address.
Additional information may be found at http://ora.georgetown.edu, http://clinicaltrials.gov/, and at http://www.icmje.org/clin_trialup.htm.

For all Department of Defense (DoD) sponsored research, please note that you must obtain approval from the DoD human subjects committee as well as the local IRB before commencing this project.

** If promotional advertisements will be used for patient recruitment, they must be submitted for IRB review and approval prior to their use.

** Any incentives for participation in research are subject to IRB review and approval as well.

Please remember to:

1. Seek and obtain prior approval for any modifications to the approved protocol.

2. Promptly report any unexpected or otherwise significant adverse effects encountered in the course of this study to the IRB within seven (7) calendar days. This includes information obtained from sources outside GU or MHRI that reveals previously unknown risks from the procedures, drugs, or devices used in this study.

Georgetown University IRB
Medical-Dental Building, SW104
3900 Reservoir Road NW
Washington, DC 20057
(202)687-1506 *telephone*
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2017-1378_ResearchMatch Contact Message.docx_IRB Stamped.pdf

Official Title: Optimizing risk messages for waterpipe tobacco cessation in young adults

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1.0 Application Information

1. Title: Optimizing Risk Messages for Promoting Waterpipe Tobacco Cessation in Young Adults
2. PI: Darren Mays
3. Co-Investigators: Isaac Lipkus, Kenneth Tercyak
6. Study Coordinator(s):
9. Additional study members:

1.1 – Training Certification
Upload all co-investigators' training

1.3 – Is the Study Human Subject Research:
1. Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? In other words, do you intend to publish or otherwise share the results outside the institution? Yes
2. Does the research involve obtaining information about living individuals? Yes
3. Does the research involve intervention or interaction with the individuals? Yes
4. Is this activity an individual use of Humanitarian Use Device (HUD)? No

1.5 – Type of Review:
1. Please select the review type you are seeking: Expedited

1.6 – Expedited Review Category (Check all that apply)
7. Research on:
(a) Individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), OR
(b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

1.12 Expedited Review Subcategory
(b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

2.0 – Type of research: Oncology
2.0.1 – Status of research: Other
2.0.2 – Pediatric Oncology: No
2.1 – GHUCCTS network: No
2.4 – Initiating Site: 1. Lombardi 2. Site accrual: 210
2.5 – MedStar Network Study: No
2.7 – NCI IRB: No
2.9 – Collaborating with another institution: Yes
2.10 – Is the Georgetown University IRB the IRB of Record for the study? Yes

3.0 – Funding:
1. Is the project being sponsored or funded by the GHUCCTS? No
2. Does the project utilize GHUCCTS services or facilities? No
3. Please select the source of funding for your project:
Federal/NIH
4.0 – Conflict of Interest: None

3.5 Funding – Federal NIH
1. NIH Agency: National Cancer Institute (NCI)
2. Grant awarded: Awarded (R01217861)
3. Primary award institution: GU is the primary awardee institution

5.0 – Regulatory Information:
5.1 – Study Phase: N/A
5.2 – Scientific Review: No
5.4 – Drug/Device/Biologics: None (blank)
6.0 – Biohazards: No
6.4 – Radioisotopes: No
6.8 – Fetal Tissue: No
6.10 – Placebo: No
6.12 – Collection of Bio Specimens: No

7.0 – Categories of Scientific Review
1. Scientific review category: NCI
2. Scientific review subcategory:
3. Program Type: CPC
4. Trial Type: Correlative
5. Cooperative group: none (blank)

8.0 Required Summary (Please create a brief summary, in Layman's Terms (8th grade language) of 200 words or less for this protocol, outlining the salient features that may be useful to the public and/or health care professionals).
Waterpipe (i.e., hookah) tobacco is one of the most commonly used tobacco products among U.S. young adults [1, 2]. It exposes users to dozens of harmful toxicants, is linked to symptoms of addiction [3, 4], progression to use other tobacco (e.g., cigarette smoking) [5-7], and long-term waterpipe use is associated with negative health outcomes including lung disease and cancer [8-10]. Despite these data, there is accumulating evidence that the high prevalence of use among young adults is driven by commonly held perceptions that hookah tobacco is not harmful or addictive [11-17]. Public health messaging is urgently needed to correct these misperceptions and curb hookah tobacco use among young adults [18-20]. This study will develop and test an innovative approach for designing and delivering messages conveying the harms and addictiveness of hookah tobacco use, and incorporating visual imagery delivered via mobile phone MMS messages among young adults ages 18 to 30 years. The findings will inform future public health communication and behavioral intervention efforts implemented as part of a strategy to reduce the public health burden of tobacco use in the U.S.

9.0 Protocol Description
1 – Purpose of the Project
The purpose of this study is to examine the effects of messages conveying the harms and addictiveness of hookah tobacco delivered via mobile multimedia service (MMS) messaging for promoting hookah tobacco cessation among young adults ages 18 to 30.

2 – Study Design

The purpose of this study is to test the effects of messages communicating the risks (i.e., health harms, addictiveness) of hookah tobacco delivered via mobile multimedia messaging for promoting hookah

tobacco cessation. Participants will be young adults ages 18 to 30 who are current hookah tobacco smokers. The study will also compare two messaging approaches, a standard untailored approach where all participants receive the same message content, and a tailored messaging approach where message content is personalized to baseline measures of hookah tobacco use behavior, beliefs, and perceptions and interactively to exchanges that occur via mobile messaging sent and received during the exposure period. The study will consist of two elements:

Vanguard Pilot. The vanguard pilot will preliminarily test the message delivery protocol and procedures to ascertain participants' detailed feedback for changes, improvements, and modifications on the messaging content and study protocols. Through this step we will incorporate feedback from the target population into the message delivery and study processes. This portion of the study will include up to 20 total participants (10 from each study site). Eligibility criteria, recruitment, screening, and enrollment methods, and study procedures will be the same as the randomized trial described below. However, instead of implementing the full trial randomization procedures, all participants in the vanguard pilot will be assigned to receive the tailored mobile messages as described below. In addition to completing all other study procedures, participants in the pilot portion of the study will be asked to complete two additional interviews by telephone. Interviews will occur at approximately the mid-point (i.e., 3 weeks post baseline) and at the conclusion of the message exposure period (i.e., 6 weeks post baseline). Interviews will be semi-structured in nature and will include closed and open-ended questions to ascertain participants' feedback on message content and delivery, and suggestions for changes and improvement. Interviews will be conducted by a trained study team member, and audio recorded to ensure participants' responses are fully captured. Detailed notes will also be taken, recordings will be transcribed, and participants' feedback will be aggregated and analyzed for commonly-occurring themes and recommendations in participants' feedback to modify the message content and delivery prior to launching the randomized trial. Pilot participants' data will be excluded from the trial outcomes analysis.

