REFINING AND PILOTING A TEXT MESSAGING INTERVENTION TO DELAY ALCOHOL INITIATION AND REDUCE ALCOHOL USE ESCALATION AMONG ABSTAINER AND LIGHTER DRINKER COLLEGE STUDENTS

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PROTOCOL INFORMATION
Title of Research Activity: The Freshman Experience Project (Phase 2)

Name of Principal Investigator: Dana M. Litt

Institution: University of North Texas Health Science Center, Health Behavior and Health Systems

Names of each Co-Investigator: Melissa A. Lewis, Zhengyang Zhou, Heidemarie Blumenthal

Sponsoring Agency / Company (if applicable): National Institutes of Health/National Institute on Alcohol Abuse and Alcoholism

Sponsor's Protocol Number (if applicable): R34AA026004

A. Specific Aims – State the specific scientific objectives of the research.

***Note that this application is only for Aim 3 (Phase 2) of the proposed work. Aims 1 and 2 are being conducted under IRB approval 2018-128**

***Aim 1** is to conduct a series of focus groups with abstaining or lighter drinking students ages 18-19 who will evaluate and respond to possible researcher-created text message (TM) intervention content that covers the following four domains: norms, images, alternative activities, and personal goals. Participants will also be asked to review a list of keywords that can be texted to the study staff at any time to receive more information. Participants will rate the likelihood of using specific keywords ascertained through the focus groups and whether they would prefer other types of keywords or content. They will also have the opportunity to discuss other features of a TM intervention that they think would be useful in preventing initiation and escalation of alcohol use.

***Aim 2** of this proposal is to elicit responses to timing of the TM intervention, specifically determining the time of day and frequency that abstainers and lighter drinkers would like to receive TMs.

Aim 3 is to conduct a pilot study with 6 weeks of TM intervention content, a 6-week post-intervention assessment and 3, 6, and 9-month follow-ups among abstainer or lighter drinking first-year college students to determine feasibility, acceptability, and preliminary effect sizes (to estimate power and sample sizes for a future R01). After the 9-month follow-up survey, we will complete up to 15 post-intervention interviews with participants who received the intervention

and gave permission to be contacted for future research opportunities. We will not contact any participants who did not give permission to be contacted for future research opportunities. These interviews will provide further feedback on the feasibility and acceptability of this intervention. Newly enrolled first-year college students will be randomized to the TM intervention or assessment only control. We hypothesize the TM Intervention will be feasible and acceptable to abstainer and lighter drinking students, including being accessible, usable, convenient, relevant and helpful. We further hypothesize that receiving the TM intervention will be associated with less initiation and escalation of drinking, fewer negative consequences, more favorable prototypes of abstainers and lighter drinkers, greater perceived abstaining and light drinking norms, greater engagement and enjoyment of alternative activities, and greater endorsement of personal goals that do not involve alcohol at the 6-week post-intervention assessment and 3, 6, and 9-month follow-ups relative to assessment only control.

B. Background and Significance - *Briefly* sketch the background leading to the present proposal. Describe the contributions that the study may make to the health of human beings and/or to the scientific community, using documentation from the literature, where appropriate. Although it is helpful for the Board to have a decent understanding of the basis for conducting a research project, it is *not* necessary to have a full-blown literature review or extensive background and rationale for the proposed research plan of activity.

Sher and Rutledge (2007) found that although the general tendency to increase heavy drinking during the transition to college was consistent across measures of heavy drinking, most of that increase was attributable to non-heavy drinkers becoming heavy drinkers and not to a further increase in the frequency of heavy drinking among those who already were drinking heavily prior to college entry. Changes in alcohol use during the transition to college is particularly important in these lower level drinkers as students who are usually non-drinkers or lighter drinkers but who occasionally consume heavy amounts may even be at greater risk based on work that showed students who were not heavy drinkers experienced more negative consequences from their drinking when they did drink heavily than consistent heavy drinkers (Gruenwald, 2003; Lee et al., 2009; Lewis et al., 2009; Toomey & Wagenaar, 2002). Studies estimate that students who drink at non-extreme levels—four or fewer drinks on occasion—experience one-third to one-half of all college drinking-related problems (Gruenewald, et al., 2010; Weitzman & Nelson, 2004), which highlights the need to prevent student drinking at all levels. Therefore, preventing the initiation and escalation of alcohol use prior to experiencing negative consequences has potential to impact students' current and future drinking and consequences. Other research found that although abstainers and lighter drinkers were no less likely to enroll in a universal TM study, neither positive nor negative intervention effects were observed in this subgroup of students (Haug, 2017). Another study (using web-based methods) found that although heavy drinkers rated the intervention as more useful, there was no evidence in differences of perceptions of user-friendliness and interest between heavy drinkers and abstainers (Doumas et al., 2014). Taken together this indicates that abstainers and lighter users are no less likely to participate in TM interventions, but for students who are abstainers or lighter drinkers (and therefore the content wasn't as applicable

or salient), existing TM interventions are mostly non-effective. The proposed study will develop and pilot a TM intervention that focuses on maintaining low-risk alcohol use or abstinence during the start of the first year of college, a known window of risk for developing risky alcohol use, particularly for students who are not heavy drinkers prior to college.

C. Preliminary Studies - Summarize preliminary studies conducted by the investigator pertinent to this proposal. State "none" if applicable.

Dr. Litt has been the PI of several other NIH awards examining etiology and prevention of young adult alcohol use (R00AA020869; R21AA024163). Dr. Lewis has conducted numerous longitudinal studies utilizing web-based recruitment, assessment, and feedback interventions with high retention rates funded from NIH grants (see Lewis Biosketch). Dr. Lewis has prior experience examining intervention efficacy among lighter or non-drinking college students (Neighbors et al., 2011).

D. Investigator Experience -Provide a brief synopsis of the principal investigator's expertise, experience, and capability to perform this research. Attach a copy of the curriculum vitae of the principal investigator to this application.

My background experiences have afforded me with the expertise, leadership, and motivation necessary to successfully perform the proposed research. I received my Ph.D. in Applied Social Psychology at The George Washington University in 2010 and completed a post-doctoral fellowship on an NIAAA T-32 training grant awarded to Dr. Mary Larimer at the University of Washington in 2011 and served as faculty from 2012-2017. Since January 2018, I've been employed as an Associate Professor in the Department of Health Behavior and Health Systems in the School of Public Health at UNTHSC. The bulk of my research has focused on the application of social psychological theory to high-risk health behaviors, including alcohol use among adolescents and young adults. In addition, I have written several manuscripts that focus on the role of cognitions and behavior among those individuals who are either abstainers or lighter drinkers (Litt & Lewis, 2015; Litt & Stock, 2011). Further, I have been or am currently the Principal Investigator on two grants that examine the prevention of young adult alcohol use (R00AA020869; R21AA024163). In order to successfully accomplish the proposed research plan, I have chosen a strong co-investigator (Drs. Lewis) who provides expertise in social psychological theory, college student alcohol use, text messaging interventions, web-based recruitment and tracking in college samples, and qualitative and quantitative statistical analysis. In summary, I have demonstrated a record of successful and productive research, have put together a strong team, and my knowledge and experience will help me successfully lead and carry out the proposed research. Please see attached CV.

E. Experimental Design and Methods -

UNT University Student Directory (see Appendix D)

Undergraduate first-year students aged 18-19 from the University of North Texas (UNT) who have opted to have publicly available contact information will be selected randomly from the Student Directory. This is not the only method of recruitment that will be used for this study. In-person recruitment via the distribution of handouts and flyers will be used at orientation for incoming first-year students along with publication of an ad in their campus magazine, Connections Magazine. Online recruitment through a video accessible to freshman students attending UNT's Virtual Resource Fair will also be another method of recruitment for this study. Publicly available directory information is available via the campus registrar and is considered to be "information contained in an education record of a student which would not generally be considered harmful or an invasion of privacy if disclosed". The requested directory information requested will include name, university-assigned email address, mailing address month and day of date of birth, admit term, and classification (i.e., year in school). The university directory does not allow the request of social security number, race, ethnicity, nationality, or gender. Students who have selected to not have their directory information publicly available will not be contacted for participation in this research study. For a student to indicate that they would like to withhold their information from the public directory, they must file a formal "Request to Prevent Disclosure of Directory Information" each semester. Participants who have not opted to withdraw their directory information, are age 18-19 (based on date of birth), and are enrolled as first year students will be the only individuals contacted. A randomly selected sample from the university study directory will be sent emails. Up to 5,000 participants age 18-19 with public directory information will be randomly selected and will be sent information including an introductory email that contains a description and a link to the screening survey to determine eligibility for the study as well as a hyper-linked website address (URL) for more study information (See Appendix D for study website wording).

Dr. Litt has worked previously with the UNT IRB to procure an IAA for phase 1 of this research (IRB approval 2018-128). Once this project has been approved, Dr. Litt will work with the North Texas Regional IRB and UNT IRB to obtain any necessary approvals before beginning any data collection for phase 2.

General Recruitment.

We will utilize a multi-method approach to reach a wide cross-section of college students from the UNT Denton Campus including in-person recruitment (e.g., tabling, distributing flyers at student dorms), using flyers and advertisements, online recruitment (e.g., submitting a video to Virtual Resource Fairs accessible by freshman students participating in online orientations), and sending student directory email invitations. Our experience has demonstrated success in recruiting college students using these methods (see Preliminary Studies). In-person recruitment will consist of tabling at orientation events where UNT first-year students will be attending. Flyers advertising recruitment for the study will be distributed at the on-campus orientation events and in student dorms with general, brief information about the study, links (URL and QR codes) to the screening survey, and the study's email address, and phone number.

