# Using Counter Attitudinal Advocacy to Change Drinking Behavior

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## 2. PROJECT SUMMARY

We propose to evaluate the efficacy of a CAA-based intervention to change alcohol-related attitudes in support of moderate drinking. Specifically, heavy-drinking college students will be prompted to advocate for a counter-attitudinal topic (i.e., benefits of avoiding problems) by responding to a prompt asking them to detail how to avoid negative consequences by using self-generated protective behavioral strategies (PBS) and why this is a beneficial approach to drinking. With the understanding that their responses will inform future prevention programs, participants will then review their statements publicly with a research assistant. The new CAA intervention will be compared to (a) an assessment only (AO) control to determine absolute efficacy, and to (b) an empirically-supported personalized normative feedback (PNF)

intervention to determine relative efficacy, using a non-inferiority design. This study evaluates a novel intervention protocol linked to a clearly defined mechanism of behavior change and grounded in basic psychological research. If found to be efficacious, or at least non-inferior to the established PNF, the CAA approach will advance prevention science by targeting a separate and unique mechanism of change, and it will add to the toolbox of strategies available to colleges and universities to prevent harms related to drinking.

## 3. STUDY RATIONALE

College students drink more and experience more consequences than their same-age, non-college peers (White & Hingson, 2014). Brief prevention interventions developed for college drinkers have effectively reduced alcohol use and consequences, with small-medium effects (Carey, Scott-Sheldon, Carey, & DeMartini, 2007; Carey, Scott-Sheldon, Elliott, Garey, & Carey, 2012; Samson & Tanner-Smith, 2015; Scott-Sheldon, Carey, Elliott, Garey, & Carey, 2014). Notably, mechanisms of change targeted by these interventions have been dominated by perceived descriptive norms (Reid & Carey, 2015). The strong emphasis on normative feedback as a core mechanism of change may have contributed to a dearth of attention to alternative paradigms. To this point, research consistently demonstrates associations between attitudes toward drinking and drinking behavior (Collins & Carey, 2007; Huchting, Lac, & LaBrie, 2008; Stacy, Bentler, & Flay, 1994), and attitudes have been shown to be stronger predictors of drinking than norms (DiBello, Miller, Neighbors, Reid & Carey, 2018).

Although attitudes are a key element of many health behavior models (Montano & Kasprzyk, 2008), they are rarely directly targeted in individually-focused alcohol interventions. Attitudes are defined as evaluative judgments that can range from negative to positive and are subject to situational influences and observations of one's own behavior (Bem, 1967; Higgins, 1987). The present research adapts a classic attitude-change paradigm (counter-attitudinal advocacy, or CAA), which has been used widely and successfully in other domains such as smoking cessation (e.g., Simmons, Heckman, Fink, Small, & Brandon, 2013), for use in alcohol prevention. With CAA, individuals who voluntarily endorse a specific position (e.g., disapproval of heavy drinking), that is discrepant from their current attitude and/or behavior, come to change their attitude and/or behavior in the direction of the endorsed position. This approach is particularly effective when the professed attitude is public, self-generated, and internally motivated. (Kim, Allen, Preiss, & Peterson, 2014), and the current procedure incorporates all these elements. An advantage of the CAA approach to promoting change in drinking behavior is that participants self-generate risk reduction plans without having to self-identify as wanting to change, which is an advantage for use in prevention programs.

## 4. AIMS AND ENDPOINTS

**Aim 1. Examine the effects of CAA on alcohol outcomes**. Our primary hypothesis is that, relative to AO control, the CAA intervention will (a) increase positive moderate drinking attitudes, (b) decrease positive heavy drinking attitudes, (c) increase attitude-behavior dissonance, and (d) decrease drinks per drinking day, binge frequency, peak BAC, and alcohol consequences, and increase the use of PBS.

**Aim 2. Compare the effects of CAA vs. PNF.** A secondary hypothesis is that CAA will be no less efficacious than (i.e., not inferior to) PNF in reducing alcohol outcomes as measured by alcohol consumption and alcohol related consequences.

**Aim 3**. **Test specific theory-based mediational pathways.** Aim 3a. We predict that the effects of the CAA intervention on alcohol consumption and consequences will be mediated by increases in (a) positive attitudes towards moderate drinking and (b) dissonance (but not perceived norms). Aim 3b. We predict that the effects of the PNF intervention on alcohol

consumption and consequences will be mediated by decreases in (a) perceived descriptive norms and (b) dissonance (but not attitude change).
**Aim 4. Test intervention-specific moderators of outcome.** Aim 4a. We predict that the effect of the CAA intervention will be enhanced by stronger drinker identity, greater need for consistency, and will not differ by study site. Aim 4b. We predict that response to the PNF condition will be enhanced by weaker drinker identity, greater need for consistency, and will be stronger within a lighter drinking community (the Houston site).

## 5. STUDY DESIGN

We will use a multi-site randomized controlled trial (RCT) to evaluate the effects of counter attitudinal advocacy (CAA) relative to assessment only (AO) control on drinking and related problems among college students, and the relative effects of CAA vs. PNF on relevant drinking outcomes. Eligible students will be randomly assigned to one of 3 conditions (personalized CAA or PNF or AO control). Hypothesized mechanisms of change (alcohol-related attitudes and dissonance, perceived drinking norms) will be evaluated immediately after the intervention (posttest) and drinking outcomes (drinks per week, heavy drinking frequency, peak BAC, alcohol-related problems, PBS) will be evaluated at 1-, 3-, and 6-months post-intervention. All procedures are conducted for the purpose of research only.

We propose to conduct this study at two sites (both Carnegie Tier 1 Research universities) that have distinctly different campus and student profiles in order to explicitly test hypotheses about the differential efficacy of CAA vs PNF in different campus contexts. Brown University is a private residential 4-year college with approximately 6200 undergraduates (51% female and 43% minority) and characteristics associated with higher risk of alcohol misuse (e.g., Northeast region, Greek system, athletic tradition). All first- and second-year students and most third-year student live together in on-campus dorms. Students at Brown report high rates of drinking: 81% of Brown students drank in the past 3 months, and 51% report binge drinking in the last two weeks. In contrast, the University of Houston (UH) is a large public research university serving more than 34,716 undergraduate students (51% female and 74% minority). Roughly 80% of UH students live off campus. Located in America's fourth-largest city, UH was designated as the most ethnically diverse metropolitan research university in the United States by Forbes in 2010. UH students report a below average drinker profile, with 45% of the students reporting current drinking and 23% report binge drinking in the last month. Overall, the base rates for any drinking and binge drinking are lower at UH than at Brown. These two sites allow us to test the comparative efficacy of CAA vs PNF in contexts with both high and low base rates of heavy drinking. If site does not moderate efficacy, then the replication of the effects of CAA across sites will provide evidence of generalizability of observed effects.