Randomized Controlled Trial. Following the vanguard pilot, we will conduct a randomized controlled trial to compare the aggregate effects of mobile MMS messages conveying the harms and addictiveness of hookah tobacco use and examine differences between standard and individually tailored messaging approaches. Participants will be 420 young adult hookah tobacco users between the ages of 18-30 recruited from two study sites, Georgetown Lombardi and Duke University. Approximately half of total participants will be recruited from each study site. (Duke University will seek IRB review and approval for the site specific study protocol at their institution's IRB.) Our approach draws from studies previously conducted by the Georgetown investigators (protocols #2017-0987, 2014-1031). Participants will be recruited through flyers, advertisements, and online media detailed below. After confirming eligibility and obtaining consent, participants will complete a baseline assessment online. At the conclusion of the baseline assessment all participants will be provided a link to standard-of-care information about the risks of hookah tobacco use: the Centers for Disease Control and Prevention (CDC) "Fact Sheet – Hookahs Smoking and Tobacco Use." We will objectively capture participants' visits to this site by directly recording click-throughs to this link presented at the conclusion of the baseline assessment. Within 1 week of completing the baseline assessment, participants will be randomized to 1 of 3 conditions: 1) a control condition receiving no additional message content; 2) an untailored MMS condition; and 3) a tailored MMS condition. The MMS exposure will occur for 6-weeks. Participants randomized to both MMS conditions will receive prompts delivered to their mobile phones by an interactive messaging system on two days each week assessing hookah tobacco perceptions and behavior. After responding, participants will immediately receive MMS messages on harms and addictiveness of hookah tobacco. For the tailored MMS condition, messages will be tailored to baseline measures of hookah beliefs and behavior, and dynamically during the intervention period to responses to the interactive text message exchanges. Those randomized to the control condition will not receive messages after the baseline assessment.

All participants will complete follow-up assessments online 6-weeks post baseline (Follow-Up 1), 3-months later (Follow-Up 2), and 6-months later (Follow-Up 3). We carefully chose these time points based on our team's preliminary work on hookah tobacco messaging [21], recommendations for follow-up duration in tobacco intervention research [22, 23], and because this follow-up frequency and duration will capture short term message effects and changes in hookah tobacco use and mediating processes over time [5, 13, 21, 22, 24-27].

The specific aims are as follows:

Aim 1: Examine the overall effects of theoretically informed messages conveying harms and addictiveness of hookah tobacco on waterpipe tobacco perceptions and behavior.

> H1: Mobile MMS messages will increase perceived risk and worry about harms and addictiveness of hookah tobacco and motivation to quit, reduce frequency of hookah use, and increase cessation relative to the control condition.

Aim 2: Investigate the added effects of message content tailored to hookah tobacco perceptions and behavior.

> H2: Tailored mobile MMS messages will produce greater increases in perceived risk and worry about harms and addictiveness of hookah tobacco and motivation to quit, greater reductions in frequency of hookah use, and higher cessation rates relative to untailored MMS messages and the control condition.

Aim 3: Investigate mediating mechanisms and moderators of message effects on motivation to quit and hookah use.

> H3a: MMS message effects will be mediated by greater perceived risk and worry about harms and addiction and greater receptivity and emotional responses to the messages.
>
> H3b: MMS message effects will be greater among monthly users versus more frequent users, less dependent users versus more dependent users, and exclusive hookah users versus those who also use other tobacco products.

3 – Rationale and Justification

The prevalence of regular and intermittent hookah tobacco use among U.S. young adults rivals that of cigarette smoking and surpasses non-combustible products such as electronic cigarettes [1, 2]. A typical hookah smoking session lasts approximately 1 hour and exposes users to harmful chemicals at much higher levels than cigarette smoking, including at least 8 classes of carcinogens linked to lung, bladder, larynx, oral cavity, and esophageal cancer [28-30]. Hookah tobacco use increases the risks of cancer, lung disease, and other health outcomes, and in-vitro studies confirm hookah smoke exposure precipitates carcinogenesis [9, 10]. Hookah use also puts young people at risk for long-term addiction: users report symptoms of dependence, failed quit attempts, and withdrawal [3, 10], they are more likely than nonusers to be cigarette smokers (i.e., dual users) [31], and dual use drastically undermines the likelihood of smoking cessation [32]. Young adulthood is an especially vulnerable period when addictions unfold and transitions to regular tobacco use occur [33], and there is evidence this occurs for hookah tobacco [5, 6, 24]. Young adult hookah tobacco use is a critically important problem for tobacco control and cancer prevention [34].

Public health messaging is urgently needed to correct these misperceptions and curb hookah tobacco use among young adults [18-20]. Our preliminary studies support the potential impact of this approach,

showing that such messages can increase young adult hookah tobacco users' perceived risk and worry about harms and addiction and motivate cessation [21, 35]. Beyond our research, there is a paucity of evidence on public health messaging for hookah tobacco use: studies have primarily examined clinical cessation interventions [36, 37] that have limited reach and impact among young adult hookah tobacco users because young adults' uptake of such interventions is low [38, 39] and they do not perceive a need for such cessation supports [3, 11].