We will recruit participants at the summer (i.e., June- August 2021) orientation events for the incoming freshman class at UNT. Orientations are 2 days long, and they serve to help students acclimate to the university by allowing them to meet classmates, faculty, and staff, learn about campus resources, and receive academic advising in preparation for registering for classes. We will have a table with study flyers, and we will notify them about an invitation email that may be sent to their UNT email before the start of the fall semester, if they choose to not take the screening survey in that moment. We will have the screening survey link available if they wish to determine their eligibility on the spot. To access the survey, we will have a Bitly URL link, as well as a QR code displayed on the flyers and handouts. At the tabling events, we will also have incentives (e.g., stickers, water bottles, t-shirts, etc.) with the study logo available for them to take. An advertisement will be placed in UNT's Connections Magazine. This magazine is given to all freshmen students during their orientation. We will still use the registrar list to recruit participants, but adding the in-person recruitment strategies will increase the number of study enrollments before the start of the fall semester.

All freshman orientations held through July 2020 and some of the orientations held from June-August 2021 were transitioned from in-person orientations to online orientations due to concerns with COVID-19. Therefore, to continue our participation in their Virtual Resource Fairs, we will submit a video students will have access to in the Virtual Resource Fairs. The 2-3 minute video will consist of study staff reviewing a PowerPoint with general information about who we are, the Freshman Experience Project, information about how to participate, what participation in the study entails, and updated contact information (e.g., website, email address, phone number, and physical address). Video content will be similar to what we would normally say to students at the in-person orientations. The QR code to the screening survey will be included at the end of the video for freshman students to access and complete the screening survey if they are interested in participating in the study.

All flyers and ads will contain language aimed to recruit the study's target population. The advertisements do not indicate that is the Freshman Experience Project is an alcohol-related study in an attempt to recruit freshmen college student drinkers and non-drinkers. If the study's advertisements highlighted alcohol use, our study population may be skewed to only those who drink alcohol and may miss those who do not drink alcohol. Recruiting abstaining and light drinkers for this study, particularly among college students aged 18-19, is essential to answer study aims. Please see Appendix D for example advertisements. Once initial contact (online) has been established and age criteria initially met, participants will be contacted via email regarding the next steps of the study.

We have received approval from Tomas Sanchez (see Appendix F), the Associate Director for Residence Life at UNT, to recruit participants within the residence halls using approved flyers and handouts with our contact information so students are able to reach us with any questions they may have. Residence Life will not have access to information about participants enrolled in the study.

Social Media Fan Pages (see Appendix D)

All Facebook, Instagram, and Twitter outreach will be from the **ST**udying **A**lcohol and **R**elated **R**isks (STARR) lab accounts. Drs. Litt and Lewis are co-directors of the STARR lab. Using social media accounts for our lab rather than specific projects allows additional protection for participants as interaction with our social media accounts will not indicate a participant in a study since multiple studies are conducted by the STARR lab. The STARR Lab Facebook, Twitter, and Instagram Fan pages will not be used by The Freshman Experience Project to recruit participants; instead, the Fan pages will only be used by the research team to keep participants (recruited by the registrar (for UNT students), in-person and online orientation events, flyers, magazine ads; see Appendix D) aware of study progress and to build rapport. The communication for the Fan pages are one-way communication platforms whereby communication will come from the study staff via STARR lab social media accounts. In all consent documents, we inform participants that if they “like” or "follow" our social media Fan pages, they may see posts by the STARR lab research team. "Liking" or "following" social media fan pages is optional, not required for study participation, and is not an indication of study participation as anyone who is a member of Facebook, Twitter, and Instagram can like the study Fan pages. In addition, because the STARR Lab Fan pages will contain information on multiple ongoing studies as well as updates on research coming out of the STARR lab, it will provide further anonymity as it will not be possible to link someone who "likes" or "follows" the Fan pages to any specific projects. Social media posts on the Fan pages will not refer to specific compensation amounts. The use of a Facebook, Twitter, and Instagram Fan pages for communications is included in the consent documents. Participants will have the option to hide or not see any posts from the STARR Lab if they so choose. If the study staff receive calls or messages from individuals interested in participating in the project after seeing our social media pages, they will be informed that they can complete the screening survey if they received an email with the survey link, or by using the QR codes or link provided in the study’s flyer/advertisement. If UNT participants are not sure if they received an email invitation, we can look them up in our database. There is no generic screening survey related to all projects, so participants may be directed by study staff to view the STARR social media accounts and look for project specific posts and take those project specific screening surveys if interested. Individuals will not be able to post comments on the social media as we will set up the pages to be one-way communication only (i.e., from study staff to participants and not the other way around). Therefore, there is no need to monitor what is posted. Individuals will be able to share the fanpage with friends if they choose. Anyone can choose to unlike or not follow the page at any time. Private messages can be sent to the research team or people can call the research team. Only research staff have access to STARR social media accounts and the lab phone numbers and emails used for The Freshman Experience Project. Thus, only those listed as key personnel on this IRB protocol will respond to participant inquiries and will do some from either the general STARR email (starr@unthsc.edu) or The Freshman Experience Project

(experiences@unthsc.edu) as appropriate. Research articles shared on the STARR social medias accounts are for information purposes for the team and their areas of research, **not** recruitment purposes

Across all materials, previously approved OBC logos (under IRB 2018-128) will be continued to be used in our study materials. See Appendix D for prior approval.

Links to our website and social media accounts are below. See Appendix D for the printouts of the social media accounts and website.

Facebook https://www.facebook.com/starr.unthsc/

Instagram https://www.instagram.com/starrlab.unthsc/?hl=en

Twitter https://twitter.com/STARRLab_UNTHSC

Website https://www.unthsc.edu/school-of-public-health/starr/freshman-experience-project/

*note that we will not update the "live" website with Phase 2 information until we are ready to launch that study. We will have the material approved beforehand but will not post until study launch in Fall of 2020 as to not confuse participants who are taking part in the focus groups (IRB 2018-128).

After receiving information about the study (by information contained in the student directory invitation email, in-person and online recruitment at the UNT orientations, campus magazine ad) and being presented with the online screening informed consent statement and HIPAA authorization form, individuals will be asked to complete an electronic signature before being directed to participate in the online screening survey, which will determine whether or not they are a good fit for the study. Only those participants who sign both the online screening consent form and HIPAA Authorization Form will be routed to the Screening Survey. Once they hit the "Next" button on the HIPAA form, they will be routed to the online screening survey. Participants who do not sign the consent and HIPAA authorization form will be routed to the screening decline page and will never view the subsequent survey items. The electronic signature will be requested via a text box where participants can draw their signature as well as type their signature. This electronic signature would include a date and time stamp.

The first question that participants will be asked in the screening survey is their age. Thereafter, the remaining survey items will be based on show-if survey logic, so that participants who mark their age as 18-19 will continue receiving screening survey questions. Participants who provide consent and are age 18-19 will receive demographic questions (i.e., birth sex, race, ethnicity,

pregnancy status) and items that assess their current levels of drinking as well as crucial eligibility questions such as “Are you a first year college student at the University of North Texas” and “Are you willing to participate in 6-week text-messaging intervention during the start of the fall semester?” All participants will be asked for basic demographics (including age, birth sex, birth date, race/ethnicity, pregnancy status if female, etc.) and for contact information during the online screening.

Individuals who indicate they are 17 or younger, or 20 and over will be automatically rerouted to the end of the survey using show-if logic, and those who indicate they have participated in alcohol treatment will be deemed ineligible. These ineligible participants will not receive any additional questions. Data from anyone age 17 or younger, or 20 and over will not be kept. If participants are deemed ineligible on any of the inclusion/exclusion criteria, they will be routed to an ineligible end page that will thank them for their time and inform them that they are not a fit for the present study. They will also receive an email informing them that they are not eligible for the study. The data of participants who are ineligible will not be saved or used in anyway. Data for ineligible participants will be dropped every 30 days and will not be used in any analyses.

Screening survey data that is kept for study purposes will be collected via Rivulent Web Design, Inc. survey software and be saved on a dedicated secure server provided by Rivulent Web Design, Inc. Data stored on the provided secure server is encrypted, password protected, and HIPAA compliant. To maintain the confidentiality of data submitted over the internet, participants will log in to a secure website using their unique PIN created for study purposes. Data transfer will be protected using Transport Layer Security (TLS) version 1.2 or higher. The TLS encrypted session will ensure that data moving from the participant to the server (i.e., participant responses) will be encrypted in transit using a 2048-bit minimum encryption key. This is the same level of encryption used for most banking transactions and offers the highest degree of protection available for data transfer. Rivulent treats all data with the same level of encryption and security that would be expected for HIPAA-protected data, even if that data does not fall under HIPAA. Rivulent does not keep copies of data anywhere other than the secured, encrypted systems. Survey data will be transferred from the survey provider to secure file storage using this same TLS encryption. Secure storage within LabArchives is located in a locally managed datacenter. The datacenter is protected by two-step verification, configured sharing permissions, monitoring of activity, disabled permanent deletions, and conduction of regular access reviews. LabArchives has strict policy and technical access controls that prohibit employee access except in rare circumstances when legally obligated to do so. In addition, they use a number of physical and electronic security measures to protect user information from unauthorized access.

Study Reminders.

For all elements of this study, once the requested task (i.e., screening survey, baseline survey, etc.) has been completed by a participant, all reminders to complete that specific task will stop.

Future Research Opportunities

We ask participants age 18-19 in the online screening survey if they would like to be contacted for future research opportunities. For eligible and ineligible individuals who indicate "yes" to being contacted for future research opportunities, *all personal contact information is kept separate from the* remaining non-identifiable survey data. With our programming, we will create a future contacts list that will be stored separately and will not be connected to any survey data. Drs. Litt and Lewis have used these procedures for their studies since 2005 and have never experienced any adverse events. We will retain this contact information until the end of the study.

Only studies conducted at UNTHSC by Drs. Litt and/or Lewis would have access to this contact list. Future IRB submissions would describe the use of the list in detail and would not be used without IRB approval.

