Parental Research on Interventions for Social Media (PRISM)
NCT04333966
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Protocol Synopsis for Research Project Involving Human Subjects

PROTOCOL INFORMATION

Title of Research Activity: Parental Research on Interventions for Social Media (Project PRISM) (Phase II)

Name of Principal Investigator: Dana M. Litt

Institution: University of North Texas Health Science Center

Names of each Co-Investigator: Melissa A. Lewis

Sponsoring Agency / Company (if applicable): NIH/NIAAA

Sponsor's Protocol Number (if applicable): R34 AA026332

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

Please note that this IRB application is being made only for Phase 2 (Aim 2) of the associated grant proposal. Aim 1 is being conducted under IRB approval 2019-035.

Aim 1 (*IRB approval 2019-035)*: Develop and refine an interactive parent based intervention (PBI) targeting the influence of social networking site (SNS) on high-risk SNS cognitions and alcohol use among adolescents. Interactive PBI content and text message prompts will be developed through focus groups, which will inform a new interactive PBI to be tested in a pilot study (Aim 2). Up to 20 focus groups (for a total of no more than 160 participants (80 parents, 80 teens) will be conducted with 8-10 people in each group with parents only being in focus groups with other parents and teens being only with other teens. Focus groups will engage in parent and teen specific focus groups in which they will be asked to view and interact with the interactive SNS PBI and generate additional PBI content.

Aim 2: Conduct a pilot study with parents and their adolescents aged 15-20 from the Dallas/Fort Worth (DFW) area to determine feasibility, acceptability, and preliminary effect sizes (to estimate power and sample size for a future R01 application). Parent/teen dyads (N=150 dyads for a total of 150 parents and 150 teens) will be randomized to interactive PBI (n=75 dyads) or active control (n=75 dyads) with a 1- and 6-month follow-up. Parents in the interactive PBI condition will receive the interactive web-based SNS PBI with text message prompts developed and finalized through Aim 1 focus groups. Parents in the active control condition will receive an emailed copy of the Surgeon General's Call to Action: A Guide for Families. General Hypotheses (parent and teen). *We hypothesize* that the interactive SNS PBI will be feasible (i.e., number of eligible participants, number of parents who gave consent, number of teens who gave consent, length of time to achieve planned recruitment and enrollment goal, rate of study completion and rate of study attrition)

and acceptable (i.e., proportion of parents and teens who find the intervention acceptable; ease of viewing and interacting with interactive PBI content; relevance of material; finding content helpful, beneficial, important; ratings of individual web-based modules and text messages of the PBI; the proportion of parents and teens who would recommend the study to other families, and the proportion of parents and teens who found the interactive PBI to be favorable overall) relative to active control. We further hypothesize that teens and parents in the interactive PBI condition will report more positive communication about alcohol and SNS at the 1- and 6-month follow-up relative to active control. *Parent Hypotheses*: We hypothesize that at 1- and 6-month follow-up, parents in the interactive PBI condition will report greater knowledge about alcohol as well as the role of SNS in alcohol use relative to active control. *Teen Hypotheses*: We hypothesize that teens in the interactive PBI condition will report less drinking, fewer alcohol-related negative consequences, less favorable attitudes toward posting about alcohol on SNS, greater perceived vulnerability to the risks of posting alcohol displays on SNS, and decreased normative perceptions about how many teens post alcohol displays on SNS relative to active control at 1- and 6-month follow-up.

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.

Although adolescents spend an increasing amount of time with their friends (Currie et al., 2012; Steinberg, 2001), parents remain an important source of support and continue to play a key role in the lives of their adolescents (Steinberg, 2002; Turrisi et al., 2000). The extensive work in this area has resulted in parent-based intervention (PBI) efforts to prevent or reduce adolescent alcohol use (Jaccard & Levitz, 2013). Research has shown that teens whose parents received a PBI reported less alcohol use and fewer alcohol-related consequences up to 9-month follow-up relative to controls (Ichiyama et al., 2009; Testa et al., 2010; Turrisi et al., 2001, 2010). However, one major limitation of PBIs is that they do not currently take into account the large role that social networking sites (SNS) play in adolescents' lives and in relation to their alcohol use. Most (90%) adolescents are on SNS (Lenhart, 2015), and their Facebook, Instagram, and Twitter profiles include alcohol content (e.g., Cavazos-Rehg et al., 2015; Moreno et al., 2007, 2009). Thus, adolescents are making and are exposed to SNS alcohol displays, and these displays are associated with high-risk cognitions and alcohol use (e.g., Fournier et al., 2013; Litt et al., 2018; Litt & Stock, 2011; Moreno et al., 2012). Research has argued that existing parental mediation techniques grounded primarily on television/film media have fundamental inadequacies when applied to more interactive media such as websites, social media, and mobile apps as they do not account for the interactivity, immersive virtual environments, and mediated communication innate to SNS (Jiow et al. 2016). Further, most PBIs are presented in static manual form (Kuntsche & Kuntsche, 2016; Turrisi et al., 2010; 2013). We are unaware of any study to date that has developed and tested an interactive PBI about alcohol use and the role of SNS in adolescent alcohol use. As such, we propose to develop and refine an interactive PBI designed to reduce both high-risk SNS cognitions and alcohol use among adolescents. This application responds to PA-18-067 "Pilot and Feasibility Studies in Preparation for Drug and Alcohol Abuse Prevention Trials" as it aims to establish feasibility and acceptability of the newly developed interactive PBI that focuses on the role of SNS in adolescent alcohol use as well as to determine preliminary effect sizes for future studies.

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

Drs. Litt and Lewis have extensive experience with recruiting and retaining representative adolescent and YA samples for clinical trials, experimental, and longitudinal research as well as obtaining parental consent. Dr. Litt conducted a Facebook study with 200 participants ages 13-15 recruited from the local community (Litt & Stock, 2011). Dr. Litt recently conducted a study (R21AA024163) with participants age 15 to 20 (N=306; mean age 18.4, 47% male) for an experimental study on SNS alcohol displays. For those participants age 15 to 17, we obtained parent consent from 87 of 93 parents (94%). Dr. Lewis has multiple funded studies that utilize the recruitment methods proposed in the application, all of which include local or national adolescent and YA samples (age 15-25) recruited via methods similar to those proposed herein. We recruited (UW ADAI) a national sample (N =370) ages 17-25 in five months. Of relevance to the current application, 201 participants age 17 completed the online screening and we obtained parent consent from 73.2% of parents of those teens. In addition, we conducted an intensive ecological momentary assessment study (UW ADAI) with participants age 15 to 25 (N=124; 41.5% age 15-17; M age =18.72, *SD* = 2.86). We recruited the sample over 4 months during the academic year (mid-Feb. to mid-June 2017). For those participants age 15 to 17 who expressed interest, we obtained parent consent from 66 of 74 parents (89%). Drs. Litt and Lewis have also used an effective process for verifying age and other inclusion criteria, as proposed herein, for potential adolescent and YA participants and their parents recruited from multiple sources for two NIAAA projects (R01AA021379, R21AA024163).