Research suggests that additional strategies are needed to optimize the impact of public health messages. There is strong evidence that message effects can be enhanced by incorporating visual imagery [40], and research demonstrates high potential reach and efficacy of mobile text messages and personally tailored mobile message content for promoting cigarette smoking cessation [41, 42]. However, these strategies have not been tested for messages targeting the unique perceptions and beliefs that set young adults' hookah tobacco use apart from cigarette smoking [11, 12, 14, 16]. Evidence-based public health messaging is a recommended component of comprehensive tobacco control efforts [43]. For cigarette smoking, strategies such as mass media campaigns and targeted messaging interventions are effective for preventing smoking uptake and promoting cessation [40, 44, 45]. Young adults' use of hookah tobacco is characterized by unique perceptions and beliefs about the harms and addictiveness of hookah [11, 12, 14, 16], and messages aimed at these factors are needed to promote behavior change. Our research supports the hypothesis that messages conveying health harms and addictive potential of hookah use resonate with young adult hookah users and can motivate cessation [21, 35], but research examining innovative strategies to optimize message impact is sorely needed to curb this growing public health problem. Novel messaging strategies are needed to reach young people with information on harms and addictiveness of hookah tobacco.

Our objective is to rigorously investigate the effects of messages conveying harms and addictiveness of hookah tobacco using text and visual imagery delivered via mobile phone multimedia messaging service (MMS) and to examine the added effects of personally tailored MMS message content. The approaches we will test have high potential for translation into population-based interventions, including FDA's public education efforts (e.g., media campaigns, mobile communications) [46, 47], mobile tobacco cessation programs (e.g., NCI's SmokeFreeTxt), and other interventions targeting young adults such as those on college campuses [48].

4 – Primary Objective

To examine the effects of messages conveying harms and addictiveness of hookah tobacco on hookah tobacco perceptions and behavior.

5 – Secondary Objective

To investigate the added effects of message content tailored to hookah tobacco perceptions and behavior; and to examine mediators and moderators of message effects.

6 – Inclusion Criteria

Eligible participants will be: (1) young adults ages 18 to 30 years who are current hookah tobacco users, defined as using hookah tobacco at least once in the past month and now using hookah tobacco on at least a monthly basis; (2) have access to the Internet to complete study assessments; and (3) have a personal mobile phone capable of sending and receiving MMS messages.

7 – Exclusion Criteria

Study exclusion criteria include: (1) individuals who are younger than 18 or older than 30; (2) those who are not current hookah tobacco users; (3) participants unable to complete study procedures including

online assessments and receiving/sending text messages to their personal mobile phones; and (3) those unable to complete all procedures in English.

8 – Treatment Plan

8.1 Recruitment & Enrollment: Recruitment will occur at the Georgetown Lombardi and Duke University sites (Duke Site PI and Collaborator Dr. Isaac Lipkus). These geographic locations provide access to large, diverse young adult populations for recruitment. In the Washington, DC area, U.S. Census Data indicate young adults within the study age range comprise approximately 25% of the population. The population features high racial/ethnic diversity with more than 60% of residents identifying as non-white racial minorities and 10% as Hispanic or Latino. In the Raleigh-Durham area, more than a quarter of the population is young adults, approximately 30% identify as non-white racial/ethnic minorities, and 15% are Hispanic or Latino according to Census data. Several major colleges and universities also provide settings for targeted recruitment.

We will use multiple recruitment media including flyering at local recruitment sites, local media ads, Internet ads (e.g., Craigslist, Facebook), and existing databases of potential research participants (e.g., ResearchMatch) to achieve accrual goals. We use these methods in ongoing protocols (Protocols 2014-1031, 2013-0646) to effectively recruit young adults for behavioral cancer prevention and tobacco control research. Additionally, through Dr. Mays' ongoing Georgetown University IRB approved protocols, we ask study participants for their permission to be re-contacted for future studies as part of the informed consent process. Each of these protocols focuses on tobacco use or other cancer-preventive behaviors among young adults within the study age range. We will review these study consent forms and tracking databases to identify participants who have provided their permission to be contacted for future studies and may be eligible to participate. We will contact them first by e-mail and then by telephone follow-up to assess their interest in participating. The protocol numbers from which potential participants will be contacted are: 2017-0987, 2012-1549, 2014-1031.

Recruitment documents will describe study procedures and direct interested individuals to complete a brief survey online assessing their eligibility and ascertaining their contact information. The eligibility screener will be administered confidentially and securely online using Qualtrics. Qualtrics is a secure, encrypted online survey data collection platform for which the university has an institutional site license maintained by University Information Services. Interested individuals who have additional questions or want more information about the study can also call or email our study team. After answering any questions they may have about the study, they will be directed to the online eligibility screener or screened for eligibility by a trained study team member by telephone depending on their preferred screening method. Once eligibility is confirmed, individuals meeting eligibility criteria will be directed to an online study informed consent form. The online consent form will also be confidentially and securely administered via Qualtrics. Participants will also be sent a copy of the consent form via email for their individual records once it is completed. Those who wish not to provide informed consent online will be sent a study informed consent form to sign and return by postal mail. All study recruitment, enrollment, and tracking milestones will be recorded in a secure database administered through REDCap. Personnel at both sites will have database access to recruit, screen, and enroll participants into the study. Once participants are enrolled, staff at the Georgetown Lombardi site will implement remaining study procedures. Please see a draft of the recruitment materials and ad language as shown in Section 14. Attachments "Recruitment Flyer","Example Online Recruitment Advertisements", and "Study Website."

8.1.2 Vanguard Pilot Procedures: The vanguard pilot will preliminarily test the message delivery protocol and procedures and ascertain participants' detailed feedback for changes, improvements, and modifications on the messaging content and protocols. This portion of the study will include up to 20 total participants. They will be recruited using the methods detailed above, and asked to complete procedures

for the trial described below. However, instead of implementing the full trial randomization procedures all participants in the vanguard pilot will only be assigned to receive the tailored mobile messages as described below. In addition to completing all other study procedures, pilot participants will complete two additional interviews by telephone. Interviews will occur at approximately the mid-point (i.e., 3 weeks post-baseline) and at the conclusion of the message exposure period (i.e., 6 weeks post-baseline). Interviews will be semi-structured in nature and will include closed and open-ended questions to ascertain participants' feedback on message content and delivery, and suggestions for changes and improvement. Interviews will be conducted by a fully trained study team member, and audio recorded to ensure participants' responses are fully captured. Detailed notes will also be taken, recordings will be transcribed, and participants' feedback will be aggregated and analyzed to modify the message content and delivery prior to launching the randomized trial.