## 6. STUDY POPULATION

**6.1. Target Sample**. The target sample for analyses is *N*=600 college student drinkers: 300 from Brown University, and 300 from the University of Houston. We will randomize 100 eligible students from each site to the CAA (n=200), PNF (n=200), and AO (n=200) conditions.

**6.2. Inclusion Criteria.** Inclusion criteria are:
(1) **Age 18-26**. The age range of 18-26 (a) coincides with the distinct developmental period of "emerging adulthood" (Arnett, 2005), (b) is characterized by a high prevalence of heavy episodic drinking (Johnson et al., 2012), and (c) is representative of college students, the majority of whom are 26 years of age or younger (Digest of Education Statistics: 2012).

(2) **Male or female student at Brown University or University of Houston**. The present study represents a first step in using counter-attitudinal advocacy activities in an attempt to reduce risky drinking behavior. As such, we focus on college students because they exhibit high rates of heavy episodic drinking (Johnson et al., 2012), and their identification with other college peers facilitates the testing of the enhanced manipulation. We recruit at 2 sites that differ in drinking patterns and demographics and geographic location to evaluate the generalizability of the study findings. The findings could have implications for alcohol abuse prevention both with college students and young adults more broadly.

(3) **Past month heavy episodic drinking (for men, ≥5 drinks in one day, for women ≥4 drinks in one day)**. The 4/5 drink cutoff has been widely used as an indicator of risk (Neighbors, Larimer, & Lewis, 2004; Wechsler & Nelson, 2001) and as a screening criterion in intervention studies targeting heavy drinking students. Our preliminary studies show that heavy drinking frequency is significantly correlated with attitudes towards moderate ($r$ = -.42) and heavy ($r$ = .45) drinking. By including only drinkers who have reported heavy episodic drinking we optimize the likelihood that developing arguments in favor of moderate drinking (<4/5 drinks/occasion) will constituted counter-attitudinal advocacy, and create dissonance between the espoused attitude in favor of moderation and recent behavior.

(4) **At least two self-reported negative consequences from drinking in the past month**. Because the CAA prompt involves writing arguments about avoiding alcohol-related problems, it will be necessary to ensure participants report at least two alcohol-related problems. Note that in 2 separate samples of college drinkers we found that 91% and 87% of those who met gender-specific binge criteria also reported at least 2 alcohol-related problems.

**6.3. Exclusion Criteria.** Exclusion criteria are: (1) **Status as a graduating senior**. Any student with senior status in the spring semester will be excluded from participating in the RCT, because of potential difficulties in contacting graduated students for follow-ups. Also, post-graduation drinking patterns may change substantially (White, Labouvie, & Papadaratsakis, 2005). (2) **Status as a third-year student at Brown (AY 2019-2020 only)** During the 2019-2020 academic year ONLY, third-year students will not be recruited at Brown University due to a conflict with another study.

## 7. ENROLLMENT

### 7.1 Recruitment and Enrollment Procedure Overview

We aim to recruit 600 heavy drinking students (300 each from UH & Brown), between 18-26 years of age, from the general student bodies of both institutions. Interested students who respond to recruitment solicitations will have the opportunity to complete a brief confidential web-based survey. Students will be eligible to participate in the RCT if they report (a) at least one gender-specific episode of heavy drinking in the previous month (4/5 or more drinks on a single occasion for women/men), (b) experiencing at least two alcohol-related problems in the previous month, and (c) status as an undergraduate who is not graduating within the 6-month study period. Due to conflicts with other studies at Brown University, during the 2019-2020 academic year we did not recruit third-year students or any student who has participated in a focus group/interview study on alcohol in the past 2 months. Students will be notified at the completion of the screening survey of their eligibility to participate. Screening and scheduling of baseline assessments (for those who meet screening criteria) will occur online at the same time. At each assessment point, participants will have the option to download a Resource Sheet with contact information for substance abuse and mental health services.

#### 7.1.1 Brown recruitment

At Brown University, participants are recruited using several different methods. Primary recruitment methods include announcements posted on (a) campus-wide Today@Brown daily email listserv, (b) university group listservs serving clubs and student organizations (c) social

media platforms (e.g., Facebook, Instagram, etc.), (d) university-managed Facebook pages, (e) to the Center for Alcohol and Addiction Studies "Find a Study" page, (f) flyers posted near high traffic areas on campus (see representative materials in Appendix A, Recruitment Materials) and (g) snowball recruitment, in that participants will be invited to refer others they know to the study. Recruitment announcements include study-related information, eligibility requirements, and a link to a screener survey. Secondary recruitment methods include placing table slips in the dining halls with a study-specific number to text to receive a link to the screener and a QR code to scan. No in-person recruitment will occur at Brown. Under supervision and training of the PI, the senior Research Assistant and graduate Research Assistant will be responsible for the creation of online recruitment advertisements and dispersing/posting of flyers.

**7.1.2 UH recruitment**

At the University of Houston, we will invite a random sample of students from UH (without replacement) via email. Using email addresses provided by the Registrar, participants will be invited through the use of staggered email bursts. We will send the email bursts in cohorts of 1000- 4000 until the desired N is achieved. Interested students will be able to link to a brief confidential web-based screening survey. No in-person recruitment will occur at UH. Under supervision of the PI or research coordinator, Research Assistants will recruit participants using email addresses provided by the Registrar and posting of flyers.

**7.2 Screening (pre-COVID)**. The screening survey was compiled of questions related to demographics (enrollment, age, class year, sex, gender identity), health behaviors (biggest issue affecting students' overall health, stress, sleep habits), drinking behaviors (most alcohol consumed on an occasion in the past month, consequences related to drinking) and potential study conflicts (participation in another study, interview or focus group on the topic of alcohol use). Participants who were eligible were shown an eligibility message and re-routed to an online scheduling module to book an in-person baseline session.

**7.3 Screening (post-COVID)**

**7.3.1 Screening for remote baseline sessions (Brown site)**

To accommodate for online delivery, we changed eligibility criteria, to exclude students who were learning remotely away from the campus drinking environment. The following item was added in September 2020 to assess the individual's living and learning situation: "How would you best describe your situation this semester?" (taking classes at Brown living at home, taking classes at Brown living in the Providence area, Note currently taking any Brown classes, Other:[fill in the blank]).