Consent Documents (see Appendix A)

Consent documents and consent status are stored in our secure, HIPAA compliant database. We will easily have access to documentation that contains the typed signature and the electronic signature that is date and time stamped to verify written consent was given or not given. All electronic consent forms (online and stored forms) will be shown to IRB for approval before any data collection occurs. We will provide to the IRB the website links in which the online consents will be housed for review and verification prior to implementation. This process will show what the consent documents look like online and when stored. Individuals will be asked to enter their email to receive a link to the copy of the signed consent document whenever a consent document is signed (screening and baseline). They will receive an email with an embedded link to a page that contains two additional links. One link will send them to their consent copy, while the second link will send them to their HIPAA form copy, if relevant. In the case that a participant fails to give consent, thus does not access nor reviews the HIPAA authorization form, they will be redirected to an error page. We receive all copies of Consent/HIPAA forms, so eligible participants can also ask for a copy at any time and request to be mailed a printed copy. Participants that fail to provide a valid email address will be deemed ineligible, thus will not receive a copy of their signed consent and HIPAA copies.

Screening Survey Consent. We are requesting informed consent for the screening survey to be obtained online with an electronic signature because the first part of the study (i.e., screening) is administered online. After receiving information about the study and being presented with the online screening informed consent statement, individuals will be asked to complete an electronic signature before being directed to participate in the online screening survey, which will determine whether or not they are a good fit for the study. If a participant wishes to not provide consent for the survey (i.e., they select "No, I choose not to participate" on the consent form), they will immediately be routed to the screening decline page and will not be shown any additional information or be asked to enter any additional information. Thus, a non-consenting participant cannot proceed further. The electronic signature will be requested via a

text box where participants can draw their signature. This electronic signature would include a date and time stamp. Participants will also be asked to type their full legal name and a valid email. Survey *programming will not move participants who do not provide consent to the HIPAA form. Participants who do not provide consent would be moved to the end page. Survey programming will be done such that participants cannot advance to the Screening Survey until both consent to participate and HIPAA Authorization has been provided*. If a participant does not consent or provide a valid email, they will be routed to the end page and will not be shown the HIPAA Authorization or any survey items. Participants who are eligible will receive an email informing them of their eligibility as well as a link to the Baseline Informed Consent and HIPAA authorization form. Participants who are ineligible will receive an email notifying them of their ineligibility and thanking them for their time. All participants who provide an email will receive a link to a copy of their signed consent form and HIPAA forms if relevant.

If we do not receive the completed screening consent and HIPAA form, we will periodically send reminders – via email (up to 5).

Baseline Consent. We are requesting informed consent for the full study to be obtained online prior to the baseline assessment with an electronic signature because all assessments (i.e., baseline, 6-week, 3, 6, and 9-month follow ups) are administered online. After receiving information about the study and being presented with the online baseline informed consent statement, individuals will be asked to complete an electronic signature before being directed to participate in the online baseline survey. If a participant wishes to not provide consent for the survey (i.e., they select "No, I choose not to participate" on the consent form), they will immediately be routed to the baseline decline page and will not be shown any additional information or be asked to enter any additional information. Thus, a non-consenting participant cannot proceed further. The electronic signature will be requested via a text box where participants can draw their signature. This electronic signature would include a date and time stamp. Participants will also be asked to type their full legal name. Survey *programming will not move participants who do not provide consent to the HIPAA form. Participants who do not provide consent would be moved to the end page. Survey programming will be done such that participants cannot advance to the subsequent survey items until both consent to participate and HIPAA Authorization has been provided*. If a participant does not consent, they will be routed to the end page and will not be shown the HIPAA Authorization or any survey items. All participants who provide an email will receive a link to the copy of their signed consent form and HIPAA forms if relevant.

If we do not receive the completed baseline consent and HIPAA form, we will periodically send reminders – via email (up to 5), text (up to 5) and/or phone/voicemail (up to 3).

Post-Intervention Interview Consent Document. We are requesting informed consent for the post-intervention interviews to be obtained online prior to the interview with an electronic signature because all interview procedures will take place online. After receiving information about the post-intervention interviews and being presented with the online post-intervention

interview informed consent statement, individuals will be asked to complete an electronic signature. If a participant wishes to not provide consent for the interview (i.e., they select "No, I choose not to participate" on the consent form), they will immediately be routed to the interview decline page and will not be shown any additional information or be asked to enter any additional information. Thus, a non-consenting participant cannot proceed further. The electronic signature will be requested via a text box where participants can draw their signature. This electronic signature would include a date and time stamp. Participants will also be asked to type their full legal name. *Survey programming will move participants who do not provide consent to the end page*. All participants who provide an email will receive a link to the copy of their signed consent form. If we do not receive the completed interview consent form, we will periodically send reminders via email (up to 3), phone call/voicemail (up to 3), and text (up to 3).

Baseline Assessment, 6-week, 3, 6, and 9-Month Assessments.

Participants who meet inclusion criteria will be emailed a study link. The link will take participants to an Informed Consent Statement and HIPAA authorization form, where they will be asked to indicate study consent through two electronic signatures: 1) study consent form, and 2) HIPAA authorization form. The electronic signatures will be requested via a text box where participants can draw their signature. If participants indicate consent to the study, they will continue to the baseline survey. The baseline survey will include questions about demographics, personality, drinking and drug use, and other health behaviors and will take approximately 45 minutes to complete. Questions in the assessments will also include topics about sexual orientation, sexual experience, sexual desire, religion, and relationship status. Participants will receive an email and text message reminder that their follow-up surveys is approaching 5 days before their scheduled invitation date. We will also mail participants a letter with an incentive item valued at no more than $10 and call them shortly before the survey invitations are sent. If we do not receive the completed assessment at each follow-up (Baseline Assessment, 6-week, 3, 6, and 9-Month assessment), we will periodically send reminders – via email (up to 8), text (up to 8) and/or phone/voicemail (up to 3). Participants can earn $20 for baseline, $25 for the 6-week follow-up, $30 for the 3-month follow-up, $35 for the 6-month follow-up, $40 for the 9-month follow-up.

Post-Intervention Interview.

A total of 15 randomly selected participants assigned to the intervention condition and who agreed to be contacted for future research opportunities will be compensated $50 for the post-intervention interview.

Recruitment Stratification.

We will stratify recruitment based on age, biological sex, and ethnicity, aiming to match demographics of UNT.

Baseline and Follow up Assessments (6-week, 3, 6, 9-month) *measures (45 minutes [baseline, 6 week, 3 month] or 25-30 minutes [6 month, 9 month])*. While the baseline and follow-up measures contain overlapping content, we may decide to include or exclude a measure over the course of the study, with IRB approval via a modification. Thus, we are electing to not indicate in the consent form that the surveys will all be the same. Overlap in surveys is indicated by the overall content areas of surveys that are provided in the consents. Behavior will be reported over lifetime (baseline), past 6 weeks (6-week assessment), and 3 months (3, 6, 9-month follow ups) to reduce problems with retrospective recall and overlap. Demographics will include age, height, weight, family history characteristics. Items assessing the types of events students would be interested in hearing about will be included in the Baseline survey only. We have added items to the follow-up surveys about past and current events they attend or like. There are also items in the Demographics measure in the Baseline survey only relevant to the personalization of the 6-week text message intervention. Social phobia will be measured at 6-week and 3-month only using the Social Interaction Anxiety Scale (α = .94; Mattick & Clarke, 1998; Lindner et al., 2013). Family history of alcohol, age of first use, and lifetime alcohol use will be assessed in the baseline survey and all follow-up timepoints (Johnston et al., 2014; Miller & Marlatt, 1984). Perceived vulnerability will be assessed by asking participants how likely they think it is that certain alcohol consequences will happen to them (α = .82; Gerrard et al., 2008; Johnston et al., 2011). We will assess the frequency participants view/share posts on a variety of social networking sites related to alcohol and marijuana use using the Social Media Scale. To determine drinking initiation, questions will ask when the behavior was initiated. Drinking will be assessed with the Daily Drinking Questionnaire and Quantity Frequency Index (DDQ; α = .73; Collins et al., 1985; Dimeff et al., 1999; Lewis & Neighbors, 2004). College drinking influences will be measured using the College Drinking Influences Survey at 6-week and 3-month only (α = .71-.94; Fisher et al., 2007). Consequences will be assessed with the Young Adult Alcohol Consequences Questionnaire (α = .79; Read et al., 2006, 2007). Reasons for not drinking will be assessed using the Reasons for Not Drinking Scale (α = .79; Huang, 2011). The willingness measure will assess willingness to use alcohol in certain scenarios (α = .85; Gerrard et al., 2002, 2008). Intentions for alcohol use will be assessed by items on intended frequency and quantity (α = .83; Ajzen, 2006; Gerrard et al., 2006). Injunctive norms will be measured using statements that assess participants' perceptions of other's attitudes towards abstaining or drinking lightly (Lewis et al., 2010; Krieger et al., 2016). Descriptive norms will be measured by items that assess the perceived frequency and quantity of others' drinking using the Drinking Norms Rating Form (Baer et al., 1991). Prototypes will be measured by items that assess how favorable and similar participants feel toward the typical abstainer and lighter drinker of the same sex and age (α = .87; Gerrard et al., 2002). We will assess urgency, sensation seeking, premeditation, and perseverance using the UPPS Impulsive Behavior Scale (α = .82-.91; Whiteside & Lynam, 2001, 2003). Alternative activities will be assessed by asking how favorable participants feel toward alcohol-free activities as well as an open-ended item that asks participants what sorts of activities they enjoy doing that do not involve alcohol use. The Fear of Missing Out scale (FoMO; α = .90; Przybylski

et al., 2013) will assess the level to which one perceives that others are having rewarding experiences while one is absent.