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 in 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 four grants that examine the prevention of young adult alcohol use (R00AA020869; R21AA024163; R34AA026004; R34AA026332). In order to successfully accomplish the proposed research plan, I have chosen a strong co-investigator (Dr. 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 -

We will utilize a multi-method approach to reach a wide cross-section of parents of adolescents and young adults from Texas, including online and electronic newspaper ads, electronic flyers, and social

media. Online ads will be placed in local and social media outlets frequented by those likely to have children age 15-20. Please see Appendices for sample advertisements.

We will use paid ads on Twitter, Instagram, Facebook, and other social media platforms. Social media outreach will also consist of an online Facebook, Twitter, and Instagram Fan page. Social media outreach will be from the **ST**udying **A**lcohol and **R**elated **R**isks (STARR) lab accounts and a specific Project PRISM Facebook account (same account approved for Phase 1 of PRISM). Because most STARR Lab research is aimed at adolescents and young adults and Facebook is more popular among adults of parenting age, the PRISM Facebook page will be geared towards advertising and updates to parents, the focus of recruitment for PRISM. Drs. Litt and Lewis are co-directors of the STARR lab. By using STARR lab social media accounts for our lab in addition to the PRISM specific Facebook page, we allow additional protection for participants as interaction with our social media accounts will not indicate that a participant is in a specific study since multiple studies are conducted by the STARR lab. Moreover, there are additional individuals other than study participants who will interact with STARR lab social media and PRISM Facebook account, such as co-investigators, collaborators, and current and future graduate students. Researchers will interact with STARR lab social media by answering inquiries about the study and promoting other research studies pertaining to STARR lab. Researchers will interact with the PRISM specific Facebook page by answering inquiries about the study and sharing general information about the STARR lab and related social media. This will allow additional protection to study participants as it will not indicate study participation in a particular study or any study at all. 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 and PRISM Facebook accounts and the lab phone numbers used for Project PRISM. Thus, only those on this IRB protocol will respond to participant inquiries. Researchers will direct interested participants to the online survey link that they can find on the STARR lab and PRISM social media accounts and to the project website. Screening will only occur online so any interested participants will be directed to the online screening survey when calling. Researchers will also answer any questions interested participants might have about the study. There will be an active post for the online screening survey on all STARR lab and PRISM social media accounts for Project PRISM. This will be the only screening survey for Project PRISM. This survey will begin steps for study eligibility for Project PRISM only. There will be no generic screening survey related to all projects, only the screening survey specific to Project PRISM. The posts for Project PRISM will only be about Project PRISM and eligibility for Project PRISM. Individuals can like or share STARR and PRISM related accounts and posts. Research articles shared on the STARR and PRISM social media accounts are for information purposes for the team and their areas of research, **not** recruitment purposes. Individuals will not be able to post on the Facebook fan page without administrator approval by the research team and comments will be disabled. Online recruitment ads (e.g., Craigslist, Twitter, Instagram, Facebook, online newspapers) will provide a hyper-linked website address (URL) for more study information and eligibility screening. Other research projects that may recruit though the fan page will only be those approved by IRB beforehand and only those pertaining to STARR lab. In addition to other study information, there is a section on the study website that will lead individuals to the online consent statement and the online screening survey.

We will also recruit parents through community organizations in major Texas cities. Contacts at community organizations will be initially contacted via email by project staff. In this email, project staff will provide information about the study and encourage further questions. If they agree to share study information with their members, study staff will send them the consent link and/or QR code. Similar emails will be sent to high school administrators to recruit the parents of students.

Links to our social media accounts are below.

Project PRISM website: *To be constructed once website language is approved*.*

**Note that we will not launch the study or initiate participant recruitment for this project until a link to the live parent-based intervention website has been reviewed and verified by the IRB.*

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

PRISM Instagram: https://www.instagram.com/prism.unthsc/

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

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

STARR Twitter: https://twitter.com/STARRLab_UNTHSC

Study Reminders.

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

Recruitment Methods.

1. **Online advertising (See Appendix D)**
    a. *Social Networking Sites.* We target ads to show up in newsfeed of individuals age 30-66 in Texas. We pay for ads to show up in newsfeeds and sponsored stories on Facebook and Instagram. We do not buy ad space. Ads for this study will show up by age and/or birth sex to those in Texas. Ads do not appear based on any keywords. We submit ads directly via Facebook for both Facebook and Instagram and directly to Twitter. We do not use a recruitment agency. Ads in newsfeeds cannot be seen by anyone other than the individual. They are not permanent to newsfeeds. Because these ads are not permanent and cannot be seen by anyone other than the participant they do not increase or pose additional risk. Participants will have the option to hide or not see any ads from the STARR Lab that will promote Project PRISM on Facebook, Instagram, and Twitter if they so choose. This is always an option for any ad on Facebook, Instagram, and Twitter. Project PRISM ads from the STARR lab would not trigger any other ads related to alcohol or drugs as we do not use these keywords for ads. Ads in newsfeeds are not visible to anyone other than the participant. The use of a Facebook Fan page for study communications is included in the consent documents. Participants will not be able to post on the Facebook Fan page without administrator approval by the research team. In all consent documents, we inform parents and/or participants that if they "like" our Facebook Fan page and/or follow our Instagram or Twitter, they may see posts by the study research team. Liking the Facebook Fan page and/or following the Instagram or Twitter, is optional, are not required for study participation, and is not an indication of study participation as anyone who is a member of Facebook can like the study Facebook fan

page or follow the study Twitter or Instagram. Posts on Facebook, Instagram, and Twitter will not refer to specific compensation amounts.

b. *Other Online Channels.* Online advertising will also be administered through Craigslist and online channels (e.g., online version of the Star-Telegram, Dallas Observer).

2. In-person recruitment and flyering (see Appendix D)

a. Study staff will go to community areas (i.e., businesses and community centers) to hand out study flyers. Flyers will contain a brief description of the study, contact information, website link, and link to the online screening survey.

b. Study staff will also post flyers in community areas (i.e., business and community centers).

3. High Schools (see Appendix D)

a. Study staff will contact local high schools to post ads in their school newspaper. Once ads are approved by the high school, the ads will be published in their seasonal newsletter or newspaper. The ads will contain a brief description of the study, contact information, website link, and link to the online screening survey.

b. Study staff will contact Texas high schools to share study information to parents in their community in any form they can (e.g., via email). If the contacts (e.g., school counselors, principals, teachers, etc.) agree to share the study's information with their parents, we will share with them the study's consent link and the study's QR code. Information shared with the parents will be currently approved language (e.g., summary of the study) and study materials (e.g., flyer, consent link). We are willing to get any special authorizations required, if needed. We will follow the policies they have in place in respect to sharing information with their students.