**7.3.2 Screening for remote baseline sessions (Houston site)**

No changes were made to the screening process at the University of Houston, as the majority of students commuted to campus prior to the pandemic.

**7.4. Scheduling participants**. Participants who meet screening criteria will be invited to schedule an individual in-person session using an online scheduling module (See Appendix A, Recruitment Materials, for details). The scheduling module will direct participants to select a date and time for their session and ask participants to provide their name, phone number and email address for further research study communications. A staff member will call, text, and/or email to confirm the appointment when it is made and will remind students of their appointment time and date one or two days before the scheduled appointment. At the in-person session, participants will provide written informed consent and complete the online baseline assessment

in a private room. Assignment to condition will take place after their baseline assessment; students will be stratified across conditions based on gender, a practice that has ensured baseline equivalence in drinking across conditions in several prior studies of college drinkers.

### 7.5. Retention Plan

**Reimbursement.** A $25 electronic gift card will be provided upon completion of baseline, $25 electronic gift card for their 1-month follow up, $30 for their 3-month follow up, and $35 for their 6-month follow up assessment. Participants will only receive compensation upon completion of each phase of the study. The compensation will be sent electronically to the email address provided by the participant at the beginning of the study. The initial baseline session will take approximately 75-90 minutes and each of the follow-up assessments should take approximately 30 minutes to complete. This gradual increase in payment ($25, $30, $35) will help ensure we have strong follow-up rates through the 6-month intervention period and is consistent with payment schedules used in other studies with this population.

#### 7.5.1 Brown COVID adjustment timeline

- March 6th, 2020 – Last in-person RAVEN session
- March 12th, 2020 - Announcement made about intent to close campus
- March 16th – 20th, 2020 - Classes cancelled
- March 17th, 2020 - Amendment for remote procedures approved
- March 26th, 2020 – First remote RAVEN session
- March 22nd, 2020 - All students off campus
- March 22nd – 27th - Spring break
- March 30th, 2020 - All classes moved to remote
- September 18th – campus re-opens with restrictions, all baseline sessions starting Fall 2020 semester were conducted remotely

#### 7.5.2 UH recruitment post-COVID (remote baseline sessions)

- March 5th, 2020 – Last in-person RAVEN session
- March 10th, 2020 – Work remote suggested (not a policy)
- March 11th, 2020 – Classes paused for transition to online, work remotely if possible
- March 17th, 2020 – Social distancing/take-out only dining begins
- March 17th, 2020 - Amendment for remote procedures approved
- March 24th, 2020 – Stay-at-home order official form Harris county
- April 8th, 2020 – First remote RAVEN session
- May 5th, 2020 – Essential (i.e., can't be done remote) research labs can be opened
- June 1st, 2020 – Campus open to faculty/staff on a limited voluntary basis

### 7.6 Participant communications

#### 7.6.1 Brown participant communication pre-COVID (in-person sessions; see Appendix A)

All participant email communications are sent from the projectraven@brown.edu email address, using IRB-approved templates. Appointment text reminders are sent using an online texting application, and phone call reminders are made using staff work telephones.

#### 7.6.2 Brown participant communication post-COVID (remote sessions; see Appendix B)

Several changes to participant communications were made as a result of the change to remote baseline administration. (a) Consent is obtained verbally using Zoom, supplemented by confirmation in

the form of checking a consent box on an online form of the Consent document, rather than an in-person signature (b) Baseline sessions, some of which include a brief computerized intervention and discussion with a research assistant, will take place via Zoom rather than in-person (c) Intervention materials, including personalized feedback containing no identifying information, that would have been printed and given in person will now be emailed electronically

**7.6.3 UH participant communication pre-COVID (in-person sessions; see Appendix A)**

All participant email communications are sent from the raven@central.uh.edu email address, using IRB-approved templates. Appointment text reminders are sent using an online texting application, and phone call reminders are made using staff work telephones.

**7.6.4 UH participant communication post-COVID (remote sessions; see Appendix B)**

Several changes to participant communications were made as a result of the change to remote baseline administration. (a) Consent is obtained verbally using Zoom, supplemented by confirmation in the form of checking a consent box on an online form of the Consent document, rather than an in-person signature (b) Baseline sessions, some of which include a brief computerized intervention and discussion with a research assistant, will take place via Zoom rather than in-person (c) Intervention materials, including personalized feedback containing no identifying information, that would have been printed and given in person will now be emailed electronically. Participant communication still occurs via the raven@central.uh.edu email address and online texting application, but phone call reminders are no longer used.

**8. INTERVENTIONS (see Appendix C for intervention scripts)**

**8.1. Counter Attitudinal Advocacy Condition.** In order to prompt participants to express attitudes inconsistent with current behavior, we have pilot-tested and refined instructions to articulate how to engage in moderate drinking via self-generated PBS in order to avoid negative consequences. By design, inclusion criteria will produce a sample that has engaged in heavy episodic drinking (5+/4+ criteria for men/women, respectively) and experienced at least two consequences. The examples included in the prompt will be personalized to each participant, based on his/her responses to the baseline survey; thus, the examples will represent negative consequences actually endorsed by the participant, to optimize the chance that the argument will be experienced as counter-attitudinal. Therefore, articulating ways to avoid consequences using self-generated PBS strategies is likely to result in dissonance, which can be resolved by increasing the use of those strategies and reducing the frequency or quantity of drinking. Reviews confirm that use of PBS is associated with fewer alcohol-related problems (Pearson, 2013; Prince et al., 2013). Therefore, writing about self-generated ways to use PBS during drinking occasions should produce dissonance that can be resolved by using more PBS, and this resolution of attitude-behavior discrepancy is likely to result in fewer alcohol-related consequences.

**8.2. Personalized Normative Feedback (PNF) Condition.** Participants in the PNF condition will receive gender-identity specific personalized feedback regarding their alcohol use, consistent with previous NIAAA-funded trials using trained facilitator-delivered PNF as a brief intervention conducted by this team (e.g., R01AA014576). The PNF intervention contains both text and graphic information regarding 1) the student's own drinking quantity and frequency of drinking, 2) perceptions of typical drinking by same-sex students on campus (i.e., perceived descriptive norms), and 3) actual drinking rates by same-sex students' on campus (i.e., actual descriptive norms). Normative feedback for male or female identifying students will use data from same-sex students on campus, whereas normative feedback for non-binary or genderqueer students will use data averaged across all students on campus. The actual norms will be referenced to the survey from which norms were generated (date, N, and campus), which took place on both campuses in March 2019.