Personal goals will be appraised (during Baseline only) by having students write the top 5 goals they hope to achieve and will also be asked the extent to which they think using alcohol at differing levels will affect their goals. Other substance use, including co-use cognitions and behaviors, will be assessed for lifetime and past month frequency using the Customary Drinking and Drug Use Record (α = .70-.94; Brown et al., 1998; Schafer & Brown, 1991) as well as an adapted version that assesses co-use of substances. Drinking motives (only at 6-week and 3-month) will be assessed using the Drinking Motives Questionnaire (Grant et al., 2007). Marijuana-use will be assessed using items about their lifetime, past-year, and past-month marijuana-use frequency using the Marijuana Monitoring the Future Questionnaire. Reasons for Limiting Marijuana Use will be assessed using a modified version of the Reasons for Not Drinking Scale (α = .79; Huang, 2011) and the Motives for Abstaining from Alcohol Questionnaire- Modified (Stritzke & Butt, 2001). To determine prescription stimulant misuse, items will be added at 6-week and 3-month only over this topic. Academic Motivation (only at 6-week and 3-month) will be assessed using the Academic Motivation Scale (α = .81; Vallerand et al., 1992). Peer Pressure will be assessed using the Peer Pressure Scale (Santor et al., 2000). Protective Behaviors will be measured at 6-week and 3-month only using the Protective Behavioral Strategies Scale - 20 (Treloar et al., 2015). Thoughts on alcohol use during college will be assessed at 6-week and 3-month only using the College Life Alcohol Salience Scale (Osberk et al., 2010). Loneliness (only at 6-week and 3-month) will be assessed using the Three Item Loneliness Scale (α = .72; Hughes et al., 2004). Anxiety and depression will be measured at 6-week and 3-month only using the PROMIS Anxiety scale v1.0 (α = .96; Cella et al., 2010) and the PROMIS Depression scale (α = .96; Cella et al., 2010). Social psychological aspects of COVID-19 will be measured (only at 6-week and 3-month) using the Conway COVID-19 Measure (Conway et al., 2020).

For participants assigned to TM intervention condition, *acceptability* will be assessed with responses from a brief satisfaction survey included in the 6-week post-intervention assessment. Acceptability will be determined by (1) the proportion of participants who find the intervention acceptable (e.g., acceptability of content delivery method), usable (e.g., ease of viewing and interacting with TM intervention content), relevant (e.g., relevance of material), and helpful (e.g., finding content helpful, beneficial, important), (2) whether participants shared the texts with anyone else, (3) the proportion of participants who would recommend the study, and (4) the proportion of participants who found the program to be favorable overall.

Intervention Materials.

After baseline survey completion, participants assigned to TM intervention will receive 6 weeks of TMs.

Intervention Condition. The content for the TM Intervention will be designed to be non-confrontational in tone, seek to increase motivation to drink lightly or not at all, and based both on general information about light and non-drinking as well as information provided during the baseline assessment. Text messages will fall into 5 basic categories (images, norms, goals, protective behavioral strategies tips, and alternative activities) and will be randomly provided to participants from a master list of text messages. Please see Appendix C for a list of Text Messages. All TMs will be under 160 characters so that they may be read by all phone models and plans. The TM intervention condition will be programmed using Rivulent Inc. and will be linked with the data entry module for the baseline assessment, thereby allowing data to be imported directly from the survey into the feedback. Rivulent will randomly assign eligible participants to either the TM condition or the control (Assessment Only) condition. Participants will know they have been assigned to this condition when they receive the 6-week Intervention Reminder Email (1) informing them of their intervention start and end dates. They will also receive a 6-week intervention reminder text message. If they are in the TM group and choose to no longer participate in the study, participants can contact the Freshman Experience Project Staff and ask to be removed.

Participants in the TM Intervention condition will be provided a random selection of 2 TM per day (across 3 self-reported days they report being most likely to drink) across 6 weeks. Each TM with intervention content will be followed by a brief message with an embedded link to a one-item survey requesting the participant to rate the text from 1 (“not at all useful”) to 5 (“very useful”).

Assessment Only Control Condition. Participants in the assessment only control condition will not receive any TMs during the first 6 weeks of the study but will complete all of the online assessments (baseline, 6-week, 3, 6, 9-month follow-ups). Participants will know they have been assigned to this condition if they do not receive an email notification of when their TM intervention would begin and end, and if they do not receive text messages for a 6-week period.

1) *Data Analysis and Data Monitoring* - Describe plans for statistical analysis of data when appropriate. If a data safety monitoring committee is appropriate to protect the safety and/or welfare of subjects, describe its operation (e.g., membership, stopping rules and frequency of review).

Post-Intervention Interviews.

After the 9-Month follow-up survey, we will invite participants who were in the intervention condition and who agreed to be contacted for future research opportunities to complete an online, post-intervention interview assessing their experience of the intervention. This feedback will be used to guide future iterations of the intervention. These one-on-one interviews will be 60-minutes in duration, and participants will be compensated $50 for their time. We will complete up to 15 post-intervention interviews. Only participants who agreed to be contacted for future research opportunities will be invited to complete this interview.

Interview Consent Document. Eligible participants will be invited by email (up to 3), phone call/voicemail (up to 3), and/or text message (up to 3) to complete the interview consent document. The interview consent document will include information about the interview purpose, procedures, and risk. The informed consent will also include information detailing the rights of study participants such as their right to not answer any questions they are uncomfortable answering and their right to withdraw (either contacting the research team through verbal [phone] or written [email] contact) from the study at any time without penalty.

Interview Scheduling and Reminders. Participants who consent to participate in a post-intervention interview will be contacted by phone (up to 3), email (up to 3), and/or text message (up to 3) to schedule their interview time. Once the interview has been scheduled, the reminders to schedule will stop.

Once a participant has scheduled an interview, they will receive up to 2 emails and up to 2 text messages as a reminder of the date, time, and Zoom link of their scheduled interview. Participants can decline reminders at any time if they opt to not participate in the interview. Participants who opt out of the study will no longer receive any contacts from the research team.

Participants who do not show up for their scheduled interview will receive emails (up to 3), texts (up to 3), and phone calls (up to 3) that will provide instructions on how to reschedule for a future date/time. Participants who wish to reschedule can call and schedule on the phone with a staff member. Once a participant reschedules, the reminders to reschedule will stop. We will complete up to 15 interviews; participants who try to schedule an interview after 15 interviews have been completed will not be allowed to schedule a session.

Interview Procedure. Participants will join a Zoom meeting via a link previously provided to them and be asked to show a current driver's license/picture ID and/or a current school ID to verify identity (i.e., age, name, and enrollment at the University of North Texas). We will verify the forms of ID, including photo ID, against the information previously provided by the participant. If an individual shows up at an online interview and is not on the schedule list for that exact date/time, the individual will not be allowed to participate. We will hold up to 15 interviews each of which will cover topics related to their experiences with the intervention content as well as timing and delivery of intervention content. Participants will be compensated with a $50 Greenphire Mastercard for their participation after the interview. In order to document proceedings of the interviews, sessions will be audio and video-recorded. Participants will be informed in both the informed consent procedures prior to the interview as well as the interview introduction (see facilitator guide) that the proceedings will be audio and video-recorded and field notes may be taken and that they are to only use first names to protect privacy. Participants will also be reminded that they are not to discuss their own experiences with using alcohol and that they are free to not answer any questions they are uncomfortable answering. All interviews will be conducted in English and recordings will be transcribed by a trained and authorized key research personnel. Please see facilitation guide (Appendix C).

The consent form, which will be signed prior to being able to schedule a post-intervention interview, will be reviewed as part of the session. Participants will also be given the opportunity to ask questions. The facilitator will be instructed to make sure there aren't any final questions before beginning the interview. Participants who wish to retract their consent at this time will be allowed to leave without completing the interview. Participants who do not complete an interview will not be compensated for their time.

The interviews will follow a semi-structured interview protocol with some additional probing questions or modifications of the original questions as needed to better suit the participants' unique backgrounds and opinions. All questions will remain relevant/applicable to the study purpose and topics of interest and will not include questions that are considered more than minimal risk.

The interview questions are to be used as a general guide. Facilitators may change the order of the questions or add probing questions to gather more specific responses, but all questions will remain relevant/applicable to the study purpose and topics of interest. Since there will be variability in the type of participants in each interview, the questions may vary slightly from one interview to another. Facilitators will not include questions that are considered to be more than minimal risk style questions.

Each interview will be limited to one participant in attendance, with Drs. Litt and Lewis moderating. Interviews will last 60 minutes. The interviews will have a phenomenological focus, allowing for a free-flowing discussion with flexibility for the moderator to probe participants' responses. The moderator will provide participants with a brief overview of the study and will explain that we are seeking their input before the session begins. Please note that participants will not be asked to discuss their own drinking behavior, but rather will be asked to provide feedback on the intervention they received. Questions will focus on intervention content and delivery as well as information about drinking in general on their college campus. The goal is to obtain feedback on their experience with the intervention content and delivery as additional measures of feasibility and acceptability.

Please note that participants will not be asked to discuss their own drinking behavior, but rather will be asked to provide feedback on drinking in general on their campus as well as intervention content and delivery. There is a possibility that additional topics stemming from the questions outlined in the facilitator guide will come up through the interviews. The facilitator will ensure that any other topics that are discussed fit the overall scope of the work and do not present any additional risk. Interviews will be audio and video taped and field notes will be recorded.

After all interviews have been conducted, we will notify remaining invited participants that their participation is no longer needed.

Data Analysis and Power.

Data Analysis. In order to evaluate the pilot study, we will examine (a) recruitment and retention rates and (b) satisfaction surveys (i.e., accessible, usable, convenient, relevant, and helpful) and (c) rates of alcohol initiation and escalation, negative consequences, abstainer prototype favorability, abstainer injunctive and descriptive norms, engagement in and enjoyment of alternative activities, and endorsement of personal goals that do not involve alcohol, which will provide base rates and variance in outcomes to determine adequate power for a future clinical trial R01 application.