8.1.1 Randomize Trial Procedures:

After confirming eligibility and obtaining consent, participants will complete a baseline assessment online. The baseline assessment will be administered using Qualtrics as with online assessments and consent described above. Participants will receive a unique survey link to complete the baseline assessment, sent to them from study staff via email. This link allows us to track completion of the baseline assessment for each participant, and is encrypted to ensure confidentiality and privacy. Participants' completion of the survey will be monitored in Qualtrics and tracked in the study REDCap tracking database by study staff. The baseline survey will consist of validated items assessing participant characteristics (e.g., demographics), hookah tobacco smoking behavior, use of other tobacco products, and comprehensive assessment of hookah tobacco attitudes, beliefs, and perceptions of harms and addictiveness. Details of measures are described below, and an example of the survey is attached.

After completing the study baseline assessment online, participants will be randomized in approximately equal numbers to the three study conditions: 1) a control condition receiving no message content; 2) an untailored MMS condition; and 3) a tailored MMS condition. Randomization will be implemented using an algorithm within the study REDCap database. Randomization and the 6-week message exposure period for the untailored and tailored MMS conditions will begin within one week of completing baseline. Our approach to text message prompt and MMS message delivery is informed by prior research and the unique contexts of young adults' waterpipe tobacco use. At enrollment, we will assess participants' sleep-wake cycles and preferred times of day for message delivery. This will be included as data uploaded to schedule text message prompts and MMS message delivery. We use this strategy in our text messaging studies to maximize protocol adherence and retention [49-52].

Participants in both MMS conditions will interact with the messaging system by responding to up to two text message prompts delivered to their personal mobile phones on two days each week during the 6-week exposure period (i.e., responding to up to a total of four text message prompts per week). Prompts will be delivered on two days each week based on the timing of participants' enrollment to target the timing and social contexts in which young adults use hookah tobacco [11]. The text message prompts will capture hookah tobacco use and cognitive and emotional aspects of perceived harm and addictiveness based on measures from our recent work [35, 53]. After responding to prompts, participants will immediately receive an untailored or tailored MMS message based on the conditions to which they are randomized. This dose of text message prompts and MMS messages is based on typical patterns of young adult waterpipe tobacco use (i.e., usually non-daily use) and recommendations for message dose in mobile behavior change programs to ensure sufficient exposure and avoid burnout over time [54-56]. Total MMS messages delivered to participants will vary depending on frequency of responses to the text message prompts, which will enable us to explore MMS message dose effects in analyses [55].

MMS messages will be sent and received using the software platform Mobile Commons [57]. Mobile Commons has an extensive track record supporting NIH and privately funded research and provides the technology backbone for the NCI's national SmokeFreeTxt program. Mobile Commons provides researchers with a user-friendly, secure platform to implement interactive mobile phone text and MMS messaging protocols. The platform features a content management system that allows for the creation of preprogrammed, automated schedules to send messages and collect responses without the need for technical programming. Messaging protocols are implemented as branching tree structures specifying the parameters for delivery of text message prompts, collection of participant responses, and triggers for message content delivered in return.

8.1.2 Study Conditions:

Untailored MMS Condition. Participants randomized to the untailored MMS condition will respond to two mobile phone text message prompts delivered on two days each week assessing hookah tobacco use and perceptions during the 6-weeks exposure period. After responding to the prompts, participants will immediately receive MMS messages with text and visual imagery communicating the risks of hookah tobacco use. MMS messages will be organized as a matrix by day and theme, and delivery scheduled such that prompts assessing hookah tobacco use and perceptions and messages conveying potential health harms, toxicant exposure, and addictiveness will be alternated with no two consecutive days repeating message themes and ensuring unique MMS content is delivered in each interaction. Message delivery will be based on data uploaded to the Mobile Commons system including preferred timing of delivery. Please see the attached message matrices for examples.

Tailored MMS Condition. Baseline data from individuals randomized to the tailored MMS messaging condition will be uploaded to Mobile Commons to tailor MMS message content based on the following variables: 1) participants' preferred name and message delivery timing; 2) hookah tobacco use frequency (monthly versus weekly/daily); 3) beliefs and perceptions about the harms and addictiveness of hookah tobacco use. As with the untailored MMS condition, participants will respond to two text message prompts delivered on two days each day each week assessing hookah tobacco use and perceptions. Tailored MMS messages will be organized as matrices [58] by day, theme, and tailoring variable and uploaded in Mobile Commons. The matrices dictate the logic of branching tree structures that will be programmed to personalize message content based on baseline variables and dynamically during the intervention based on participants' reported hookah tobacco use, beliefs, and perceptions through the text messaging prompts. The system will capture participants' responses to text message prompts and using a preprogrammed algorithm will calculate a tailored MMS response based on the tailoring matrices. As in the untailored MMS condition, prompts assessing participants' hookah use and perceptions and MMS message themes will be scheduled such that no two consecutive days on which they are delivered will repeat message themes and unique MMS content will be delivered in each interaction. Our message tailoring approach is based on recommendations for the development of tailored interventions [58, 59] and prior studies [56, 60, 61]. The goal of the tailoring algorithm is to shift cognitive and emotional aspects of participants' perceptions of the harms and addictiveness hookah tobacco in order to motivate and achieve cessation based on behavioral change theoretical frameworks [58]. Please see the attached message matrices for examples.

Control Condition. For those randomized to the control condition, after completing the baseline assessment, participants in the control condition will complete study assessments only and will receive no further messages.

8.1.3 Follow-Up Assessments: All participants will complete secure, confidential follow-up assessments online 6-weeks after baseline (Follow-Up 1), 3-months later (Follow-Up 2), and 6-months later (Follow-Up 3). Follow up assessments will be administered securely and confidentially online using Qualtrics in

the same manner as the baseline assessment described above. Participants will be emailed a personal survey link to complete follow-up assessments online. Measures administered will be similar to the baseline and designed to assess changes in hookah tobacco use behavior, beliefs, attitudes and perceptions.