The RA will present the PNF sheets, populated by the participant's baseline data and will explain their format, where the normative data came from, and engage the participant in interpreting the graphic feedback. The RA will ask if the student has any questions about the information before concluding the session. This brief discussion is designed to be educational and clarifying, and to roughly equate the amount of interpersonal interaction to that in the CAA condition.

**8.3. Assessment Only Control Condition.** Participants in the assessment only control condition will receive no intervention. The only contact will consist of completing the baseline assessment in lab as well as email and telephone reminders to complete the 1-, 3-, and 6-month follow-up assessments.

## 9. STUDY ASSESSMENTS AND PROCEDURES

**9.1. Baseline Assessment.** (See Appendix C)

### 9.1.1. Descriptive measures

*Demographics* will include class year, current residence, age, race, ethnicity, international student status, status as a first-generation college student, height, weight, religion, birth sex, gender identity, relationship status, immigration status and involvement in the Greek system.

*Other substance use* questions will include the NIDA Modified ASSIST, which assesses lifetime and past month use of tobacco products, cannabis, cocaine, prescription stimulants, methamphetamine, inhalants, sedatives or sleeping pills, hallucinogens and street opioids.

### 9.1.2. Primary and secondary outcomes

Alcohol consumption will be assessed with the Quantity-Frequency-Peak Alcohol Use Index (QFP; Baer, 1993; Marlatt, Baer, & Larimer, 1995), and the Daily Drinking Questionnaire (DDQ; Collins, Parks, & Marlatt, 1985; Kivlahan, Marlatt, Fromme, Coppel, & Williams, 1990). The Quantity-Frequency-Peak Alcohol Use Index is a five-item questionnaire that includes two items characterizing the occasion where respondents drank the most during the previous month (from which we calculate peak BAC), two items addressing typical weekend drinking in the previous month, and one item addressing typical number of drinking days per week in the past month. Typical weekly drinking and typical drinks per occasion will be assessed with the DDQ. Participants fill in the average number of standard drinks they consumed and the time period of consumption for each day of a typical week in the past month. The primary source for assessing drinking outcomes will be the DDQ, and QFP, which we have used in several previous RCTs in this population.

Alcohol-related negative consequences will be assessed with the 48-item Young Adult Alcohol Consequences Questionnaire (YAACQ; (Read, Kahler, Strong, & Colder, 2006). The YAACQ is a self-administered checklist of problems related to drinking that is tailored to college drinkers; responses are dichotomous (yes/no) and refer to past month. The YAACQ is reliable and free of gender bias.

Protective behavioral strategies will be measured with the 15-item Protective Behavioral Strategies Scale (Martens, Pedersen, LaBrie, Ferrier & Cimini, 2007) The PBSS assesses contingent frequency of using each strategy when drinking (1=never, 6=always) and is reliable and valid for use with college drinkers. This will be supplemented with the 4-item "Alternatives to drinking" factor (e.g., "Found other ways besides drinking to reduce stress") from the Protective Behavioral Strategies Questionnaire (Sugarman & Carey, 2007).

Drinking intentions will be assessed using a modified version the daily drinking questionnaire (DDQ; Collins, Parks, & Marlatt, 1985; Kivlahan, Marlatt, Fromme, Coppel, & Williams, 1990: Modified DDQ Intentions; Young, Rodriguez, & Neighbors, 2013). Participants fill in the average number of standard drinks they intend to consume and the time period of intended consumption for each day of a typical week in the next month.

### 9.1.3. Hypothesized moderators

Drinker identity will be assessed using the 5-item Alcohol Self-Concept Scale (ASCS). The ASCS was adapted from the Smoker Self-Concept Scale (Shadel & Mermelstein, 1996), and contains statements about the extent to which drinking plays a part in one's life and personality and others' perceptions of alcohol's role in one's life (e.g., Drinking is a part of 'who I am'). The ASCS is anticipated to serve as a moderator of the CAA interventions in tests of AIM 4. Specifically, we hypothesize that those higher in drinker identity will experience more dissonance and behavior change as a result of the CAA activity. In contrast, individual's who identify more strongly with drinking (Drinking is a part of 'who I am') will be less likely to change following PNF.

Preference for consistency will be assessed using the 9-item Preference for Consistency (PFC) scale. The PFC (Cialdini, Trost, & Newsom, 1995) contains statements such as, "I am uncomfortable holding two beliefs that are inconsistent." The PFC is anticipated to serve as a moderator of the CAA intervention in tests of AIM 2. Specifically, we hypothesize that the CAA will be more efficacious for those reporting a greater preference for consistency as they will change their attitudes and behavior in the argued direction more than those who report a lower preference for consistency. Similarly the PNF should be more efficacious for those with stronger preference for consistency because they are less comfortable deviating from the campus norms.

### 9.1.4. Hypothesized mediators

Attitudes toward moderate consumption and attitudes toward heavy consumption will be assessed with measures modified from previous research (Hagger et al., 2012; Norman, 2011). For moderate consumption, the stem will read, "Keeping my alcohol drinking within what is considered moderate drinking for adults (i.e. at 4 or fewer drinks for men or at 3 or fewer drinks for women) on each individual occasion over the next month would be…" For heavy consumption, the stem will read, "Having five or more drinks (for males)/four or more drinks (for females) in a sitting over the next month would be…" For both measures, there are five semantic differential scales that range from 1 to 5: unenjoyable-enjoyable, bad-good, harmful-beneficial, foolish-wise, and unpleasant-pleasant. To test AIM 3, changes in attitudes toward heavy drinking and attitudes toward moderate drinking are anticipated to serve as a mediator of the CAA (but not PNF) intervention effects.

Cognitive dissonance will be assessed using the Dissonance Thermometer (Devine, Tauer, Barron, Elliot, & Vance, 1999; Elliot & Devine, 1994; Simmons & Brandon, 2007; Simmons et al., 2004; Simmons, et al., 2013). Items include asking participants how uncomfortable, angry at themselves, shameful, uneasy, friendly (reverse sored), disgusted with themselves, embarrassed, bothered, optimistic (reverse scored), annoyed at themselves, disappointed at themselves, happy (reverse scored), energetic (reverse scored), and good (reverse scored) they feel immediately following the CAA activity. The 3-item affective discomfort factor has been found to be susceptible to cognitive dissonance inductions resembling our CAA procedure, with other target behaviors (Devine et al., 1999; Simmons et al., 2013). In Aim 3 we will test dissonance as a mediator of both CAA and PNF interventions.