4. Future Contact List

a. Individuals that previously completed the screening survey for Project PATH (IRB #2018-077) will receive one email invitation and 2 reminder emails to participate in this study. They will only receive this invitation if they indicated that they wish to be contacted for future research in the online screening survey they initially completed. For eligible and ineligible individuals that indicated "yes" to being contacted for future research opportunities, all personal contact information was kept separate from their non-identifiable survey data. The email invitation will include information about Project PRISM as well as a link to the parent consent and screening survey. It will be sent to the email they provided in the Project PATH screening survey. If teens are interested, they can encourage their parents to read about the study and take the parent screening survey.

b. Individuals that previously completed the screening survey for The Freshman Experience Project (IRB #2018-128) will receive one email invitation and 2 reminder emails to participate in this study. They will only receive this invitation if they are within the eligible age range and indicated that they wish to be contacted for future research in the online screening survey they initially completed. Participants were only asked this question if they were 18-19 years of age. For eligible and ineligible individuals that indicated "yes" to being contacted for future research opportunities, all personal contact information was kept separate from their non-identifiable survey data. The email invitation will include information about Project PRISM as well as a link to the parent consent and screening survey. It will be sent to the email they provided in The Freshman Experience Project screening survey. If teens are interested, they can encourage their parents to read about the study and take the parent screening survey.

c. Individuals that previously completed the screening survey for Project EQUIP (IRB #2020-139) will receive one email invitation and 2 reminder emails to participate in this study. They will only receive this invitation if they indicated that they wish to be contacted for future opportunities in the online screening survey they initially completed. For eligible and ineligible individuals that

indicated “yes” to being contacted for future research opportunities, all personal contact information was kept separate from their non-identifiable survey data. The email invitation will include information about Project PRISM as well as a link to the parent consent and screening survey. It will be sent to the email they provided in Project EQUIP screening survey. If teens are interested, they can encourage their parents to read about the study and take the parent screening survey.

5. **Community Organizations (See Appendix D)**
    a. Study staff will contact Texas community organizations to share study information (e.g., via email). If the contacts agree to share the study’s information with individuals in their organization, we will share with them the study’s consent link and the study’s QR code for easy access. Any information shared will be currently approved language (e.g., summary of the study) and study materials (e.g., flyer, consent link). We are willing to get any special authorizations required. We will follow the policies they have in place in respect to sharing information with individuals in their organization.

Online Screening (see Appendix B)

Parents. After receiving information about the study and being presented with the online informed consent statement that covers the screening survey, intervention, and follow-up surveys, if eligible (Appendix A), 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. 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. Only those participants who sign both the online consent/assent form and HIPAA Authorization Form (one for themselves; one for their child if age 15-17) will be routed to the Screening Welcome Page. The consent form will include signature boxes for parent consent for self and parent consent for their child if age 15-17. HIPAA forms will be separated for parent and for their child. Once they hit the “Next” button on the screening welcome page, they will be routed to the online screening consent survey. Participants who do not provide consent for themselves (and consent for their teen if age 15-17) as well as HIPAA authorization forms for themselves (and their teen if age 15-17) will be routed to the screening decline page and will never view the screening survey. 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.

Participants who provide consent will receive demographic questions (i.e., birth sex, race, ethnicity,) and items that assess crucial eligibility questions such as “Which social networking sites (SNSs) do you think *(INSERT TEEN’S NAME) has an active profile with?” and “Are you willing to participate in a study that involves a parenting program and a series of online surveys with your teen?” The survey for parents will ask them to provide their contact information as well as their child’s contact information (and parental consent and HIPAA authorization if their teen is age 15-17). Parents do not need to provide consent or HIPAA authorization for their teen if they are age 18-20, but they will still need to provide their teen’s contact information so that we can contact their teen with more information about participating in the study. Participants will receive an online copy of their consent form via email and can request to be mailed a printed copy of their signed consent form. In addition, confirmation emails will be sent to participants to indicate receipt of their online screening survey. 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 good fit for the present study. They will also receive an email informing them that they are not eligible for the study. If a parent consents but

does not complete the screening survey, they will receive up to 3 email reminders to complete the screening survey.

Parents are informed in the Parent Consent Form that their teen will be asked to sign their own consent/assent form to indicate whether or not they want to participate in the research study. In the event that we do not receive a completed teen consent form, parents will be sent an email, SMS, and up to 5 call reminders.

Participants age 15-20. Once a parent has been deemed eligible and provided contact information (and consent and HIPAA form for their teen age 15-17), their teen will be sent a link (using the contact information their parent provided) to the consent form and screening survey. Only participants age 15-20 who have a parent who has completed the online screening survey (and provided consent for their teen age 15-17) will be sent a secure link to complete their screening survey. We will send up to 7 email, 7 text, and 5 call reminders to teens who do not respond to the screening invitation. Participants will be presented with an online informed consent statement and 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. 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. Only those participants who sign both the online consent form and HIPAA Authorization Form will be routed to the Screening Welcome Page. Once they hit the "Next" button on the screening welcome page, 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 or ineligible page and will never view the screening welcome page. 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. Participants who are age 15-20 will receive demographic questions (i.e., birth sex, race, ethnicity,) and items that assess crucial eligibility questions such as "Which social networking sites (SNSs) do you have an active profile with? Check all that apply)" and "Are you willing to complete 3 45-minute online surveys over the course of 6 months?" Participants will receive an online copy of their consent form via email and can request to be mailed a printed copy of their signed consent form. In addition, confirmation emails will be sent to participants to indicate receipt of their online screening survey.

If a participant age 15-20 declines to participate or is not eligible, their parents will not be informed of the reason. Instead, the parent who initially screened into the study will be sent an email informing them that their participation (and their teen's) is no longer needed. In cases where a teen does not grant consent/assent or does not respond to the consent invitation or reminders, the teen's contact information as provided by the parent will be deleted within 120 days after the end of the study. If a parent decides to no longer participate before completing the baseline survey, their teen will also be informed via an email that their participation is no longer needed. Please see Appendix C for sample email. After both a parent and their teen have completed the baseline survey, the parent may opt out without opting the teen out, and vice versa.

Participants (teens of eligible parents) who indicate they are 14 or younger, or 21 and over will be deemed ineligible and automatically routed to the end of the survey using show-if logic so they will not be shown any additional items. These ineligible participants will not receive any additional questions.. 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 good 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 consented but are ineligible will be retained indefinitely.

Online screening data will be collected via Rivulent Web Design, Inc. and saved on the HIPAA compliant LabArchives. Both Rivulent Web Design, Inc. and LabArchives meet HIPAA security regulations. To maintain the confidentiality of data submitted over the internet and to ensure that only children of parents who are eligible for the study and have provided their teen's contact info (and consent if age 15-17) can access the 15-20 year old screening survey, 15-20 year old participants will be sent a unique survey link with their embedded unique identifier. Embedding the unique identifier into 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 this unique identifier embedded as this 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 unique identifier would require doing so in a separate communication than the survey link*, thus doubling any communications that would involve a unique identifier.*

Screening survey data 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 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.