Feasibility will be assessed by (1) the proportion of first-year college students ages *18-19* who meet inclusion criteria and enroll for the study and (2) the proportion of participants who complete the TM intervention, the 6-week post-intervention assessment and *3, 6, and 9-month follow-ups* compared to *assessment* only control. The length of time to recruit our target enrollment will be assessed as an outcome of feasibility.

Acceptability will be assessed with responses from a brief satisfaction survey included in the 6-week post-intervention assessment. Acceptability will be determined by (1) the proportion of participants who find the intervention acceptable (e.g., acceptability of content delivery method), usable (e.g., ease of viewing and interacting with TM intervention content), relevant (e.g., relevance of material), and helpful (e.g., finding content helpful, beneficial, important), (2) participants' ratings of individual TMs, (3) whether participants shared the texts with anyone else, (4) the proportion of participants who would recommend the study, and (5) the proportion of participants who found the program to be favorable overall. Responses from the post-intervention interviews will also be used as a measure of acceptability.

To *explore treatment differences and to determine preliminary effect sizes* in drinking outcomes, this pilot will have five repeated measures (i.e., baseline, 6-week post-intervention, 3, 6, and 9-month follow-ups), yielding up to 1500 Level 1 observations (repeated-measures) across 300 Level 2 cases (people). Prior to inferential statistics, univariate and bivariate descriptive statistics will be used to assess distributions and simple associations among variables. Primary outcomes are alcohol initiation (binary outcome) and escalation in terms of number of drinks and consequences (both count outcomes). Additional outcomes are abstainer prototype favorability, abstainer injunctive and descriptive norms, engagement in and enjoyment of alternative activities, and endorsement of personal goals that do not involve alcohol, which are modeled as normally distributed outcomes. Given the repeated measures design, generalized linear mixed models (GLMM; Raudenbush & Bryk, 2002) will be used. GLMM (aka hierarchical generalized linear models) allow for non-normal outcomes and missing data. The model below represents the basic analytic model for a count outcome:

Level 1: $\log(E[DV_{ti}]) = \pi_{0i} + \pi_{1i}(\text{6-week})_{ti} + \pi_{2i}(\text{3-month})_{ti} + \pi_{3i}(\text{6-month})_{ti} + \pi_{4i}(\text{9-month})_{ti}$ (1)

Level 2:
$\pi_{0i} = \beta_{00} + \beta_{01}(Tx)_i + r_{00i}$ $\quad\quad$ $\pi_{3i} = \beta_{30} + \beta_{31}(Tx)_i + r_{30i}$
$\pi_{1i} = \beta_{10} + \beta_{11}(Tx)_i + r_{10i}$ $\quad\quad$ $\pi_{4i} = \beta_{40} + \beta_{41}(Tx)_i + r_{40i}$
$\pi_{2i} = \beta_{20} + \beta_{21}(Tx)_i + r_{20i}$

where *t* indexes time point and *i* indexes participants. DV_{ti} represents the outcome for each individual at each time point. Time will be coded with *four* dummy variables (6-*week*$_{ti}$, *3-month*$_{ti}$, *6-month*$_{ti}$, *and 9-month*$_{ti}$) that compare follow-up assessments to baseline (reference category). Tx is a dummy coded variable comparing the TM intervention condition to the AOC condition. We will test sex and age in all analyses. We will determine preliminary effect sizes using the

model shown in equation 1. The four treatment by time interactions (β_{11} to β_{41}) compare the change in the outcome since baseline between intervention and control.

Post-Intervention Interview Data. The interviews will be audio and videotaped and field notes will be recorded. Audio and video-recording will be used to ensure the best quality possible. Immediately after each interview, the recording will be backed up on a password-protected computer and on LabArchives, a secure HIPAA compliant server. This secure computer and Lab Archives will only be accessible to key study personnel. Within 1 year of each interview, trained and authorized research personnel will transcribe all audio and video recordings. The transcripts will not include any personally identifying information and will be stored on the secure computer and server separately from the original audio and video recordings. Drs. Litt and Lewis will review the qualitative data separately and highlight significant statements, sentences, or quotes that provide an understanding of how abstainer and lighter drinker college students respond to intervention content. These significant statements will be organized into clusters of meaning or themes. Drs. Litt and Lewis will then collaborate to develop an agreed-upon coding scheme which will become the coding template to identify and organize the overarching themes. This multiple coding ensures the qualitative analog of inter-rater reliability. The resulting themes will be discussed to explore feedback and implications for intervention materials. Atlas.ti.8, a qualitative software program, will be used to organize, code, and display themes of the data.

2) *Data Storage and Confidentiality* – Describe where the research data will be stored during the study and how it will be secured. The investigator must take necessary steps to maintain confidentiality of data. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to data. State who will have access to the data. If data with subject identifiers will be released, specify the person (s) or agency to whom the information will be released and the purpose of the release.

Online Assessments. *Data from all online assessments will be identified only by an eight-digit unique identifier randomly generated for research purposes, and will not be identified by participants' names.* Participants are assigned a unique identifier at the start of the online screening survey. This unique identifier will be embedded in all communications in which a link to surveys is sent. The unique identifier embedded in the survey link means that the link is specific to that individual and their survey data will be connected to that unique identifier. Thus, participants will not ever need to enter their unique identifier for purposes to complete study surveys. Participants are further protected by having an embedded unique identifier. An embedded unique identifier is more secure than emailing the unique identifier to participants as participants do not have to worry about keeping this information private. There is also less participant burden with the use of an embedded unique identifier as emailing the non-embedded PIN would require doing so in a separate communication than the survey link. The *participant's* unique identifier *is kept separate (i.e. stored in separate secure files on our HIPAA compliant*

server) from their personal information, so that without their unique identifier*, none of their answers can be linked to anything that might identify them. Identifiable data that will be kept separate and destroyed by the end of the study includes the user's IP address, name, contact information, date of birth, and apartment, street, city, and zip code of residency. Participants* will not be identified in any research reports or presentations of the research. Their name and contact information will be accessible only to research staff for the purposes of contacting them to complete the study, and will be stored separately from their data on computers with password protection and in locked file cabinets. The survey data will be retained indefinitely and will be identified only by the PIN. *The master list of identifiable data from personal data forms will be destroyed by the end of the full research study (i.e. when funding ends).*

Rivulent Web Design, Inc. will be programming screening survey and online scheduler for this project. All Freshman Experience Project survey data that is kept for study purposes will be collected via Rivulent Web Design, Inc. survey software and data will be saved on a secure server with dedicated space for Dr. Litt's research projects provided by Rivulent Web Design, Inc. Rivulent Web Design, Inc. employees and contractors are HIPAA certified. Data stored on the provided secure server is encrypted, password protected, and HIPAA compliant. To maintain the confidentiality of data submitted over the internet, participants will log in to a secure website using their unique PIN created for study purposes. Data transfer will be protected using Transport Layer Security (TLS) version 1.2 or higher. The TLS encrypted session will ensure that data moving from the participant to the server (i.e., participant responses) will be encrypted in transit using a 2048-bit minimum encryption key. Data downloaded from the dedicated Rivulent Web Design, Inc. server will be stored by the research team with secure storage within LabArchives network, and is located in a locally managed datacenter. The datacenter is protected by two-step verification, configured sharing permissions, monitoring of activity, disabled permanent deletions, and conduction of regular access reviews.

Any data stored for ineligible participants will not be used or saved in any way; instead it will be dropped (i.e. permanently deleted from survey data sets where information was collected from participants) after 30 days.

Post-Intervention Interview Data Storage. Each interview will be audio and video-recorded using the recording feature in Zoom, and field notes will be taken. The digital recording feature will not be accessible to participants since only the moderator has automatic access to this feature in Zoom. Unless the moderator chooses to make this feature available to the participants, no one will be able to record the interview through Zoom. The moderator will not grant participants the ability to record in Zoom and this feature will only be used for the described interviews. No other digital recording devices will be used (i.e., cell phones). Appropriate security measures are in place to ensure data confidentiality among research personnel. Data will only be collected and transcribed by study personnel. Electronic data (i.e., audio and video-recordings, transcripts, and field notes) will be stored on the HIPAA compliant LabArchives network following the conclusion of the interview. The interview recording will not to be saved on Zoom's server at any point. The recordings will be directly saved and stored in the

HIPAA compliant LabArchives network. Data will be stored by the research team with secure storage within the HIPAA compliant LabArchives network, and is located in a locally managed datacenter. The datacenter is protected by two-step verification, configured sharing permissions, monitoring of activity, disabled permanent deletions, and conduction of regular access reviews. The PI is responsible for the management of all data. Personal identifiers (including names and PINS) will be removed from all transcriptions and will not be reported, thus it will not be possible to link survey answers to interview data. Original audio and video-files will be transcribed within 1 year of recording date and will be deleted from the secure LabArchives network after transcription is complete. Each interview will be a separate digital file thus recordings can be deleted as each interview is transcribed. Participants are asked to not identify themselves by last name during the interview. Thus, audio and video files will not identify participants by full name. If participants disclose any identifying information (i.e., their full name), it will be redacted from all transcripts. Participants also have the option of using a nickname or alternative name during the interview if they do not want to use their first name. If a participant wishes to withdraw their responses before the audio and video recording is destroyed they may do so by contacting one of the key personnel. However, as stated in the consent form, once the audio and video recordings are transcribed that is no longer a possibility.