Perceived descriptive norms will be measured by a modified version of the Drinking Norms Rating Form (DNRF; Baer et al., 1991). The gender-specific version (Lewis & Neighbors, 2004) assesses perceived typical number of drinks consumed per drinking occasion (e.g., "how many drinks on average do you think a typical male/female Brown/UH student consumes on a given occasion?"), and perceived frequency of drinking occasions (e.g., "how often do you think a typical male/female Brown/UH student consumes alcohol?"). The DNRF assesses perceived typical weekly drinking by having participants fill in the average number of standard drinks they think the typical (male/female) Brown/UH student consumes for each day of the week over the previous month. The DNRF has been used in multiple studies of college drinking and has shown good concurrent and prospective validity (Neighbors, Dillard, Lewis, Bergstrom, & Neil, 2006). In Aim 3 we test changes in descriptive norms as mediators of the PNF (but not CAA)

effects.

Perceived Injunctive norms will also be assessed using an adaptation of the DNRF shown to be reliably associated with respondent drinking (Krieger et al., 2016). This drink-based injunctive norms assessment includes (a) "maximum number of drinks a typical male/female Brown/UH student approves of consuming on one occasion?", (b) "maximum frequency of drinking a typical male/female Brown/UH student would approve of in a week?"), and (c) "what is the maximum number of drinks a typical male/female Brown/UH student would consider acceptable to consume on each day of the week?." Neighbors et al. (in preparation) recently demonstrated support for personalized injunctive norms feedback based using this measure (see preliminary studies). Additionally, injunctive norms will be assessed for negative consequences of drinking. Rating scales will be used to assess how unacceptable and acceptable experiencing specific drinking consequences is believed to be (Prince et al., 2015). These consequences include driving after drinking, drinking enough to pass out, blacking out due to drinking, etc. In Aim 3 we test changes in injunctive norms as mediators of the PNF (but not CAA) effects.

**9.2. Follow-up Assessments**. At 1-, 3-, and 6- months following their baseline assessment, participants receive an email inviting them to complete each follow-up assessment and containing a link to the online survey. All follow-up assessments will be completed using web-assessment, and measures will be identical to those given at baseline. Participants will receive an additional $25 electronic gift card for their 1-month follow up, $30 for their 3-month follow up, and $35 for their 6-month follow up. This gradual increase in payment will help ensure we have strong follow-up rates through the 6-month intervention period. Each follow up assessment should take approximately 30 minutes.

## 10. STATISTICAL CONSIDERATIONS

**10.1. Sample Size**. Power analyses focus on estimating a sample size large enough to detect "true" effects, thereby avoiding Type II errors. Sample size estimates were obtained for intervention contrasts. Necessary sample sizes were assessed via sample size and power equations for multi-level models using the Optimal Design software program. Based on previous findings using CAA and PNF approaches, we anticipate intervention effects relative to the neutral control condition to be in the small to medium range but at least comparable to effects which have been reported for personalized normative feedback, which are typically in the .28 range (e.g., Dotson et al., 2015). Based on the proposed sample size of 600, given four assessment points, we anticipate the ability to detect effects of intervention contrasts and moderation effects across the small to medium range. Considering maximum anticipated attrition rates of 15% (N=510) we will have .70, .80, and .90 power to detect effects sizes of delta = .24, .27, and .32, respectively.

**10.2. Analysis Plan**. Aims will be evaluated using generalized linear mixed models, an extension of general linear models allowing for multi-level data with non-normal distributions (e.g. Atkins, Baldwin, Zheng, Gallop, & Neighbors, 2013; Hedeker & Gibbons, 2006). With respect to evaluating main effects of experimental conditions on drinking, each participant will provide up to four assessments (baseline, 1-month, 3-month, and 6-month follow-up data). Hypotheses will be tested using specific contrast vectors, using a general linear hypothesis framework (Fox, 2008).

Hypotheses associated with Aim 1 will be evaluated examining outcomes as a function of two dummy coded variables representing CAA and PNF with control as the reference group. Time X CAA outcomes will provide direct tests of differences in change between CAA and control groups. We will utilize a Bonferroni correction with Šídák adjustment for correlated outcomes to reduce alpha inflation associated with multiple outcomes (i.e., moderation attitudes, heavy drinking attitudes, dissonance, drinks per drinking day, binge frequency, peak BAC, alcohol consequences, and PBS use.

For these analyses, each participant will provide up to 4 repeated measures (i.e., baseline, 1-month, 3- months, 6-months), yielding up to 2400 Level 1 cases (repeated-measures) across 600 Level 2

cases). Assuming outcomes follow a negative binomial distribution with a natural log link, the following model will be the basis for evaluating intervention effects as specified in Aim 1 hypotheses:

$$\text{Level 1:} \quad \log(E[DV]_{ti}) = \pi_{0i} + \pi_{1i}(Time)_{ti} + \varepsilon_{ti} \qquad \varepsilon_{ti} \sim N(0,\ I\sigma_{\varepsilon}^{2})$$

$$\text{Level 2:} \quad \pi_{0i} = \beta_{00} + \beta_{01}(site)_i + \beta_{02}(CAA)_i + \beta_{03}(PNF)_i + \beta + r_{00i}$$

$$\pi_{1i} = \beta_{10} + \beta_{11}(site)_i + \beta_{12}(CAA)_i + \beta_{13}(PNF)_i + r_{10i}$$

where *t* indexes repeated-measures and *i* indexes participants. Campus represents the differences between Brown and UH, CAA represents the difference between CAA and the Control group, and PNF represents the difference between PNF and the control group. *DVti* represents the outcome vector for each individual at each assessment point. *Time ti* measures weeks since baseline. Hypotheses associated with Aim 2 will test the relative efficacy of CAA vs. PNF using a non-inferiority design. Following the procedures outlined by Schumi & Wittes (2011), we have consulted a recent metaanalysis to obtain an effect size estimate of PNF efficacy (vs. Control) on drinking quantity ($d$ = .289, 95% CI [0.117, 0.451]) and consequences ($d$ = .157, 95% CI[0.037, 0.278]) (Dotson, Dunn, & Bowers, 2015). Next, we use the lower bound of each confidence interval as the basis for deriving our margin with respect to declaring non-inferiority. Thus M1= 0.117 for quantity and M1=.037 for consequences; these represent the most conservative estimate of the PNF effect. Then we select a smaller margin (M2) that represents the largest acceptable loss of effect when CAA is compared to PNF. Using a conservative estimate of M2 (50% of M1; USFDA, 2016), we establish non-inferiority if we retain at least half of the effect of PNF. Thus, if the lower bound confidence interval for the effect of CAA vs PNF is larger than half the lower bound estimate of the effects on drinking quantity (.117/2 = .0585) and consequences (.037/2 = .0185), we will be able to declare CAA is non-inferior to PNF.