Future Research Opportunities

We ask all participants (parents and teens) in the online consent form if they would like to be contacted for future research opportunities. Parents of teens age 15-17 will also be asked if they would like for their teen to be contacted for future research opportunities. Participants that agree to be contacted for future research will NOT be required to participate in this future research, they are only giving permission to be informed of future IRB-approved opportunities conducted by the STARR Lab. For eligible and ineligible individuals who indicate "yes" to being contacted for future research opportunities, all personal contact/demographic information is kept separate from the remaining non-identifiable survey data. Contact/demographic information from eligible participants who provide permission (and parent has provided permission for 15-17 year old individuals) will be kept indefinitely. If an 18 or older individual is ineligible, but provides permission for future contact, contact/demographic information will be kept indefinitely as well. Examples of identifiable data that will be kept separate includes age,

sex, date of birth, name, contact information, city, state, and zip code of residency. We will retain demographic information alongside contact information to allow us to contact participants for relevant research opportunities. Drs. Litt and Lewis have used these procedures for their studies since 2005 and have never experienced any adverse events. All data for consenting ineligible and eligible participants will be kept indefinitely, but we will only contact participants about future research opportunities if they gave permission to be contacted.

Future research conducted at UNTHSC by Drs. Litt and/or Lewis would be the only research that 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. Individuals will receive a copy of their signed consent document via email when their consent document is signed and can request to be mailed a printed copy of their signed consent form.

Parent Full Study Consent

Please see study flow charts that demonstrate participant flow, including the consent process.

We are requesting informed consent for the screening survey, baseline, intervention, and follow-up surveys to be obtained online with an electronic signature because the entire study is administered online. The electronic signature will be requested via a text box where participants can draw their signature. Participants will provide informed consent (and assent if their child is age 15-17) for the screening survey, baseline, intervention, and follow-up surveys with electronic signatures. Parents who indicate that they are not the legal guardians of their child age 15-17 will be automatically marked ineligible and routed to the end page of the survey. Participants who decline to provide consent will be sent to the end page of the survey. For participants who do not provide consent, survey programming will skip the remainder of the survey, thus instructing them to not sign the form is not necessary. Participants who do not provide consent for themselves (and consent for their teen if age 15-17) would be moved straight to the survey end page. If a parent consents but does not complete the screening survey, they will receive up to 3 email reminders to complete the screening survey.

We will ask parents for consent for their teen (if age 15-17) for the full study (screening, baseline, and follow-up surveys) before commencing the screening survey. As such, teens age 15-17 who are eligible will have parent consent for baseline and follow-ups. Teen consent/assent will be obtained for the full study before commencing the screening survey. Thus, a separate consent form will not be signed at the beginning of each follow-up survey.

Parents will be informed in the informed consent and screening survey that in order to be eligible for the study, their child must also assent/consent to and be eligible to participate in the study.

We ask for parent contact information as a way to track their own participation as well as to track participants whose parents indicated consent or non-consent throughout the study as an additional check to only recruit

teens with parent/guardian consent. We can program our tracking database to flag any parent contact information (email) that was previously given from parents/guardians who rescinded their consent. We also use parent/guardian contact information as a way to ensure that the parent/guardian and the teen have different email addresses. If duplicate emails are used, this is flagged in our system as part of the parent verification process and the teen will not be moved forward in the study and will receive the not eligible end survey page.

Participants Age 15-20 Full Study Assent/Consent

Please see study flow charts that demonstrate participant flow, including the consent process.

We are requesting informed consent/assent for the screening survey, baseline, and follow-up surveys to be obtained online with an electronic signature because the entire study is administered online. The electronic signature will be requested via a text box where participants can draw their signature. Participants will provide informed consent for themselves (or assent if age 15-17) for the screening survey and follow-up surveys with electronic signatures. For participants who do not provide consent, survey programming will skip the remainder of the survey, thus instructing them to not sign the form is unnecessary. Participants who do not provide consent would be moved straight to the end page. Participants will not be allowed to complete the screening survey unless their parent has already completed screening, been deemed eligible, and provided their contact information and parental consent if age 15-17.

In order to reduce participant burden, consent/assent will be obtained for the full study (if eligible) for all participants before commencing the screening survey. Thus, a separate consent/assent form will not be signed at the beginning of each follow-up survey

We ask for parent contact information as a way to track their own participation as well as an additional check to ensure that the teens/young adults completing the surveys are the children of the parents who previously screened in. We also use parent/guardian contact information as a way to ensure that the parent/guardian and the teen have different email addresses. If duplicate emails are used, this is flagged in our system as part of the verification process and the teen will not be moved forward in the study and will receive the not eligible end survey page. We will retain this contact information until the end of the study. Survey programming will not move teens/young adults who do not provide consent to the HIPAA form, thus instructing them to not sign the form is not necessary. Teens/young adults who do not provide consent will be routed straight to a survey decline confirmation page, where they will have the opportunity to return to the consent form or confirm declining consent. Participants who decline consent will skip the remainder of the survey and go straight to the survey end page. Survey programming will be done such that participants cannot advance to the HIPAA Authorization form until consent to participate has been provided. Survey programming will be done such that participants cannot advance to the survey items until both consent to participate and HIPAA Authorization has been provided.

If we do not receive the completed consent/assent form or screening survey by the 15-20 year old, we will periodically send reminders – via email (up to 7), text (up to 7) and/or phone/voicemail (up to 5). If we do not receive the participant's (age 15-20) completed consent/assent form, we will send an email reminder to the parent to speak to their teen. If a consent decision is provided by the participant (age 15-20), then all reminder contacts for consent procedures would end. Parents will indicate consent or non-consent for the informed consent form and the HIPAA authorization form through an electronic signature and submit it through our online server. In cases where a teen does not grant consent/assent or does not respond to the consent invitation or reminders, the teen's contact information as provided by the parent will be deleted within 120 days after the end

of the study. Parents will be considered ineligible *if we do not have a response from the child (age 15-20) following the consent invitation/reminders.* Parents may also decline participation for their teen (age 15-17) at any time throughout the study by contacting our study office.

Consent Procedures for When Minors Become Adults.

Please see study flow charts that demonstrate participant flow, including the consent process.

Since this is a longitudinal study, there may be participants who are 17 years old when initially enrolled who turn 18 years of age (i.e., adult) while still engaged in the study. These participants will be re-consented as adults when they turn 18 years of age. Participants will re-consent as adults using the same consent/assent form they completed as a minor but the reconsent process will be documented in our participant tracking system by a time and date stamp and will be labeled as "Adult Reconsent" in our tracking system. To re-consent participants as adults, participants will be shown the online re-consent form before their nearest online survey (i.e., baseline, 1-month, or 6-month survey). Participants who do not provide re-consent or decline re-consent will not be allowed to access their next survey. Participants who do not provide a response to re-consent at the 1-month survey time point will not be able to access the 1-month survey; however, they will be shown the re-consent form again at the 6-month time point, where they could re-consent and resume their participation. During the online consent form, participants will be asked to re-consent to the study with an electronic signature and typed full name. The electronic signature will be requested via a text box where participants can draw their signature. Participants will also be asked to complete the HIPAA Research Authorization form again. Participants who do not complete the re-consent and HIPAA forms will continue to receive their survey reminder emails (up to 7), text messages (up to 7), and phone calls/voicemails (up to 3) until the re-consent, HIPAA forms, and online survey for the time point they turned 18 years of age are completed. A copy of the consent statement and HIPAA Research Authorization form will be sent to the email entered in the consent statement. If a participant fails to enter an email, a copy will be sent to the current email on file. Individuals may also request a copy of their consent form by contacting the project staff and requesting to be mailed a printed copy.