In addition to the above-described data safeguards, participants will be reminded both in the consent form and throughout the interviews to only use their first names and not discuss their personal drinking behaviors or provide any other identifying personal information. Next, all members of the research team have received or will receive training that includes emphasis upon the importance of confidentiality of information, and all personnel on the project (including research assistants and study staff) will complete the required NIH training in protection of human research participants. All staff will sign confidentiality statements. In addition, we will automatically be issued (upon notice of award) a federal Certificate of Confidentiality through the Department of Health and Human Services. This certificate offers the highest protection available by law for research data. We previously used these certificates in our work with high school students, college student gamblers, drinkers, marijuana users, and those who engage in risky sexual behavior. Participants will be informed of these risks and protections in the informed consent process. All recruitment contacts will emphasize the voluntary nature of participation to reduce risks of experienced coercion.

3) *Setting* - Describe briefly where the study will be conducted, e.g., private outpatient clinics, physicians' offices.
   NOTE: If other institutional review committees (IRBs) or approvals are required, note them by name, affiliation and contact person. Also, be aware that the approval of other institutions' IRBs must be obtained before initiation of the project (but are not essential for North Texas Regional IRB *review* to begin).

The study will be conducted online.

Each interview will be held in an online, encrypted Zoom session.

4) *Laboratory methods and facilities* - Indicate where specific laboratory tests will be performed; e.g., hospital chemistry laboratory, investigators' laboratory, radiology clinic, etc. If None, state N/A
N/A

5) *Estimated Period of Time to Complete the Study* – Describe the stages and total time of subject participation as well as overall time for the entire study (start to completion). Also, if study involves more than one visit, describe time range estimates for each visit (e.g., 20-30 minutes; 2 – 3 hrs, etc.). Where possible, use a table or "bullet-point" format to clearly illustrate the flow of activities and procedures.

Start to finish: 9 months
Online screening survey: 5-10 minutes
Online baseline survey: 45 minutes
6 weeks Intervention Content: 1-2 minutes per text message
Online 6-week, 3-month surveys: 45 minutes
Online 6-month, 9-month surveys: 25-30 minutes
Online interview: 60 minutes

F. Human Subjects - Describe the characteristics of the research population:

1) *Sample Size*: Number of subjects to be enrolled in this study at this site. Approximately 300 subjects at 1 sites in the U.S. will be enrolled in the study overall. Half of the subjects (150) will be randomized to the TM intervention and the other half to the control group.
For Clinical Trial studies, indicate number of subjects to be randomized N/A

2) Describe both *Inclusion AND Exclusion Criteria*. BE SPECIFIC! Also, if children (persons under age 18) are excluded from this study provide scientific justification for such exclusion. Include physical, mental, cognitive, medical, and other relevant Inclusion and Exclusion criteria.

Inclusion criteria:

1) Age 18-19 (If a participant screens in at age 19 and turns 20 prior to the start of the pilot study, the participant will be allowed to be in the research study.)

2) Birthdate that is consistent with their given age

3) First-year college student at the University of North Texas

4) Valid email address

5) Provide a valid mobile phone number and have a text messaging plan on their mobile phone

6) Consumed alcohol on average once a week or less in the last month

7) No episodes in the past month of consuming 5/4 drinks in the past month for men/women

8) Used marijuana once a week or less on average in the last month

9) Express any level of willingness to take a sip of alcohol

10) If female, must not be pregnant or trying to get pregnant

11) Have not received treatment for alcohol use

12) Willing to participate in the pilot study

Exclusion criteria include not meeting inclusion criteria, unwillingness to participate, failure to provide consent (e.g., declining participation in the study), providing inconsistent responses (e.g., age) identified by the survey, and having already participated in the study (*IRB* 2018-128 or this protocol) as identified by overlap or consistency in computer IP addresses, contact information, and demographics.

3) Describe intended *gender, age range, intended racial and ethnic distribution*. If any vulnerable subjects are involved in this study (e.g., those with limited autonomy or decision-making capabilities), justification must be provided.

We will aim to recruit an equal number of respondents for each age (18, 19) and to sample based on demographics of the University of North Texas.

4) Identify the *source(s) from which you will obtain your study population*.

We will reach a wide cross-section of 18-19 year-old first-year college students from the University of North Texas by recruiting via the University of North Texas student directory and in-person recruitment via handouts and flyers at orientation for incoming

first-year students and in residence halls. We will also be posting an ad in the UNT campus magazine, Connections Magazine. Lastly, we will be recruiting online through Virtual Resource Fairs for students who attend an online freshman orientation.

5) Describe plans for *recruitment of subjects*. All materials (e.g., flyers, ads, emails, letters, postings, handouts, etc.) to be used for recruiting subjects must be submitted to the IRB for review.

We will utilize a multi-method approach to reach a wide cross-section of college students from the UNT Denton Campus including in-person recruitment (e.g., tabling, distributing flyers and handouts at student dorms), using flyers and advertisements, online recruitment (e.g., submitting a video to Virtual Resource Fairs accessible by freshman students participating in online orientations), and sending student directory email invitations. See General Recruitment above for more information as well as information below.

UNT University Student Directory (see Appendix D)

Undergraduate first-year students aged 18-19 from the University of North Texas (UNT) who have opted to have publicly available contact information will be selected randomly from the Student Directory. Publicly available directory information is available via the campus registrar and is considered to be "information contained in an education record of a student which would not generally be considered harmful or an invasion of privacy if disclosed". The requested directory information requested will include name, university-assigned email address, mailing address, month and day of date of birth, admit term, and classification (i.e. year in school). The university directory does not allow the request of social security number, race, ethnicity, nationality, or gender. Students who have selected to not have their directory information publicly available will not be contacted for participation in this research study. For a student to indicate that they would like to withhold their information from the public directory, they must file a formal "Request to Prevent Disclosure of Directory Information" each semester. Participants who have not opted to withdraw their directory information, are age 18-19 (based on date of birth), and are enrolled as first-year students will be the only individuals contacted. A randomly selected sample from the university study directory will be sent emails. Up to 5,000 participants age 18-19 with public directory information will be randomly selected and will be sent information including an introductory email that contains a description and a unique link to the screening survey to determine eligibility for the study as well as a hyper-linked website address (URL) for more study information (See Appendix D for study website wording).

UNT Orientation and Magazine (See Appendix D)
In addition to the UNT registrar list, we will also conduct in-person recruitment via the distribution of handouts and flyers at orientations for incoming first-year students along with publication of an ad in their campus magazine, Connections Magazine. We will also conduct online recruitment via Virtual Resource fairs offered to freshman student who

participate in an online orientation. We will create and submit a video with information about us, the study, and what their participation in the study looks like.

UNT Residence Hall Flyers (See Appendix F)
Through collaboration with the Associate Director of Residence Life at UNT, Tomas Sanchez, we will be sharing study information with the UNT first-year students residing in their halls. We will share general information about what the study is about and what participation will look like with students. We will also be passing out currently approved flyers and handouts to students with our contact information so students are able to reach out to us with any questions they may have. Residence Life will not have access to information about participants enrolled in the study.

G. Risk/Benefit Assessment

1) Describe the *level of risk*, and if more than minimal, describe how this research holds the prospect of a *direct benefit for the subjects*. If there is NO direct benefit to subjects, state such in protocol and in the consent documents.

There is potential risk for participating in The Freshman Experience Project. The risks associated with participation are primarily related to the sensitivity of some of the questions. Participants will be asked about thoughts, feelings, and personal difficulties that may be private, as well as behaviors such as alcohol use and drug use. These questions may make participants feel uncomfortable or may seem intrusive, or participants may become concerned about their drinking or other health behaviors as they answer the questions. In addition, participants are asked to report on illegal behaviors, such as drinking under the legal age, or using controlled substances. Participants are free to skip over any questions they do not wish to answer. There is also risk for confidentiality; we discuss procedures below to protect participant confidentiality.

Although the Freshman Experience Project is not specifically designed to benefit participants there is potential for direct benefits for participants. The process of completing alcohol assessments is often illuminating for participants. Reactivity is the possibility that the research methods themselves affect the behavior under study. Research has shown that there is reactivity to alcohol assessment for longitudinal surveys such as those proposed in this project. Reactivity to alcohol assessment occurs when completing alcohol surveys is associated with changes in alcohol use, specifically reduced alcohol use. Thus, participants in The Freshman Experience Project have the potential to benefit from completing longitudinal surveys (screening, baseline, 6-week, 3, 6, and 9-month) and in addition to the intervention text messages which together should reduce their alcohol use as a result of completing all parts of the study.

2) Describe how the anticipated benefit justifies the risk.

As described above there is potential for reactivity to assessments including longitudinal surveys. Reactivity is the possibility that the research methods themselves affect the behavior under study. The process of completing alcohol assessments is often illuminating for participants such that they react by reducing their risk behavior. Research has shown that there is reactivity to alcohol assessment for longitudinal surveys (McCambridge & Kypri; 2011; Walters et al. 2009). Reactivity to alcohol assessment occurs when completing alcohol surveys is associated with changes in alcohol use, specifically reduced alcohol use. Thus, participants in The Freshman Experience Project have the potential to benefit from completing longitudinal surveys (baseline, 6-week, 3, 6, 9-month surveys) in addition to (for those in intervention group) receiving TM content aimed at reducing alcohol use. Thus, enrollment in the study over a course of 9 months may reduce their alcohol use as a result of completing The Freshman Experience Project assessments.

We believe that the potential risks of the study are reasonable in relation to the importance of the knowledge gained and justifies the risk regarding comfort to survey items and risk of confidentiality. The potential for reactivity from The Freshman Experience Project alcohol assessments (i.e., potential for participants to reduce alcohol use as part of the research study) are a potential benefit and we feel justifies the risks of The Freshman Experience Project; specifically, potential benefits from reactivity leading to reduced alcohol use justifies participants comfort with questions and confidentiality (discussed below). The fact that some individuals may have discomfort in reporting alcohol use may lead to the benefits of assessment reactivity, specifically reducing alcohol use. Given the rates of alcohol use in college students, and the negative health and behavioral consequences, increasing our understanding of the etiology of alcohol use has the potential to contribute to the development of interventions.