Hypotheses associated with Aim 3 will evaluate mediators of intervention effects. We will follow procedures described by MacKinnon and colleagues (e.g., MacKinnon, Fairchild, & Fritz, 2007) to assess mediation. Mediation will test indirect effects using the AB products method with bootstrapped standard errors where A will represent effects of intervention contrasts by time interactions on mediators. B will represent the associations of mediators on subsequent drinking outcomes. Both A and B paths will control for baseline outcomes. Hypotheses associated with Aim 4 will follow a similar approach but will add prospective moderators and products of prospective moderators and contrasts

## 11. RISK/BENEFIT ASSESSMENT

**11.1. Possible Risks**. The level of risk that our volunteer participants will be exposed to by completing online surveys of their drinking practices and related cognitions, or by engaging in writing or computer feedback activities about promoting safer drinking practices on campus is minimal. The main risks of participation include (a) a breach of confidentiality or (b) discomfort or distress answering questions about drinking behavior and/or consequences.

Confidentiality could be breached by research staff or if data stored electronically were accessed by an unauthorized source. The seriousness of the consequences of a breach of confidentiality would depend on the nature of the information revealed and to whom the information was revealed. Some participants will be under the legal drinking age of 21, and will be reporting past episodes of underage drinking. However, this is a relatively small risk because, as a general rule, reports of past drinking carry minimal legal liability because of the difficulty in proving the behavior after the fact. Given the numerous steps we take to protect participant confidentiality (as described below), we think the risk of a breach of confidentiality is low.

Participants may feel uncomfortable or distressed answering questions about their drinking behavior on surveys. Participants will have been informed of the types of questions they will be asked to answer, and they likely would not choose to participate if these types of questions made them feel uncomfortable. Participants have the option of refusing to answer the questions or withdrawing from the

study if they think the questions are too personal. In our previous research using similar survey questions with thousands of college students, none of the participants reported being significantly distressed by the questions. At each assessment point, participants will have the option to download a Resource Sheet with contact information for substance abuse and mental health services (see Appendix C, Mental Health Safety Plan).

**11.2. Protection against Possible Risks**

**Minimization of risk -- Confidentiality.** Several steps will be taken to ensure that data remain confidential. These steps have successfully maintained confidentiality in our previous work with college student drinkers.

**(a) Identification numbers.** All participants will be assigned a unique study identification (ID) number upon enrollment, and the study ID will be the only identifier linked to participant responses on the online surveys and digitized audio versions of the orally delivered CAA essays and PNF feedback sessions. For participants in the RCT this ID number will be the only identifier in the database containing participant responses; the study ID number will be stored electronically in a tracking database with contact information and used to link the baseline, posttest, and follow-up surveys. The tracking database will be stored on a password-protected computer, and only study personnel will have access to the database linking names, contact information, and ID numbers. All identifying information will be destroyed upon completion of data collection.

**(b) Data storage.** All data will be stored electronically on secure servers by Qualtrics and then downloaded to the secure server at the Brown Center for Alcohol and Addiction Studies. A password will be required to access data that are stored electronically, and only personnel involved with the project will have access to the electronic data. In the RCT, names and identifying information required for follow-up reminders and follow-up payments will always be kept separate from research data. The data generated in the RCT will remain confidential until the final follow-up is completed, and then identifying information will be removed and the data de-identified.

**(c) Staff training.** All study staff will receive training in maintaining confidentiality. Training will focus on procedures for making sure data are not accessed by individuals outside of the research team, keeping identifying information separate from data, and not disclosing participant information or participant names to individuals outside of the research team. All staff will complete an online CITI ethics training, and will sign an agreement to keep all research information confidential. When hiring project staff, we will recruit individuals with previous research experience who demonstrate understanding of the importance of confidentiality and research ethics and convince the research team of their high personal integrity.

**(d) Presentation of published data.** Quantitative data will be published in aggregate form only. Data from individual participants will not be identifiable in reports or manuscripts.

**Minimization of risk -- Distress.** We will take several steps to reduce the possible discomfort or distress participants may feel about answering the survey questions or participating in the experimental manipulations.

**(a) Screening questions and study clearly explained.** Before answering screening questions, participants will be informed that responses are confidential, and they will only be used to identify who is eligible to proceed to consent to the study. None of the screening questions will be set to "force response" in Qualtrics, but if key eligibility criteria are skipped, the student will see a pop-up message acknowledging that they can't be determined to be eligible or not if the item is skipped. For those who are eligible, a detailed explanation of the study, including what study participation would involve, the nature of the questions participants will

be asked to answer, their right not to answer any question, the structure of the in-person session, and the right to withdraw from the study at any time without penalty will be provided to the participants, both in writing (through the informed consent form) and verbally (by the RA). Participants will be encouraged to ask questions about the study. Participants who are uncomfortable answering these types of questions or participating in this type of intervention can choose not to participate. Those who elect to participate but are uncomfortable with the procedures can choose to withdraw from the study.

**(b) Privacy.** Participants will also have the right to decide what they want to reveal about themselves. Participants will be told they have the right to refuse to answer any survey question, and they do not have to engage in any personal discussions that they are uncomfortable with during the experimental procedures.

**(c) Referrals.** At the end of each online survey (at baseline and all follow-ups), participants will be provided with a list of counseling centers and alcohol and drug resources, including ones both inside and outside of the university, and the phone number for a 24-hour crisis hotline.

**(d) Staff training.** We will hire staff with strong interpersonal and communication skills and the ability to empathize with others. Study team members will receive extensive training in respectful treatment of human subjects (i.e., CITI certification) and close supervision from Dr. Carey (a licensed clinical psychologist) and Drs. Neighbors and DiBello, all experienced researchers.