Because consent from both a parent and teen is necessary to enroll in the full study, if a teen is asked to provide re-consent before the baseline survey and does not provide it, neither teen nor parent will be allowed to participate in the online parenting program nor receive the 1- or 6-month surveys. If a teen is asked to provide re-consent before the 1-month or 6-month surveys and does not provide it, their parent will still be allowed to participate. Participants who are shown the re-consent form at the 1-month time point but do not complete it will have another opportunity to provide re-consent at the 6-month time point. In this case, the participant would not participate in the study until they re-consented. The re-consent will be obtained prior to any continued data collection.

Phone Verification.

After an eligible parent has provided consent and completed the screening survey, they will receive a confirmation email. Additionally, they will receive a phone call from study staff within approximately 3 business days. The purpose of this call is to verify that the information provided online is accurate and to give the participant additional details about the study. Participants will receive up to 5 calls to complete the phone verification. Participants will also receive email reminders (up to 5) and text message reminders (up to 5) that verification is required to continue with the study. Once the parent has been verified, this process will be repeated with their teen. Participants who have not been verified after 21 days will be considered ineligible, and

their participation will end. Dyads (both parent and teen) who are still deemed a good fit for the study and who are interested will be asked to complete the baseline survey to continue participation.

Intervention Content

After both parent and teen take the baseline assessment, randomization to condition (intervention or control) will use a stratified, blocked randomization, where assignment will be balanced across gender of teen and alcohol use.

Parents in the intervention condition will be sent an email containing a link to the intervention website and a text message with a link to the intervention website** (See Appendix C) along with an email explaining the study and providing guidelines for working through the modules with their teen. Parents may revisit the website as many times as they like over the course of a month prior to the 1-month survey. Parents will also be sent a series of text messages and emails encouraging them to spend time on the website and encouraging them to speak with their children (see Appendix C for intervention text message/email scripts).

Parents in the control condition will be sent an email with a link to The Surgeon General's Call to Action to Prevent and Reduce Underage Drinking: A Guide to Action for Families. This manual is publicly available via the Surgeon General's Website (see Appendix C). Parents in the control condition will be sent a series of text messages and emails encouraging them to spend time reviewing the website. *Parents in the control condition will be provided the link to the intervention condition website at the end of study completion for them and their teen.*

***Please note that we are submitting word documents that contain intervention website wording and content that match what has been programmed into the intervention the website. As requested, we are submitting the final programmed website for IRB review prior to launching the study.*

Link to Project PRISM Intervention Website: https://project-prism.rivulent.com/

Baseline Assessment, 1-Month, and 6-Month Assessments.

Parent/teen dyads who meet inclusion criteria and pass phone verification will be emailed and texted a baseline survey link. The baseline survey will include questions about demographics, social media literacy, parenting, drinking and drug use, drinking cognitions, mental health, and other health behaviors and will take approximately 45 minutes to complete. Questions in the assessments will also include topics about sexual orientation, gender identity, religion, and relationship status. For those in the Intervention group, items in the 1-month follow-up survey will assess satisfaction with the intervention website. If we do not receive the completed assessment at each follow-up (Baseline Assessment, 1-month, and 6-month assessment), we will periodically send reminders – via email (up to 8), text (up to 8) and/or phone/voicemail (up to 5). Parents and teens can earn $25 for baseline, $35 for the 1-month follow-up, $40 for the 6-month follow-up, meaning that all participants can earn up to $100.

Baseline Assessment, 1-Month, and 6-Month Measures.
While the baseline, 1-month, and 6-month surveys will 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 three surveys will be the same. Overlap in surveys is indicated by the overall content areas of surveys that are provided in the consent form. Behavior will be reported over lifetime

(baseline) and the past month to reduce problems with retrospective recall and overlap. Demographics will include age, height, weight, and family history characteristics. Parent-teen relationships will be evaluated in terms of parent-teen communication regarding both alcohol and social media (α =.53-.75; Turrisi et al., 2000), and parent-teen relationship closeness (α = .90; Buchanan et al., 1991). To determine the nature of parental involvement and monitoring of teens, parental monitoring will be assessed with the Parental Monitoring and Knowledge Scale (α = .81; Branstetter & Furman, 2013) and the Parental Monitoring of SNS measures (α = .67-.88; Livingstone & Helsper, 2008). In order to evaluate parental attitudes towards teen drinking, parents will complete the Parental Approval of Drinking Scale (α = .85; Wood et al., 2004). Teens' perception of parental attitudes toward drinking will be assessed with the Perceived Parent Approval of Drinking Scale (α = .85; Wood et al., 2004). Both parent and teens will be asked about their own social media use with the Social Media Scale, parents will also report perceptions of their teen's social media use with the same scale. Social media literacy will be determined with the Alcohol Specific Media Literacy Scale and the Alcohol Specific Social Media Literacy Scale (Martino et al., 2016; Unger et al., 2003).

Teens will be evaluated on additional items related to social media use and beliefs. Perceived exposure to ads will be determined by questions related to reported ads observed on various types of media devices (Martino et al., 2016; Unger et al., 2003). Social media descriptive norms will be assessed by asking the perceived frequency and quantity of alcohol related social media engagement (Baer et al., 1991). Social media attitudes items will ask how much the participant approves or disapproves of a series of social media behaviors. Social media injunctive norms will be measured using series of statements that assess participants' perceptions of other's attitudes and close friends' attitudes toward sharing social media content related to alcohol. Social media perceived vulnerability will be assessed by asking participants how likely they think it is that certain social media consequences will happen to them (Gerrard et al., 2008; Johnston et al., 2011). Social media prototypes will be measured by items that assess how favorable participants feel toward the typical peer of the same sex and age who posts alcohol related social media content (α = .87; Gerrard et al., 2006). The social media willingness measure will assess willingness to post alcohol related social media content in certain scenarios (α = .85; Gerrard et al., 2008).