8.1.4. Measures
The proposed measures for this study have all been validated and found to be reliable assessments across our studies and research by others. These measures follow recommendations for assessment of hookah tobacco use and related constructs. Baseline measures will assess demographics, motivation to quit hookah tobacco (9,10) and frequency of use in the past 30 days (9, 140) as the primary outcomes, as well as hypothesized mediators (9,10), moderators (9,10, 28,37), and potential covariates (4-6,21,28, 80,87,143,144-149). Follow-ups at 6-weeks (Follow-Up 1), 3-months (Follow-Up 2), and 6-months (Follow-Up 3) will measure similar outcomes. For details of measures to be implemented at each of these time points please see the attachments in Section 12.9.

8.1.5 Study Retention & Follow-Up Procedures: Assessment completion will be monitored in real time through Qualtrics and tracked in the study REDCap database by the Georgetown Lombardi study staff. The RA will conduct telephone/email follow-up with participants to ensure assessments are completed according to the protocol and to address any questions or challenges encountered. Participants will also be encouraged to contact research staff if they encounter any difficulties with study procedures. For the MMS conditions, message delivery and receipt will be recorded in real time in Mobile Commons and the RA will follow up by phone with participants as needed to provide technical support, resolve any problems, and bolster adherence. Participants will receive gift cards to acknowledge their time devoted to achieving study milestones: $20 for baseline, $25 for the 6-week and 3-month follow-up, and $30 for completing the 6-month follow-up. Vanguard pilot participants will receive an additional $10 gift card for each telephone interview completed. We have used these procedures in our research described above with good adherence to online and mobile messaging protocols and high prospective sample retention (Protocol 2014-1031).

9 – Primary End Point
Hookah tobacco use perceptions, beliefs, attitudes, and behavior.

10 – Setting
Study procedures will take place at the Georgetown Lombardi Comprehensive Cancer Center and Duke University.

11. Multicenter
Yes

13. Local Accrual
210

14. Total Accrual
420

15. Duration of Accrual
4 years

16 – Duration of Study
5 years

17 – Open Protocols
No

18- Sample Size
Please provide a description of the statistical considerations (justifications for sample size or n, power or degree of change):
Descriptive analyses will characterize study participants overall, by trial condition, and by study site, and will evaluate for assumptions of normality/equality of variance for continuous variables. Non-normal data will be transformed as needed. Bivariate analyses will examine if baseline covariates have non-trivial associations ($p < 0.10$) with six-month outcome measures; those associated with outcome measures will be included in analyses as covariates. For Aim 1, since the primary outcomes are continuously measured variables at the 6-month follow-up (Follow-up 3), we will utilize an Analysis of Covariance (ANCOVA) model. The ANCOVA model will include the baseline covariates significantly associated with the outcomes of interest in the bivariate analyses and the stratification variables used for randomization. In exploratory analyses we will repeat this type of analysis for the 6-week and 3-month time points and also perform a longitudinal data analysis using mixed effects models [62] to examine if the effect of study condition (control versus combined MMS conditions) varies by time (a study condition by time interaction), controlling for any covariates associated with the outcome of interest. The primary outcomes and analytic approach for Aim 2 are similar to Aim 1, however we will compare differences in the 6-month outcomes across the control, untailored MMS, and tailored MMS conditions to evaluate the added effects of tailored messaging.

For Aim 3, we will draw from traditional mediation frameworks for preliminary analyses [63] and applying more robust methods to formally test for mediation [64]. We will also conduct exploratory analyses of MMS message dose effects in the untailored and tailored MMS conditions. After examining the distribution of message exposures and responses, we will explore dose effects in two ways: 1) dichotomized on whether a participant received less than or equal to or greater than the median MMS dose; and 2) as a continuous variable based on a count of total MMS messages delivered. Based on prior research [55], we will use ANCOVA and logistic regression to explore the potential effects of message dose on the primary outcome measures at 6-months controlling for any baseline variables that are associated with the message dose and the primary outcome measures.

We calculated statistical power to test our study hypotheses assuming a two tailed $\alpha = .05$ and 80% sample retention at 6-months based on our ongoing and previous work. The power calculations were performed for 6-month outcome measures. For the continuous outcome variables, a baseline sample of 400 participants for the randomized trial (approximately 130 per condition and excluding participants from the vanguard pilot) with 80% retention at 6-month follow-up will provide 80% power to detect effect sizes smaller than Cohen's $d = 0.37$ in analyses comparing the combined MMS conditions to the control condition for Aim 1. For the binary hookah tobacco cessation outcome, this sample will provide 80% power to detect differences in proportions such as 51% vs. 30% between any two conditions. For Aim 2, in analyses comparing continuously measured outcomes between any two conditions we will have 80% power to detect effect sizes smaller than Cohen's $d = 0.43$. For Aim 3, simulation studies provide estimated power to detect mediation effects using bias-corrected bootstrap analyses [65]. The sample will provide 80% power to detect medium indirect (i.e., coefficients in the range of 0.40) effects. Similarly, for analyses of the interaction between study condition and two-level moderators we will have 80% power to detect moderator effects smaller than Cohen's $f = 0.22$. These effect sizes are comparable to those observed in our recent work after a single exposure to messages online [35, 53].

19 – Importance/Value
Young adult hookah tobacco use is a critically important problem for tobacco control and cancer prevention [34]. Personally tailored message content can enhance the impact on cigarette smoking

cessation [41, 66], but this has not been tested for messages targeting hookah tobacco use. There is a critical need to adapt intervention strategies that have proven efficacy for cigarette smoking cessation to target factors known to influence young adults' waterpipe use [67]. Our study will test an innovative strategy for personalizing hookah tobacco message content by engaging in a two-way, interactive exchange where participant-generated data dynamically shape message content to enhance their impact.

9.2 – Risks

This study does not involve drugs, devices, or medical procedures. The primary potential source of risks in this study is the risk of gathering behavioral information about tobacco use and viewing messages about the potential harms and addictiveness of tobacco use.