3) Describe how the anticipated benefit of this research is at least as favorable to the subjects as that to be received by available alternative approaches for the subjects.

If the participant chooses not to participate in the study but has questions about alcohol or other substances, we can provide them with a list of information and referrals within the community. See Referral Information Email.

4) Describe any potential RISKS OR DISCOMFORTS in detail. Use evidence from clinical and/or animal studies to evaluate the level of potential hazards associated with participation in the research protocol. Indicate the methods for detecting adverse reactions. Describe the procedures for protecting against or minimizing potential risks (e.g., confidentiality, reputational injury, direct injury or harm to subject, etc.) and assess their effectiveness. Discuss why the risks to the subjects are reasonable in relation to proposed benefits to mankind. Be sure to describe any anticipated adverse events that might occur during the course of the study.

The study procedures involve potential risk to participants. The consent procedures will make clear all of the potential risks of study participation. The most significant risk to participants in this research is loss of privacy and unauthorized release of confidential information. This could occur if the online Zoom interviews were hacked or if data on an individual participant, or the information that he or she was participating in a study of alcohol behavior, were to be released to anyone outside the study. Some of the questions asked may be a sensitive behavior. Such questions may make the participant feel uncomfortable, or be perceived as an invasion of privacy. In addition, participants are asked to report on illegal behaviors, such as drinking or marijuana use under the legal age and driving after drinking. Answers to these questions could pose a risk if the information were known and linked to identifiable individuals. We will receive a Certificate of Confidentiality from the National Institute on Alcohol Abuse and Alcoholism to prevent disclosure of sensitive or illegal behaviors. Further, all participants will be informed of the types of questions during the initial consent/training session.

We do not ask any survey items that assess suicide, child abuse, or child neglect, so we would have no data related to these topics to report. However, if a participant discloses this information we will report it to the appropriate official/agency.

Reporting alcohol use and consequences may make participants realize they are putting themselves at risk for negative consequences, potentially causing distress. We have procedures in place for referral to resources in the community (please see below).

Alternative treatments and procedures: Alternatives to web reports of drinking and its consequences include in-person interviews or self-administered written questionnaires. We believe that our web-based and automated procedures have several advantages over alternative methods of collecting this information. Our procedures do not carry any more risk than these alternatives, and may carry less risk and burden than using self-administered paper questionnaires or having to come into our offices multiple times to complete surveys.

We have taken steps to protect participants against potential risks posed by their participation in this research. Participants will be fully informed of the range of items and the most sensitive and personal items in the consent form, and will be informed that they are free not to answer any question they wish not to answer, and can refuse to participate or withdraw from participation at any time without penalty. Participants will still be able to submit a survey with unanswered questions and will still receive full compensation when submitting a survey with unanswered questions. Psychological risks of experienced invasion of privacy or increased awareness or concern about one's behavior as a result of completing the assessments and interview and potential loss of confidentiality will be addressed as a risk in the consent documents. All data and other information in the proposed research will be maintained confidentially, but will not be anonymous due to the longitudinal nature of participation. In order to protect against risks posed by a potential loss of confidentiality, we will take the following steps: First, all data will be identified only by a unique PIN, which will be randomly generated for study purposes. PINs will be embedded in individual survey links such that PINs do not need to be entered by participants or known by participants. Identifiable information entered online (such as contact information)

will be downloaded and stored separately from participants' responses, but will be identified by the PIN. A master list of names and PINs will be stored in a password-protected database, on a password-protected computer with restricted access, and will be available only to senior research staff and the PI on this project. Electronic data (i.e. audio and video-recordings and transcripts) will be stored on password-protected secure computers only accessible to study personnel. Second, all members of the research team have received or will receive training that includes emphasis upon the importance of confidentiality of information, and all personnel on the project (including research assistants and study staff) will complete the required NIH training in protection of human research participants. All staff will sign confidentiality statements. Third, to maintain confidentiality of data submitted over the internet, participants will be required to log into a secure and HIPAA compliant servers using their unique PIN created for study purposes. The PI has extensive experience with conducting online recruitment and assessment with no adverse events ever occurring from this method of data collection or stated procedures. Fourth, we will receive a federal Certificate of Confidentiality through the Department of Health and Human Services. This certificate offers the highest protection available by law for research data. We previously used these certificates in our work with high school students, college student gamblers, drinkers, marijuana users, and those who engage in risky sexual behavior. Participants will be informed of these risks and protections in the informed consent process. All recruitment contacts will emphasize the voluntary nature of participation, to reduce risks of experienced coercion. Fifth, to maintain confidentiality through the use of Zoom, connection to the online session will be protected using 256-bit Transport Layer Security (TLS). The use of TLS encryption will provide safety against the online training session being intruded. Additionally, through the use of waiting rooms on Zoom, the interview facilitator will have the ability to only let into the online session the correct participant and not any unwanted guests. This will minimize the possibility of the Zoom server being hacked and the resulting loss of confidentiality. Finally, participants will be notified of the potential risk that the information provided may not be helpful, and will be provided with information about where else they might seek information about alcohol use, or receive alcohol-related services if desired.

Participants are encouraged to contact the investigators at any time to discuss any concerns they might have. Participants who express interest in seeking help for substance-related problems or for psychological distress will be offered referral information. Participants will not be restricted from seeking other alcohol or mental health education, prevention, or treatment opportunities, and we will assess for use of other services at each assessment.

A plan is in place for identifying and referring individuals who report significantly worsening alcohol use trajectories as well as consumption of potentially lethal doses of alcohol (BAC's above .35). Specifically, the baseline, 6-week post-intervention and 3, 6, and 9-month follow-up surveys will be screened for indication of significant risk based on criteria established in our prior trials of this nature and the research literature (i.e., endorsement of "I've not been able to remember large stretches of time while drinking heavily" in combination with a BAC in the past month exceeding .35%; Chung et al., 2000; 2002). Thus, both outcomes will be used to assess hazardous alcohol use for referral in combination of .35% BAC. Once identified, these individuals will be emailed local referral information. If participants meet this criterion a second

time, these individuals will be contacted by Dr. Litt within 48 hours to explain their risk and to provide referral. In our ongoing trials, we have used this procedure without incident, and have provided referrals for both alcohol and mental health treatment. Information regarding the potential for a follow-up contact by the investigators to clarify responses or provide information is included in the consent documents. Participants are also informed in the consent form that they are free to seek other services for their alcohol use. This structure is currently in place and approved at both the local and federal level on all our existing drinking and health-risk behavior studies. All participants, at the end of participation, will be provided with a brochure regarding referral resources available in the local area.

Please see Appendix C for the clinical call script.

H. Payment/Compensation - Describe any financial payments for subject participation (e.g. compensation for time and travel). Indicate any partial payment schedule for less than complete study participation. Recall that payments cannot be perceived as coercive (overpayment for time and effort). Remember: payments are NOT benefits.

Intervention. Participants can earn $20 for baseline, $25 for the 6-week follow-up, $30 for the 3-month follow-up, $35 for the 6-month follow-up, $40 for the 9-month follow-up, meaning that participants can earn up to $150. Upon completion of the baseline survey, participants will be mailed a Greenphire Mastercard (not yet loaded with $20 for the online baseline survey) that can be loaded with compensation for completing future study assessments. Participants are notified in the baseline survey end page and in the frequently asked question sheet (mailed to them with their Greenphire Mastercard) that they will need to contact us via email or phone when they receive their card. At this point, we will load the money onto their Mastercard. If a participant does not call/email confirming they have received their Greenphire Mastercard within 1-2 weeks after their card was mailed, we will periodically contact them over the phone to confirm if they have received their card. In the event they have not received it after a prolonged period of time, we will re-send them another Greenphire Mastercard to their preferred mailing address. See Appendix C for what a Greenphire Mastercard looks like. For all follow-up survey payments, research team members log into the Greenphire platform, select the correct study participant, and then selects the correct amount of compensation credit to be loaded onto the card. Within 24-48 hours that amount is loaded onto the participant's Greenphire Card and available for use. Participants will receive text (up to 5) and email (up to 5) notifications when their card is loaded with payments (Appendix C) across the study. Participants will be provided Greenphire ClinCard FAQs and information on how the Greenphire ClinCard can be used (Appendix C).

Post-Intervention Interview. Participants who complete the post-intervention interview can earn $50 and will have their payment loaded on their existing Greenphire mastercard that was used for the follow-up survey payments or will be mailed a new Greenphire Mastercard if needed. If a new card is sent, it will be used to pay them $50 for completing the interview.

Each Greenphire Mastercard has a unique identifier. In monthly Greenphire reports, this identifier will indicate payment amount and payment date for each payment to participants. This monthly Greenphire report will verify each and every payment for compliance purposes. Greenphire has an option to request or not request social security numbers for payment. We do not request this information as it is not a requirement for Greenphire or for study purposes.

We will advise individuals without a government-issued photo ID that they will not be able to use their Greenphire Mastercard to get a cash advance at a bank.

Compensation:

Online screening: No incentive
Baseline: 45 minutes, $20
6-week follow-up: 45 minutes, $25
3-month follow-up: 45 minutes, $30
6-month follow-up: 25-30 minutes, $35 and additional incentive item*
9-month follow-up: 25-30 minutes, $40 and additional incentive item*
Post-intervention interview: 60 minutes, $50

*Additional incentive items: Each participant will receive an incentive item (e.g., phone pop holder, cell phone charger) valued at no more than $10 shortly before the start of their 6-month and 9-month surveys.

Total Possible Over the Course of Intervention: $150
Total Possible for Post-Intervention Interview: $50

I. Subject Costs - Describe any anticipated costs to research subject. If none, state such.

Participants in the intervention condition need a smartphone for the 6 weeks of TM intervention content and the use of their phone may contribute to the use of their data use/data plan.