Parents and teens will be asked questions regarding their alcohol and substance use. Family history of alcohol (baseline only) as well as lifetime and past year alcohol use (teen only) will be assessed (Johnston et al., 2014; Miller & Marlatt, 1984). Marijuana Use (Johnston et al., 2012) will be measured with items including lifetime and past year marijuana use for teens, and past month marijuana use for both parents and teens. Teens will also be asked about their perceived access to marijuana (Harpin et al., 2018). 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 (baseline only; α = .70-.94; Brown et al., 1998; Schafer & Brown, 1991) as well as an adapted version that assesses co-use of substances. Drinking will be assessed with the Daily Drinking Questionnaire and the Quantity Frequency Index (DDQ; α = .73; Collins et al., 1985; Dimeff et al., 1999; Lewis & Neighbors, 2004), and the Alcohol Use Disorders Identification Test (α = .85; Babor et al., 2001, Daeppen et al., 2000).

Teens will be asked about additional behaviors, cognitions, and perceptions related to their substance use. Consequences will be assessed with the Young Adult Alcohol Consequences Questionnaire (α = .79; Read et al., 2006, 2007). Descriptive norms will be assessed by asking the perceived frequency and quantity of drinking and marijuana (α = .80; Baer et al., 1991; Lewis & Neighbors, 2004; Neighbors et al., 2008) among typical men/women their age as well as close friends. Attitudes items will ask how much the participant approves or disapproves of a series of alcohol behaviors (α = .85; Ajzen, 2006; Todd & Mullan, 2011). Injunctive norms will be measured using a series of statements that assess participants' perceptions of other's attitudes and close

friends' attitudes towards toward drinking and marijuana use (α = .70-.93; Lewis et al., 2010; LaBrie et al., 2010). 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; Litt & Stock, 2011). Prototypes will be measured by items that assess how favorable participants feel toward the typical drinker of the same sex and age (α = .87; Gerrard et al., 2002, 2006). Experience of alcohol use will consist of one indicator of several key variables (i.e., age at first drink, quantity, frequency, perceived close friend alcohol use, and perceived access to alcohol). 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). Perceived access to substance use will be assessed with a modified version of The Perceived Access to Alcohol and Other Drug Scale (α = .86; Kuntsche et al., 2008). Anxiety and depression will be measured using the PROMIS Anxiety v1.0 and PROMIS Pediatric Anxiety v1.1 Short Form (α = .96; Cella et al., 2010) and the PROMIS Depression and PROMIS Pediatric Depression v1.1 Short Form instruments (α = .96; Cella et al., 2010), respectively.

Lastly, both parents and teens in the intervention group will be asked to complete a 1 month satisfaction scale related to their experience, perceptions, and interactions with the intervention website.

1. *Data Analysis and Data Monitoring* –

In order to evaluate the pilot study in Phase 2 (Aim 2), we will examine (a) recruitment and retention rates,(b) parent post-intervention feedback as measured at 1 month follow-up (i.e., accessible, usable, convenient, relevant, and helpful),(c) teens' rates of alcohol initiation and use, alcohol-related negative consequences, attitudes toward posting about alcohol on SNS, perceived vulnerability to the risks of posting alcohol displays on SNS, and normative perceptions about how many teens post alcohol displays on SNS, d) parental knowledge and attitudes toward alcohol and SNS, and e) parent and teen report of alcohol and SNS related communication 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 parents who meet inclusion criteria and enroll for the study, (2) the proportion of teens who meet inclusion criteria and enroll in the study, and (3) the proportion of parent and teens who complete the *interactive SNS* PBI at 1 month follow-up. Finally, the length of time it took to recruit our target enrollment number will also be used as an outcome of feasibility.

Acceptability will be assessed with parent and teen responses at 1 month. Acceptability will be determined by (1) the proportion of eligible parent/teen dyads enrolled, with 80% of eligible dyads agreeing to participate, (2) the proportion of participants (both parents and teens) who find the intervention acceptable (e.g., acceptability of content delivery method), usable (e.g., ease of viewing and interacting with *interactive* PBI content), relevant (e.g., relevance of material), and helpful (e.g., finding content helpful, beneficial, important), (3) parents' and teens' ratings of individual modules in the SNS PBI, (4) whether teens would like to have additional conversations on this topic, (5) whether parents would share the information in the PBI with anyone else, (6) the proportion of parents and teens who would recommend the study, and (7) the proportion of parents and teens who found the program to be favorable overall. Acceptability will be specifically determined if *acceptability for the interactive SNS PBI is higher than control and if at least* 80% of responses in each domain are rated a 4 or higher (out of 5).

This pilot will *explore treatment differences and determine preliminary effect sizes* for teens' drinking and risky cognitions as well as parents' knowledge about alcohol and SNS, and parent- and teen-reported outcomes will be analyzed in separate models. All models will have *three* repeated measures (i.e., baseline, 1 month, and 6 month follow-up), yielding up to 450 Level 1 observations (repeated-measures) across 150 Level 2 cases (teens or parents). Prior to inferential statistics, univariate and bivariate descriptive statistics will be used to assess distributions and simple associations among variables. Primary teen-reported outcomes are alcohol use and negative consequences (both count outcomes) as well as cognitions (attitudes, norms, and perceived vulnerability related to SNS alcohol displays; all modeled as normally distributed outcomes). Primary parent-reported outcomes will be knowledge about alcohol and SNS (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.

2. *Data Storage and Confidentiality* –

Screening, Baseline, 1 and 6 Month Data. Data from all online surveys will be identified only by a seven-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 includes name, contact information, city, state, and zip code of residency, and parent contact information. 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).

If a participant agrees to be contacted for future research opportunities, their personal contact/demographic information will be stored on our secure LabArchives network which is protected by two-step verification, configured sharing permissions, monitoring of activity, disabled permanent deletions, and conduction of regular access reviews. Personal contact/demographic information will only be retained for participants who give permission to be contacted for future research opportunities. This information will be kept separate from the raw research data and will only be used to inform consenting participants of future research opportunities. The master list which connects identifiers to research data will be destroyed at the close of the study, preventing any connection between the future contact information and the raw research data.

Rivulent Web Design, Inc. will be programming screening survey for this project. All Project PRISM 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.

3. *Setting* - Describe briefly where the study will be conducted, e.g., private outpatient clinics, physicians' offices.

   Screening, baseline, website module intervention content, and the 1 and 6-month follow-up surveys for the study will be conducted online.

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.

   Overall time for the entire study, start to finish: 6 months

   Total time of subject participation: 2 hours and 20 minutes, plus the time parents allocate for either the intervention website or the Surgeon General's Call to Action.

   The brief online screening and consent should take approximately 5 minutes to complete.

   The online baseline survey should take approximately 45 minutes to complete.

   Intervention content will be administered during a 4-week period.

   The online 1-month follow-up survey should take approximately 45 minutes to complete.

   The online 6-month follow-up survey should take approximately 45 minutes to complete.

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 (150 parents; 150 teens) subjects at 1 sites in the U.S. will be enrolled in the study overall.