9.3 – Data Safety and Monitoring

The primary potential source of risks in this study is the social risk of gathering behavioral information about hookah tobacco use. This includes potential embarrassment and fear of disclosure of potentially sensitive information about waterpipe and other tobacco product use and confidentiality concerns. Additionally, the messages that we will test will include text and images that may be unsettling to certain participants. We have plans in place to protect participants with respect to both of these risks.

Because the primary risks associated with this study are participant privacy and confidentiality, data security and privacy of records are of upmost importance. Participants' privacy and confidentiality will be protected in several ways. We have several institutional and procedural safeguards in place to ensure that all study data are treated as secure and confidential. No data collected on assessments for this research will be directly linked to participant identifying information (e.g., names, birthdates).Any paper study records will be stored in a locked file cabinet within locked offices at Georgetown Lombardi and Duke University study sites in order to ensure records are kept secure. This includes study data collected at the participant recruitment and screening stages. Only the site PIs and authorized staff will have access to these hard copy records.

Participant screening, enrollment, and study tracking will be securely maintained and entered in a dedicated study REDCap database. REDCap is a secure data management resource maintained by Georgetown University's Information Services data center. The REDCap application and databases are secured on Georgetown University Information Service's server with firewall, backup, and environmental and user-level controls. Study eligibility screeners, assessments, and online consents will be separately administered using Qualtrics. Qualtrics is a secure survey software platform, the license for which is maintained by Georgetown University's Information Services. Assessment completion will be monitored in Qualtrics and separately recorded in the REDCap tracking database by study personnel as Qualtrics is monitored. All electronic study data files from REDCap and Qualtrics, and electronic recordings of telephone interviews, will be securely stored on a GUMC/LCCC network drive. This network space is encrypted and directories are password-protected at the individual user level to ensure electronic data files are treated as secure and confidential. Only the PI, co-investigators, and fully trained, authorized study personnel will be granted access to the data after appropriate permissions are established. These data security layers ensure electronic study tracking and assessment data are securely maintained with rigorous access restrictions.

Mobile phone text message prompts and participants' responses among those randomized to the untailored and tailored MMS conditions will be sent and received using Mobile Commons, a secure, encrypted online software system available through a subscription. The study will be administered through a research-dedicated Mobile Commons account and short code (a six digit phone number) that will be used to send and receive messages for the study. This service allows for advance programming of scheduled text message assessments using a script to automate delivery and personalized MMS message

tailoring as described in the research plan. To protect participant confidentiality, prompts will not gather participant identifying information directly. Mobile Commons specializes in providing researchers with an IRB and HIPAA compliant service for text message protocols. Details of Mobile Common's information security protocols are available in a security document on the Mobile Commons website (https://uplandsoftware.com/mobilecommons/resources/white-paper/hipaa-text-messaging-whitepaper/). Participant responses are stored confidentially using a dedicated research identifier that our staff will assign. .Participant responses and tracking data such as the dates and times when messages were sent and responses were received will be recorded using their identifier into a secure study database. At the conclusion of the study, the database will be downloaded from Mobile Commons and stored on GUMC/LCCC's secure data server and permanently removed from the Mobile Commons system. Similar backups will be periodically downloaded and stored on GUMC/LCCC servers throughout the study.

Finally, participants will be viewing messages about hookah tobacco use, some of which will include text and visual images emphasizing the potential health harms and addictiveness of waterpipe tobacco and may be upsetting. Although we have not experienced such an adverse event in our research to date testing similar messages for behaviors such as cigarette smoking and the occurrence is unlikely, throughout the enrollment and informed consent process and over the course of the study participants will be encouraged to contact Georgetown Lombardi study staff or the study PI Dr. Mays if they have any questions or if the experience feelings of discomfort or distress as a result of participation. We will re-emphasize this again in instructions for all study assessments. In the event that a participant contacts the study staff or the PI and reports experiencing distress, they will be referred to the study co-investigator Dr. Tercyak for consultation and follow-up. Dr. Tercyak is a licensed clinical psychologist and will assess participants who may experience elevated stress and refer these participants for additional follow up as needed.

2. Adverse event
Dr. Mays is responsible for reporting unexpected problematic events involving any aspect of the study to the Georgetown IRB according to institutional guidelines. Safety monitoring will also be conducted by the PI on an ongoing basis. Unanticipated problems to be assessed include adverse events, deviations from the study design or protocol, problems with informed consent, and confidentiality violations. Dr. Mays will report unanticipated problems to the IRB within 7 business days of the occurrence. The Georgetown IRB will review such cases and determine what actions must be taken to address or resolve the situation. Participants will be encouraged to contact Dr. Mays at any time during the study.

3 Risk/benefits
The primary potential source of risk in this study is the social risk of gathering behavioral information about tobacco use behaviors and perceptions. These include potential embarrassment and fear of disclosure of information about tobacco use behavior, and discomfort due to viewing messages about the potential health risks of tobacco use. Participants will be apprised of these risks as part of the consent process. There are no direct benefits to young adults who choose to participate in this research. The knowledge gained may contribute to advances in tobacco control research, including how to optimally communicate the risks of hookah tobacco.

4 DSMB – No

5 Safety monitoring
Safety monitoring will be performed by the Principal Investigator Dr. Mays and in consultation with study co-investigators as needed. Participants will receive full contact information to the study investigators and the IRB as part of the informed consent process to report any issues or adverse events that occur, and will be encouraged to do so in the informed consent process and instructions for online assessments.

For all components of this research, safety data will be gathered and reviewed by the PI Dr. Mays. Dr. Mays will be the primary person responsible for evaluating any unanticipated problems and determining whether they affect the risk/benefit ratio of the study and whether modifications to the protocol and consent processes are required. A monitoring report will be generated at the end of each year of the study period. Dr. Mays will be responsible for reporting any unexpected problematic events involving any aspect of the study to the local IRB per institutional guidelines. Unanticipated problems to be assessed include adverse events, deviations from the study design or protocol, problems with informed consent, and confidentiality violations. Dr. Mays will report unanticipated problems to the IRB within 7 business days of their occurrence, per institutional policy.

6 Plans for interim analyses
Monitoring study progress and safety of participants is ongoing throughout data collection as noted above.