J. List of KEY PERSONNEL. List all individuals directly involved in the conduct, design or reporting of research involving human subjects in this study, including anyone who may be consenting subjects. This list will include the Principal Investigator, Co-Investigators, collaborating investigators, study coordinators, etc.

Name & Degree: Dana M. Litt, Ph.D.
Department: Health Behavior and Health Systems in the School of Public Health at the University of North Texas Health Science Center
Role: Principal Investigator
Responsibilities: Dr. Litt will dedicate FTE in all years and will be responsible for the overall scientific direction of the research, including design and development of protocols, assessments, materials, participant recruitment and retention, human subjects' compliance, data analysis, and dissemination of results. Dr. Litt will oversee the duties of project staff. She

will also take an active part in the data analysis and dissemination efforts, being responsible for first authoring several papers, conducting data analyses, and supporting co-authors in dissemination efforts. Dr. Lewis has a long history of collaboration with each member of the research team as evidenced by collaboration on current NIH grants or publications. As Principal Investigator, Dr. Litt will be responsible for monitoring and reporting all adverse events. Dr. Litt will conduct regular staff and investigator meetings and closely monitor all project activities to insure that the project is successfully completed efficiently and on time.

Name & Degree: Melissa A. Lewis, Ph.D.
Department: Health Behavior and Health Systems in the School of Public Health at the University of North Texas Health Science Center
Role: Co-Investigator
Responsibilities: Dr. Lewis will collaborate with Dr. Litt and the research team to provide expertise in recruitment and retention of participants as well as expertise related to text messaging interventions. Dr. Lewis will dedicate FTE working with Dr. Litt and other investigators and staff members, attending staff meetings, and providing expertise as previously described. She will also collaborate with the research team in the dissemination of research findings and preparation of scientific reports.

Name & Degree: Zhengyang Zhou, Ph.D.
Department: Health Behavior and Health Systems in the School of Public Health at the University of North Texas Health Science Center
Role: Co-Investigator
Responsibilities: Dr. Zhou will run data analyses and collaborate with the research team in the dissemination of research findings and preparation of scientific reports.

Name & Degree: Heidemarie Blumenthal, Ph.D.
Department: Department of Psychology at the University of North Texas
Role: Co-Investigator
Responsibilities: Dr. Blumenthal will be working with Dr. Litt and other investigators and staff members. She will also collaborate with the research team in the dissemination of research findings and preparation of scientific reports.

Name & Degree: Morgan Seamster, BS

Department: Health Behavior and Health Systems in the School of Public Health at the University of North Texas Health Science Center

Role: Graduate Student

Responsibilities: Morgan Seamster will assist the Research Assistant as needed in the coordination of project tasks, scheduling of team meetings with investigators, monitoring

participant email and phone communications, participating in meetings with study investigators, and coordination of recruitment materials. She will also assist the Research Assistant in preparation, review, and modification of human subjects forms and scripts; preparation of materials to be mailed to participants; and subject payments. She will also assist in facilitating focus groups. This individual will assist with the preparation of timely status reports and updates for the investigators. In addition, she will assist in dissemination of research findings through assistance with manuscript preparation.

Name & Degree: Allison Cross, MS

Department: Health Behavior and Health Systems in the School of Public Health at the University of North Texas Health Science Center

Role: Graduate Student

Responsibilities: Allison Cross will assist the Research Assistant as needed in the coordination of project tasks, scheduling of team meetings with investigators, monitoring participant email and phone communications, participating in meetings with study investigators, and coordination of recruitment materials. She will also assist the Research Assistant in preparation, review, and modification of human subjects forms and scripts; preparation of materials to be mailed to participants; and subject payments. She will also assist in facilitating focus groups. This individual will assist with the preparation of timely status reports and updates for the investigators. In addition, she will assist in dissemination of research findings through assistance with manuscript preparation.

Name & Degree: Katherine Vrotsos, MS

Department: Health Behavior and Health Systems in the School of Public Health at the University of North Texas Health Science Center

Role: Graduate Student

Responsibilities: Katherine Vrotsos will assist the Research Assistant as needed in the coordination of project tasks, scheduling of team meetings with investigators, monitoring participant email and phone communications, participating in meetings with study investigators, and coordination of recruitment materials. She will also assist the Research Assistant in preparation, review, and modification of human subjects forms and scripts; preparation of materials to be mailed to participants; and subject payments. She will also assist in facilitating focus groups. This individual will assist with the preparation of timely status reports and updates for the investigators. In addition, she will assist in dissemination of research findings through assistance with manuscript preparation.

Name & Degree: Haleigh Hicks, BA

Department: Health Behavior and Health Systems in the School of Public Health at the University of North Texas Health Science Center

Role: Research Assistant

Responsibilities: The Research Assistant will coordinate project tasks with Dr. Litt and Dr. Lewis, coordinate scheduling of team meetings with investigators, monitor participant email and phone communications, participate in meetings with study investigators, work with Dr. Litt in coordination of recruitment materials, and being the primary contact for participants. She will manage the secure database that records participant information not kept with the data files (e.g., contact and other personal information), as well as program the initial screening. The Research Assistant will also be responsible for assisting in preparation, review, and modification of human subjects forms and scripts; preparation of materials to be mailed to participants; and subject payments. This individual will assist with the preparation of timely status reports and updates for the investigators. In addition, the Research Assistant will assist in dissemination of research findings through assistance with manuscript preparation

Name & Degree: Delaney Miller, BS

Department: Health Behavior and Health Systems in the School of Public Health at the University of North Texas Health Science Center

Role: Research Assistant

Responsibilities: The Research Assistant will coordinate project tasks with Dr. Litt and Dr. Lewis, coordinate scheduling of team meetings with investigators, monitor participant email and phone communications, participate in meetings with study investigators, work with Dr. Litt in coordination of recruitment materials, and being the primary contact for participants. She will manage the secure database that records participant information not kept with the data files (e.g., contact and other personal information), as well as program the initial screening. The Research Assistant will also be responsible for assisting in preparation, review, and modification of human subjects forms and scripts; preparation of materials to be mailed to participants; and subject payments. This individual will assist with the preparation of timely status reports and updates for the investigators. In addition, the Research Assistant will assist in dissemination of research findings through assistance with manuscript preparation

K. Literature Cited – If any, the references should be limited to relevant and current literature pertinent to the proposed research.

Doumas, D. M., Hausheer, R., Esp, S., & Cuffee, C. (2014). Reducing alcohol use among 9th grade students: 6 month outcomes of a brief, Web-based intervention. *Journal of Substance Abuse Treatment*, *47*(1), 102-105. doi:10.1016/j.jsat.2014.02.006

Gruenewald, P. J., Johnson, F.W., Light, J.M., Lipton, R., & Saltz, R.F. (2003). Understanding college drinking: assessing dose response from survey self-reports. *Journal of Studies on Alcohol, 64*(4), 500-514. doi: 10.15288/jsa.2003.64.500

Gruenewald, P. J., Johnson, F. W., Ponicki, W. R., & LaScala, E. A. (2010). A dose response perspective on college drinking and related problems. *Addiction*, *105*(2), 257-269. doi:10.1111/j.1360-0443.2009.02767.x

Haug, S., Castro, P.R., Kowatsch, T., Filler, A., & Schaub, M.P. (2017). Efficacy of a web- and text messaging-based intervention to reduce problem drinking in adolescents: Result of a cluster-randomized controlled trial. *Journal of Consulting and Clinical Psychology, 85*(2), 147-159. doi: 10.1037/ccp0000138

King, K. M., & Chassin, L. (2008). Adolescent stressors, psychopathology, and young adult substance dependence: A prospective study. *Journal of Studies on Alcohol and Drugs*, *69*(5), 629-638. doi: 10.15288/jsad.2008.69.629

Lee, C. M., Lewis, M. A., & Neighbors, C. (2009). Preliminary examination of Spring Break alcohol use and related consequences. *Psychology of Addictive Behaviors, 23*(4), 689-694. doi: 10.1037/a0016482

Lewis, M. A., Rees, M., & Lee, C. M. (2009). Gender-specific normative perceptions of alcohol-related protective behavioral strategies. *Psychology of Addictive Behaviors, 23*(3), 539. doi: 10.1037/a0015176

Litt, D. M., Fairlie, A. M., Neighbors, C., & Lewis, M. A. (2017). Efficacy of a dual-process based personalized feedback intervention for alcohol use. *Manuscript in preparation.*

Sher, K. J., & Rutledge, P. C. (2007). Heavy drinking across the transition to college: Predicting first-semester heavy drinking from precollege variables. *Addictive Behaviors*, *32*(4), 819-835. doi: 10.1016/j.addbeh.2006.06.024

Toomey, T.L. & Wagenaar, A.C. (2002). Environmental policies to reduce college drinking: options and research findings. *Journal of Studies on Alcohol, Supplement, (s14),* 193-205. doi:10.15288/jsas.2002.s14.193

Weitzman, E. R., & Nelson, T. F. (2004). College student binge drinking and the 'prevention paradox': Implications for prevention and harm reduction. *Journal of Drug Education*, *34*(3), 247-265. doi:10.2190/W6L6-G171-M4FT-TWAP

Attachments (in this order):

I. *Consent Form* - THE CONSENT FORM IS TO BE A SEPARATE DOCUMENT. It is important that this form follows the IRB-prescribed format and includes all the required elements and certain other elements when appropriate.

II. Recruitment Materials (ads, flyers, emails, etc.) to be used in this Study

III. Study Documents (questionnaires, survey instruments, clinical trial protocol, investigator's brochure, etc.)

IV. Evidence of Human Subject Training for ALL Key Personnel listed in the protocol.

V. Conflict of Interest Form, completed and signed by EACH Key personnel listed in the protocol.