For Clinical Trial studies, indicate number of subjects to be randomized __300

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 for Parents/Legal Guardians:

1) have a child between the ages of 15-20 who currently lives with them
2) believe that their child is active on at least one SNS
3) live in Texas
4) did not participate in a Phase 1 focus group
5) provide a valid email address
6) own a cell phone with text messaging capabilities and be okay with receiving messages
7) provide valid contact information for their teen
8) willing to participate in a study that involves a parenting program and a series of online surveys with their teen
9) provide a valid phone number

Inclusion criteria for Teens:

1) have an eligible parent with whom they currently live
2) between the ages of 15-20
3) live in Texas

4) did not participate in a Phase 1 focus group

5) active on at least one SNS

6) provide a valid email address

7) own a cell phone with text messaging capabilities and be okay with receiving messages

8) willing to complete 3 45-minute online surveys over the course of 6 months

9) Note that both parent and teen must be eligible to enroll in the study.

10) provide a valid phone number

Eligibility questions will be embedded in other questions so as not to make the criteria obvious. Screening will be conducted to ensure the participant meets eligibility criteria and also provides age, date of birth, and unique person items. If an individual meets criteria at screening, the programmed algorithm will trigger a request to enter contact information. We will monitor individuals' personal information (e.g., home address, phone numbers, date of birth, computer IP address) to ensure that individuals cannot participate multiple times.

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 and date of birth) identified by the survey, and having already participated in the study 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 stratify recruitment based on age, gender, and ethnicity, recruiting equal numbers of parents with adolescents in each of the age categories (i.e., 15, 16, 17, 18, 19, 20) and targeting equal numbers of males and females in each age group. We will recruit all minority parents to be above local census estimates.

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

Participants will be selected by targeted online (Facebook/Instagram/Twitter; Craigslist and online newspapers) advertisements, community organizations, schools, and in-person flyering and handouts.

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 multiple recruitment methods to reach a variety of parents with children age 15-20 from Texas. Our experience has demonstrated success in recruiting participants using the proposed methods. Online ads will be placed in media outlets. Social media outreach will consist of a Facebook Fan page that will provide a brief study description and links to the study website. We will use Facebook's advertising platform to also show our ads on Instagram. The Facebook Fan page is open to the public. Liking the Fan page is not an indicator of study enrollment. The communication for the Fan page is a one-way communication platform whereby communication will come from the study staff via Facebook. Individuals will not be able to post or comment within the Fan page. They can share posts from the page on their newsfeed. We ask participants to like or share our Fan page but we do not ask them to post anything on the Fan page. Additionally, we created Twitter and Instagram accounts. We will use paid Facebook, Twitter, and Instagram sponsored ads, stories, and promoted boosts on our Fan page/Twitter/Instagram accounts to increase our online presence. We will also advertise in local online versions of newspapers and in high school newspapers. Online (e.g., Craigslist, Facebook, Twitter, Instagram, newspaper) recruitment ads will provide a hyper-linked website address for more information and eligibility screening. Print advertisements in local newspapers will contain a brief description of the study and various methods of contact for the study (website, phone number, email). We will also share flyers and handouts with community organizations and schools either by mail or email.

Study staff will visit community areas (i.e., businesses and community centers) to hand out study flyers. Flyers will contain a brief description of the study, contact information, website link, and link to the online screening survey. Study staff will also post flyers in community areas (i.e., business and community centers).

We are targeting ads to show up in newsfeeds of individuals age 30-66 in Texas. We pay for ads to show up in newsfeeds in Facebook and Instagram. We do not buy ad space. Ads for this study will be targeted by age and/or by birth sex to those in Texas. Ads do not appear based on any keywords. We submit ads directly via Facebook for both Facebook and Instagram as well as directly to Twitter. We do not use a recruitment agency. Ads in newsfeeds cannot be seen by anyone other than the individual. They are not permanent posts to newsfeeds. Because these ads are not permanent and cannot be seen by anyone other than the participant they do not increase or pose additional risk. Participants will have the option to hide or not see any ads from Project PRISM on Facebook, Instagram, and Twitter if they so choose. This is always an option for any ad on Facebook, Instagram, or Twitter.

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 Project PRISM.

2) Describe how the anticipated benefit justifies the risk.

There are several potential direct benefits for both parents and teens who participate in this study. **Parents in the control condition will be sent the intervention website link at the end of study**

completion, thus all participants may directly benefit from participation in this study not just those originally randomized to intervention. First, because this is an intervention specifically designed to improve parental communication and reduce risky social media use and drinking among adolescents and young adults, enrollment in the study over a course of 6 months is likely to have a direct benefit on both parents and teens as it may increase parent-teen communication and reduce adolescent and young adult alcohol as a result of completing Project PRISM. Any study that involves an intervention could have an anticipated direct benefit as participants will receive an intervention that they would not otherwise receive. Research indicates that parent-based interventions, such as the one proposed herein, have proven successful at reducing the odds that nondrinking teens and young adults will initiate alcohol use (Ichiyama et al., 2009) and on general alcohol consumption (e.g., Doumas et al., 2013; Ichiyama et al., 2009; Turrisi et al., 2001, 2010, 2013). A systematic review (Kuntsche & Kuntsche, 2016) supported the idea of using parents in prevention programs. Across studies and concepts, they found evidence that participating in parent-based interventions *improved* parenting measures such as rule-setting, monitoring and parent-child communication as well as the *prevention and reduction of adolescent substance use*. Thus, both parents and teens may directly benefit from participation in a parent-based intervention such as Project PRISM. Second, much of the intervention content related to parent-teen communication and engaging in non-reactive and non-judgmental conversations with their teens is in line with mindful parenting, which can be defined as the ongoing process of intentionally bringing moment-to-moment, non-judgmental awareness and communication to parenting (Duncan et al., 2009). This non-judgmental moment-to-moment communication can support parents in becoming more aware of what and how they communicate and allows parents to pause and reflect before communication and consider current communication and relationships in context of the long-term relationship that they have with their teen, as well as attend to their teen's needs. Research indicates that parents who either have a natural capacity for, or learn practices of mindful parenting will be more likely to develop higher quality relationships with their children (Duncan et al., 2009) and that teens whose parents follow practices of mindful parenting including non-judgmental communication and listening with full attention and openness are less likely to experience conflict with their parents and thus are more likely to self-disclose when they have concerns (Smetana et al., 2006). Given that many of the recommendations in the proposed intervention focus on mindful parenting (e.g., non-judgmental and non-reactive communication, relationship building, honesty and openness, listening with full attention, compassion for self and child), participation in this study may have direct benefit on the quality of communication and relationships between parent and teens.

Second, there is a direct benefit related to the potential for reactivity to behavioral survey assessments, including the surveys utilized in this research study. Reactivity is the possibility that the research methods themselves affect the behavior under study. The process of completing substance use assessments is often illuminating for participants such that they react by reducing their risk behavior. Reactivity to alcohol assessment occurs when completing alcohol surveys is associated with changes in alcohol use, specifically reduced alcohol use. Research has shown that there is reactivity to alcohol assessment for longitudinal surveys (McCambridge & Kypri; 2011; Walters et al. 2009) such that participants reduce alcohol use over time as a result of repeated assessments. Further, research indicates that completing assessments about a range of health behaviors can lead to increases in health-promoting behaviors (Miles et al., 2020; Wood et al., 2016). Thus, both parent and teen participants in Project PRISM have the potential to directly benefit from completing longitudinal behavioral assessment surveys (screening, baseline, 1-month, and 6-month surveys).