**11.3. Expected Benefits**. The research may directly benefit **participants** in several ways. First, in our previous research with college students, participants frequently report that they enjoyed completing self-report surveys that increase their awareness of their health behaviors. Some also report that completing the surveys led to their engaging in fewer health-risk behaviors. Second, participants who receive the counter attitudinal advocacy manipulation or the personalized normative feedback are expected to benefit from these "interventions" and reduce their risk of heavy episodic drinking. Third, some participants will find participating in the research is fulfilling because it affords them an opportunity for altruism, that is, they appreciate the chance to contribute to a prosocial activity that may help others like themselves reduce their risk of alcohol-related consequences.

The study will also benefit **the public health community and society in general**. Indeed, the overall goal of the research is to develop an intervention that will help college students to avoid drinking related-harms (injury, assault, property damage) to themselves and to others. Based on our findings, campus communities may be better prepared to prevent the onset of risky drinking practices.

**11.4 Data Safety and Monitoring Plan**. (See Appendix D)

**11.5. Adverse Events and Serious Adverse Events**.

We notified the Brown IRB, which is the lead IRB for this study, about two reportable events as described below. The IRB determined that no further action was needed.

Adverse Event #2

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| **Date of event:** | 12/2/2020 |
| **Date PI became aware** | 12/2/2020 |
| **Nature of event** | Any breach of privacy or confidentiality, including lost or stolen confidential information. |
| **Detailed description of event** | On 12/2/2020, an appointment reminder via text message was sent to the appropriate party including the participant's first name and |

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| | appointment time. However, due to a subsequent copy and paste error, an additional appointment reminder text was then sent to this same participant's phone number with an incorrect first name and appointment time. |
| **Corrective action or change to the protocol, planned or already taken, to ensure that the Reportable Event is corrected and will not occur again.** | In order to avoid the possibility of this event occurring in the future, all future participant communication via text messaging will exclude first names in the greeting.<br>Before sending the reminder text, double-check that the appointment information in the text is correct and corresponds to the participant you are scheduling.<br>Because this is a multisite study, this will be added to the protocol at both sites and implemented by all research assistants. |
| **Assessment of whether any subjects or others were placed at risk as a result of the Reportable Event, or suffered any physical, social, or psychological harm and (ii) any plan to address these consequences, and any other relevant information.** | (i) We do not believe any subjects were placed at risk as a result of this event. Only a first name was disclosed. Additionally, because this was a baseline session reminder text message, there is no way of the participant knowing if said individual joined the study.<br>(ii) We do not plan to take any additional action other than correcting our text message protocol as laid out above in Section III, as we do not believe any subjects were placed at risk as a result of this event. |

Adverse Event #1

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| **Date of event:** | 4/24/2020 |
| **Date PI became aware** | 4/24/2020 |
| **Nature of event** | Any breach of privacy or confidentiality, including lost or stolen confidential information. |
| **Detailed description of event** | On April 24th a participant was mistakenly sent a baseline session reminder email that contained the first name of another participant. The error was in the greeting line of the email, "Hi [participant name]". Only the first name of the participant was used. |
| **Corrective action or change to the protocol, planned or already taken, to ensure that the Reportable Event is corrected and will not occur again.** | The following text has been added to our study protocol for baseline session reminder emails.<br>"Open the Zoom Invitation email template.<br>Fill in the participant's name in the greeting. |

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| | Copy and paste their individualized Zoom meeting information into the body of the email. Sign your name in the signature line of the email. Before sending the reminder email, double-check that the information in the email is correct and corresponds to the participant you are scheduling."<br>Because this is a multisite study, this will be added to the protocol at both sites and implemented by all research assistants. |
| **Assessment of whether any subjects or others were placed at risk as a result of the Reportable Event, or suffered any physical, social, or psychological harm and (ii) any plan to address these consequences, and any other relevant information.** | (i) We do not believe any subjects were placed at risk as a result of this event. Only a first name was disclosed. Additionally, because this was just a baseline session reminder email, there is no way of the participant knowing if said individual actually joined the study.<br>(ii) We do not plan to take any action, as we do not believe any subjects were placed at risk as a result of this event. |

## 12. REGULATORY CONSIDERATIONS

**12.1. Consent.** Prior to COVID, participants consented to partake in the in-person baseline session via hardcopies of a consent form. The research assistant described the main points of the consent form verbally (as outlined in the Consent Script Checklist below) and the participant had an opportunity to read the consent form in its entirety before choosing to sign and date the form. Consent forms at both UH and Brown (see Appendix D) were kept in a secure location in the lab as well as scanned and saved to a secure folder in the respective PI's network drive as a permanent record.

Consent forms were altered slightly at both sites to accommodate a virtual format via Zoom baseline sessions post-COVID (see Appendix D).

**Consent Script Checklist (read verbally by research assistant both during in-person and virtual baseline session)**

The consent form generally covers what to expect of the study and your rights as a participant
The purpose of the study is to compare health promotion activities for college students
Participation is voluntary, you may withdraw at any point without penalty
Participants are assigned to 1 of 3 possible conditions randomly
If asked to participate in an activity condition, the activity will take about 20-30 minutes
If asked to participate in an activity condition, interactions with the RA may be recorded to ensure that research assistants are following the appropriate procedures
Following the activity, there will be an additional 10-minute survey
This study has been approved by an overseeing Institutional Review Board
For completing today's session they will receive a $25 amazon gift card code
Compensation for completing all parts of the study (Including follow-ups) will total $115 worth of amazon gift card codes
Do you have any questions about the study?

**12.2. Research Material Obtained from Human Subjects.**
Participants will be the sole source of data for this study and all data will be obtained specifically and exclusively for research purposes. Data collection will take place during in-person or remote baseline sessions, and remotely via online follow-up surveys. All collected data will be held confidential. Survey software Qualtrics ensures protection of information through its firewall systems and regular scans for vulnerabilities. The confidential system component design restricts access to outside parties and Qualtrics' use of Transport Layer Security (TLS) encryption protects all transmitted data.