7 Plans for ensuring compliance
Dr. Mays will be responsible for reporting unexpected adverse events involving any aspect of the study to the Georgetown IRB according to institutional guidelines. Dr. Mays will report unanticipated problems to the IRB within 7 business days of the occurrence. The Georgetown IRB will review such cases and determine what actions must be taken to address or resolve the situation.

8 Plans for recruitment/follow up
Our proactive recruitment procedures will ensure that study participants complete all procedures. See details in the treatment plan for details of the follow up and retention procedures.

9 Risk categorization
Minimal Risk

9.5 – Information for Protocol Review [Unanticipated Problems and Procedures for Minimizing Risks]
1. Individuals and/or entities to whom unanticipated problems will be reported: PI
2. Individual/entity primarily responsible for reporting unanticipated problems: Darren Mays, Principal Investigator
3. Safety Contact Information: Please indicate who will manage subjects and be responsible for assessing subjects' response including potential unanticipated problems during their participation in the protocol

Name: Darren Mays
Role on Study: PI
Can be contacted 24/7: Yes
Contact Information: (202) 687-8937

4. N/A

5. Please describe what will happen to the data if subjects decide to withdraw/dropout before study completion. Please include examples of reasons that may prompt subject withdrawal/dropout:
We anticipate subject attrition to be 10% or less based on previous studies. Reasons for which subjects may drop out over the course of the study might include loss of interest in participating or lack of time to complete the procedures. Subject data collected prior to withdrawal will be analyzed.

6. Please describe partial withdrawal and its safety implications: Not applicable; withdrawal/partial withdrawal has no safety implications for participants.

7. Potential Benefits: While the direct benefits to participants are likely to be minimal, the findings of this study will be applied to inform future research and tobacco control efforts designed to reduce the population-level burden of tobacco-induced morbidity and mortality.

8. Alternative to participating: The only alternative is not participating.

11.0 Recruitment Techniques
Other

11.1 – Other
We will use multiple recruitment outlets including flyers at local college campuses and online advertisements (e.g., student/community newspapers, websites, and internet classifieds such as Craigslist, Facebook) to achieve accrual goals, a cost-efficient strategy for young adult smoking studies [68]. We will also re-contact participants who have consented to previous research studies and granted their permission to be re-contacted as part of the consent process (2017-0987, 2012-1549, 2014-1031). Finally, we will recruit participants via ResearchMatch, a free national database supported by the GHUCCTS and maintained by NIH.

11.5 Advertisements (Check all that apply)
1. Physical placement (e.g. bulletin board, hallway, doorway, kiosk, etc.)
2. Online advertisements

11.6 – Selection of Subjects
1. Please enter the age range of the subjects: Adults ages 18 to 30.
2. Please select the gender of subjects (select all that apply): Male and Female
3. Please describe your source of subjects:
Recruited locally from study sites Washington, D.C. and Durham, NC.

11.8 – Safeguards for vulnerable populations:
Please describe the additional safeguards that will be put in place to protect this population from coercion or undue influence to participate: No vulnerable populations are included in this research. The consent form emphasizes the voluntary and confidential nature of the research, states the limits to confidentiality, and assures participants that they may withdraw from the study at any time without penalty.

12.0 – Population Exclusions: 1. Open to men and women of all racial groups?: Yes, 2. Separate accrual targets?: No, 3. Subgroup analysis for difference in gender, race, and interaction: Yes;

12.6 – Specify Population Exclusions: Pediatric populations excluded.
12.8 - Please explain the rationale for excluding these populations: The study focuses on adults ages 18 to 30, therefore pediatric populations are not eligible to participate.
12.9 Type of Consent – Written Consent
Online Consent: Vanguard Pilot
Online Consent: Randomized Trial
Draft Baseline Survey
Draft 6-Week Survey
Draft 3-Month Survey
Draft 6-Month Survey
Message Matrices

12.12 - Informed Consent Process

1. Please describe the process that will be used to obtain consent for this study:

This study will include young adults ages 18-30 years who are current waterpipe tobacco users and consent procedures will be implemented based on the age of participants who are recruited for participation. Therefore, adults ages 18 – 30 will provide their own electronic informed consent to participate in the study.

Trained study staff will be responsible for monitoring eligibility screening and informed consent as described above. These steps will primarily occur online. Additionally, trained study staff may administer screening participants for eligibility and facilitate the informed consent process among eligible young adults who are interested in participating but respond to study recruitment advertisements via telephone or e-mail. To obtain informed consent, interested eligible participants will be directed to an electronic-consent form. Electronic-Consent allows participants to complete informed consent at home using a computer based consent form rather than traditional paper documentation and returning signed consent forms by postal mail. Consent forms will be implemented in Qualtrics and participants can access consent forms via any internet enabled device (i.e., computer, mobile phone, or tablet). Those who wish not to provide informed consent online will be sent a study informed consent form to sign and return by postal mail. The consent will use institutional templates to include clear written instructions to participants to guide the consent process, and our research staff will also be available to follow-up by telephone and email to discuss the study and clarify any questions that potential participants may have. The consent forms are based on standard institutional templates and protocols from the Georgetown University IRB. The forms emphasize the voluntary and confidential nature of the research, state the limits to confidentiality, and assure participants that they may withdraw from the study at any time without penalty. Please see the informed consent document attached with this protocol.

12.13 - Collection of Private Information On Individuals Other Than Study Subject

1. Will this research involve collection of private information pertaining to individuals other than the study subject who is giving consent (i.e. third parties)? No

12.18 - Subject Compensation

1. Will subjects receive any compensation for participation either in cash or in kind? Yes

12.19 Subject Compensation

Participants will receive gift cards for achieving study milestones: $20 for baseline, $25 for 6-week follow-up (Follow-up 1), $25 for the 3-month follow-up (Follow-up 2), and $30 for the 6-month follow-up (Follow-up 3). Participants in the vanguard pilot will receive an additional $10 gift card for each of the two telephone interviews completed (up to $20 in total).

13.0 Privacy and Confidentiality of Study Records

1. Describe methods for protecting the confidentiality of data provided by study participants. Please address the following in the description: What information about study participants is being collected, why it is necessary to the conduct of this study, what is the plan for protecting these data from improper use and disclosure, and when and how the plan will be initiated.