In addition, all participants may directly benefit through the provision of resources on a variety of topics including alcohol use, substance use, mental health, etc. In addition, we have a plan for identifying and referring individuals who report significantly worsening alcohol use trajectories as well as consumption of potentially lethal doses of alcohol as reported on their survey assessments. This screening process is also a potential direct benefit for participants as they have the opportunity to learn more about their drinking and potentially be referred to services, if needed. **All participants (parents and teens), at the end of participation, will be provided with referral resources available both locally and nationally, which is a direct benefit of participating in the proposed study.**

We believe that the potential risks of the study (please see below) are reasonable in relation to the importance of the knowledge gained and potential direct study benefits, which justifies the risk regarding uncomfortable survey items and risk of confidentiality. First, as noted above the direct benefit of potentially improving parent-teen communication and alcohol use outcomes outweighs potential risks related to sensitivity of questions and potential loss of privacy. Further, given that parents in the control condition will be sent the intervention website link at the end of study completion for them and their teen, all participants have potential to directly benefit from participation in this study. In addition, the potential for reactivity from Project PRISM alcohol assessments (i.e., potential for participants to reduce alcohol use as part of the research study) is a potential direct benefit. We feel the above benefits justify the risks of Project PRISM; specifically, potential benefits from reactivity leading to reduced alcohol use and benefits for parental communication justifies participants' possible discomfort with questions and confidentiality (discussed below). All participants (parents and teens) will be provided with referral resources both locally and nationally, which is a direct benefit of participating in Project PRISM. In sum, there are a multitude of direct benefits available to all Project PRISM participants.

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 Resource Information Email (Appendix C).

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 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. Psychological risks posed by the research are primarily related to the sensitivity of some of the survey items. Items include thoughts, feelings, and personal difficulties that may be private and personal behavior such as alcohol use and related

negative consequences. These questions may make participants uncomfortable, or be perceived as an intrusion on their privacy. In addition, participants are asked to report on potentially illegal behaviors such as drinking under the legal drinking age or using marijuana in the state of Texas. Answers to these questions could pose a risk if the information were known and linked to identifiable individuals. We were automatically issued a Certificate of Confidentiality from NIAAA to prevent disclosure of sensitive or illegal behaviors. We have been using similar procedures on multiple NIH-funded studies with no adverse events or loss of confidentiality on any project. 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 topics 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. Psychological risks of experienced invasion of privacy or increased awareness or concern about one's behavior as a result of completing the surveys and potential loss of confidentiality will be addressed as a risk in the consent documents. 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 and will be emailed a copy of the Resource List (see Resource List Email). Participants will not be restricted from seeking other alcohol, substance use, or mental health education, prevention, or treatment opportunities, and we will assess for use of other services at each assessment.

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 according to Texas State Law.

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 forms including alcohol and marijuana use, 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. Psychological risks of experienced invasion of privacy or increased awareness or concern about one's behavior as a result of completing the surveys and potential loss of confidentiality will be addressed as a risk in the consent documents. 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 identifier, which will be randomly generated for study purposes. These unique identifiers will be embedded in individual survey links such that they 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 unique identifier. A master list of names and unique identifiers 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. 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 identifier 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, NIH issues 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 drinkers, marijuana users, high school students, college student gamblers, 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. 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, marijuana use, or receive substance use-related services if desired.

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) and potential for alcohol use disorder as measured on the AUDIT. Specifically, the baseline, 1-month, and 6-month surveys will be screened immediately upon submission for indication of significant risk based on criteria established in our prior trials of this nature and the research literature (i.e., a score of 8 or more (age 18-25)/a score of 4 or more (age 15-17) on the AUDIT on baseline,1-month, or 6-month surveys in combination with a BAC in the past month exceeding .35%; Chung et al., 2000; 2002). The AUDIT total score is used to assess the risk of alcohol use disorder. A score of 8 or more is suggested for identifying hazardous drinking behaviors among adults, and a score of 4 or more is suggested for identifying hazardous drinking behaviors among adolescents as young as 13. Thus, both outcomes (8+AUDIT and 4+AUDIT, respectively) will be used to assess hazardous alcohol use for referral in combination of .35% BAC. Participants who meet this criterion will be emailed local referral information. All such contact will be noted in the tracking database. In our ongoing trials, we have used this procedure without incident. 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 Informed Consent 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 (parents and teens), at the end of participation, will be provided with referral resources available both locally and nationally.**

If an adolescent in the study reports significantly worsening alcohol use trajectories or consuming potentially lethal doses alcohol, their parents will **not** be informed about this report due to confidentiality.

See Referral Information Email in Appendices.

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, substance use (i.e., marijuana) or mental health education, prevention, or treatment opportunities.

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.

Compensation. Each participant will be mailed a Greenphire Mastercard that will be loaded with $25 for completion of the baseline survey. See Appendix C what a Greenphire Mastercard looks like. Participants will also be provided Greenphire Mastercard FAQs and information on how the Greenphire Mastercard can be used via mail after completion of the baseline survey. Participants are notified in the baseline survey end page and in the frequently asked question sheet 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 via phone, text, and email 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 address.

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 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 ID that they will not be able to use their Greenphire Mastercard to get a cash advance at a bank.

Compensation Schedule:

Online screening survey: 5-10 minutes, no incentive
Online baseline survey: 45 minutes, $25 Greenphire Mastercard
Online 1-month follow-up survey: 45 minutes, $35 Greenphire Mastercard
Online 6-month follow-up survey: 45 minutes, $40 Greenphire Mastercard

Total Possible Over the Course of Study: $100

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

None

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 will be responsible for the overall scientific direction of the research, including design and development of protocols, assessments, materials, participant recruitment and retention, intervention development, and human subject compliance. She will also take a key role in the data analysis and

dissemination efforts, being responsible for first authoring several papers, helping conduct data analyses, and supporting co-authors in dissemination efforts. 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 ensure that the project be completed efficiently and on time.

Name & Degree: Melissa A. Lewis, PhD
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 assist Dr. Litt in the development of the retention procedures, procedures for assessment reminders, development and implementation of participant tracking protocols; and intervention development and refinement. Dr. Lewis will work with Dr. Litt in conducting data analyses and dissemination efforts.

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. 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, 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

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. 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.
**Please note that although Dr. Robert Turrisi appears on the "About Us" section of the Project PRISM intervention website, he is not listed as key personnel on this project. Dr. Turrisi appears on the website as a professional courtesy given that his research on parent-based interventions served as the basis of the present study. Dr. Turrisi will not communicate with participants in any way nor will he have access to participant data or files. Dr. Turrisi will not be involved in any aspects of project coordination. As such, he is not listed as a key personnel on this project.*

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

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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.