Any paper records of eligibility screening and recruitment process will be stored inside of a locked office within a locked file cabinet at the study recruitment sites. All files for this study will be confidential, using a unique study identifier. This study identifier will not include any personally identifiable information. This study identifier will only be linked to personally identifiable information within REDCap that will be accessible only to the study Principal Investigator and authorized, trained study personnel. Access to data files will be limited to fully-trained members of the study team, all of whom have received human subjects and HIPAA certification.

The primary assessments completed for this study will be conducted online in Qualtrics. As with any study that relies on online communication, security of information that is provided via online study assessments is a concern. All online assessments will be confidential, using a unique individual link. Survey data will be downloaded by authorized personnel and stored in a password protected database behind Georgetown's server. Electronic recordings from telephone interviews for the vanguard pilot will be stored in a similar, secured fashion. Access to these data will be strictly controlled by the PI and will only be accessible by study staff with permission and training to do so.

Study data collected from text message prompts and responses will be collected using Mobile Commons, a secure, encrypted, HIPAA compliant tool available through a software subscription. Mobile Commons maintains a comprehensive set of information security policies, and has implemented procedures to ensure compliance with these policies. The Mobile Commons information security program includes measures to protect the confidentiality, integrity, and availability of sensitive client data, including Electronic Protected Health Information (EPHI). All sensitive data, including PHI and authentication credentials for system and application access, are transmitted via encrypted protocols (SSL or SSHv2) when traversing public or untrusted networks. Strong encryption is used for sensitive data stored on Mobile Commons systems.

2. Will Protected Health Information be accessed or used in this study? Yes

13.2 - Privacy and Confidentiality of Data Records - PHI Sources
Please select the source(s) of protected health information:
Interviews/questionnaires

13.6 - Privacy and Confidentiality of Data Records - Recording of Health Information
1. Please indicate how the research team will receive health information: Without any identifiers
2. Please indicate how the research team will record health information: Without any identifiers

13.10 - Privacy and Confidentiality of Data Records - Protection / HIPAA Waiver
1. Retain this info: Data will be retained for a minimum of 3 years following the completion of the study, per institutional policy.
2. Info Shared: This information will not be shared.

3. Plan to protect privacy of participants:
Paper study records will be stored in a locked file cabinet within a locked office at in the study recruitment sites in order to ensure records are kept secure. This includes study data collected at the participant recruitment and screening stages and any paper records associated with data collection or participant tracking. Only the PI and authorized staff will have access to these hard copy records.

All online assessments administered will be confidential, completed using a personalized survey link provided by Qualtrics. No data collected on assessments will be directly linked to participant identifying information (e.g., names). Assessment completion will be recorded in the REDCap tracking database by study personnel as Qualtrics is monitored. Survey data will be downloaded by authorized personnel and stored in a password protected database behind Georgetown's server. User-level restrictions will be in place to ensure only authorized, fully trained study staff have access to these data.

Text message prompts and participants' responses will be sent and received through Mobile Commons, a secure, encrypted online tool available through a software subscription. We will have a research-dedicated account that will be used to administer messages for this study. Prompts will not gather

participant identifying information directly, but use only the unique study identifier to access. We will record participants' responses and tracking data such as the dates and times when prompts were sent and responses were received directly into a study REDCap database.

4. No HIPAA Form

6. Confidentiality maintained for research data:

A primary source of risk for this study is the risk for improper or unauthorized disclosure of personal information. We will carefully monitor and report any issues including unauthorized access to the data to the IRB according to our plan for monitoring study safety and reporting adverse protocol events detailed in this protocol. Additionally, information obtained during this study will be kept secure and access will be limited to trained study staff only. All study data will be stored securely on password-protected computers within locked offices at the LCCC. The study team has many safeguards in place to maintain confidentiality of study data gathered with the platforms utilized in this study, detailed below.

All online study assessments will be administered using Qualtrics, which uses a SSL cryptographic protocol in order to ensure secure transmission of information provided through the surveys. Qualtrics is a survey software licensed to the University and managed by University Information Services. This data will be downloaded by authorized personnel and stored on highly secure servers maintained by Georgetown University Information Systems (UIS). These servers have firewall protection, backup, as well as environmental and user-level controls. Access to electronic study data files is restricted at the individual user NetID level. Data collected through Mobile Commons will similarly be collected through a secure encrypted network. Mobile Commons has a comprehensive information security program in place that addresses the requirements set forth by federal regulations such as Health Information Technology for Economic and Clinical Health (HITECH) and other regulations and best-practice security standards. Only the Principal Investigator and authorized staff with required human subject protections training will have access to this data.

7. Please provide details on the measures taken to ensure the confidentiality of electronically transmitted data:
All online assessments will be administered using a secure commercially available survey platform Qualtrics that utilizes a state-of-the-art encryption protocol in order to ensure secure transmission of information provided through the study assessments. This encryption protocol secures a connection between a client (i.e., study participant) and server (i.e., online survey tool) to ensure that data are transmitted securely that is commonly used by online banking websites and other sites that require secure transmission of client information. Participants will complete the online survey using a unique survey link and no personally identifying information will be collected directly via the survey. Data collected online will be downloaded by authorized personnel and stored in a password protected database behind Georgetown's server. Furthermore, text message prompts and participants' responses will be sent using Mobile Commons, which has implemented security controls and associated processes that are appropriately aligned with standard information security requirements. Prompts will not gather participant identifying information directly. Participants' responses will be recorded directly in the Mobile Commons database along with the date/time prompts were sent and responses were received. All messages will be sent and received using Mobile Commons' secure server with encryption and firewalls to maintain confidentiality of electronically transmitted data.

8. No names

9. No recordings made public

13.13 – Privacy and Confidentiality of Data Records:
1. Electronic data storage: Secure network; Password access
2. Hardcopy data storage: Locked suite, locked office
3. Length info retained: We intend to retain the information for a minimum of 3 years as is required by the institution and until all analyses are completed.
4. Data destroyed: Electronic data will be securely destroyed, including any stored backups to network files.
6. No one/not applicable
7. Data sharing: The data will not be shared
8. N/A
14.0 – Attachments:

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