**12.3. Access to Individually Identifiable Information.**
All participants will be assigned a unique ID. These IDs will be used to identify all participants on all research materials, surveys, tracking forms, as well as the database. Participants' names will never appear in any report resulting from the project. Separate from research records, an identifier key will be created that will link the participant ID to subject names and contact information, to facilitate follow-up with participants; contact information will have participant ID numbers but will not have any data. All data will be stored separately from identifying documents (e.g., participant tracking data base with names and phone numbers). Only the PIs and the research assistants will have access to project data until it is de-identified. Electronic data will be secured and accessible only through password protected computers. We will adopt the following measures to safeguard the data and participant confidentiality:

- All staff will be trained in procedures for maintaining confidentiality of participant information
- Electronic data collection forms will be identified by a unique identification number linked to an identifier list;
- The identifier key will be stored separately from the data collection forms and accessible by the only the research staff;
- Data will be stored on our password-protected computers and backed up to a secure server. Access to this server is password protected and only known to the PIs and RAs and backed up daily.
- We recommend that participants respond to follow-up surveys in a private location, and upon completion they close their browser to protect their privacy.
- At the end of the study, all personally identifying information will be erased. The data may be posted online when research results are published but it will not contain any information that could identify an individual or their participation in this research study.

**12.4. Programming Technology and Web Security.**
Information submitted via web-based surveys at baseline and at the follow-up assessments will be stored in a secure server at Brown University. The technology for transmitting and storing data includes Transport Layer Security (TLS) encryption (also known as HTTPS) and firewalls to protect the data and to prevent unauthorized access. We will download data from the Qualtrics website, and upload it to the secure Brown servers, at the end of each semester. When the study is over, we will ensure that the data are all removed from Qualtrics servers.
The screening survey will be completed anonymously, and screening data are unlinked to contact information obtained in the scheduler, so that we will not know the identities of students who complete the screener. During the RCT, face-to-face contact with participants is limited to the baseline/intervention session; research staff will be trained to identify adverse events (defined below) and report the to the site-specific contact. Similarly, any safety concerns raised by participants through study-related electronic/phone communications will be reported by research staff to the site-contacts, who will be prepared to provide referrals to their respective campus counseling centers. Finally, electronic surveys completed by participants will not be monitored at an individual basis, because of assurances that

responses to questions will not be associated with names, but each will end with a list of counseling centers and alcohol and drug services, as well as the number for a 24-hour crisis hotline.
All data will be stored electronically on the secure server at the Brown Center for Alcohol and Addiction Studies. A password will be required to access data that are stored electronically, and only personnel involved with the project will have access to the electronic data.

**12.5. Protocol Amendment History**

IRB submissions
Project: CAA R01, Using Counter Attitudinal Advocacy to Change Drinking Behavior (R01AA025043)
Year 1 start date: 9/15/18
Year 2 start date: 7/1/19

IRB Submissions
Project: PROJECT RAVEN: Using Counter Attitudinal Advocacy to Change Drinking Behavior

| | Brown # 1906002478 | | |
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| Submission type | Content | Date submitted or revised | Date approved |
| Initial application | Full application for RCT at Brown and UH; Brown IRB leads | 6/28/19 | |
| Revisions requested by IRB | **Questions/Requests**:<br>▪ The application is checked that you have completed GCP training, but I don't see that certification in CITI. If you completed GCP through another institution in the past 3 years, would you forward that certificate to me? If not, would you complete one of Brown's CITI *GCP modules*?<br>▪ In the Baseline Survey - Demographics, #18 (Immigration Generation), what is the justification for asking about the immigration status of the participant and their parents? Although written in general terms, this question has the potential to cause discomfort or distress.<br>▪ The consent document with my comments and track-changed recommended revisions is attached. Please accept the recommendations you like, address the question, and correct the document for any errors caused by the track changes.<br><br>**Application Revisions**:<br>▪ Part III, #3 (Intervention) states that "the oral presentation component of the CAA activity serves (a) to make the statement public." Do you intend to make these presentations publicly available? If so, please confirm that all identifiable information will be redacted before release. | 8/12/2019 | 8/21/19 |

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| | ▪ Part III, #5 (Recruitment Methods) states that this study does not involve an intervention, but the study meets the definition of a *clinical trial* and involves a behavioral intervention. Would you update this section with the applicable information?<br>▪ Part V, #2 (Facilitating Understanding) states that only English-speaking participants will be enrolled. Considering this is a large clinical trial, what is the justification for excluding non-English speakers?<br>▪ The checked box in Part VII, #1D is not clear on whether the data meets Level 2 or Level 3 risk. Would you clarify this section?<br><br>**Recruitment and Communication Material Revisions**:<br><br>▪ In all Brown and UH recruitment material, please remove all references to compensation in titles/headers and language throughout that may cause undue influence (for example, "Help advance" or "Help improve"), as this type of language is not allowable per the HRPP *recruitment policy*.<br>▪ In the CAAS Find A Study, please add "research," as it does not specify the recruitment is for a research study.<br>▪ In the Flyer Text, please remove any language throughout that may cause undue influence (for example, "advance" or "improve"), as this type of language is not allowable per the HRPP *recruitment policy*.<br>▪ In the Post on Facebook Class Pages, it says "(If from personal account...)." Will research staff recruit prospective participants from their personal Facebook accounts? If so, what is the rationale behind this, as opposed to creating a Project RAVEN Facebook page?<br>▪ In the Electronic Communications with Participants, please ensure the e-mails consistently specify the communication is for a "research" study. | | |
| Amendment 1 submitted by us | ▪ To establish an IAA with Houston using Brown as the IRB of Record | 8/12/2019 | 9/26/2019 |
| Amendment 2 submitted by us | ▪ Changed one item on the screener survey<br>▪ Removed one sentence from consent | 9/27/2019; revision requested and resubmitted on 10/25/19 | 10/25/2019 |
| Amendment 3 submitted by us | ▪ Addition of remote procedures<br>▪ Remote/Online consent form | 3/13/2020; revision request & | 3/17/2020 |

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| | ▪ Remote recruitment materials (revised appendix A) | resubmitted on 3/17/2020 | |
| Amendment 4 submitted by us | ▪ At all timepoints: Addition of COVID-specific measures, Perceived Stress Scale, study abroad intentions<br>▪ At 6-month timepoint: study recall, Attempted Control Scale<br>▪ At remote baseline: environmental description | 4/15/2020; revision request & resubmitted on 5/15/2020 | 5/18/2020 |
| | Revisions Requested:<br>▪ Addition of a risk assessment about the impact of COVID-19, as well as provide a list of relevant support resources (new Brown COVID policy)<br>▪ Will the addition of these questions to the surveys increase the time involved in the study? If so, do the consent documents and recruitment materials also need to be revised to reflect the added time involved in each study session? (Response: No) | | |
| Reportable Event 1 | ▪ Event Description: On April 24th a participant was mistakenly sent a baseline session reminder email that contained the first name of another participant. The error was in the greeting line of the email, "Hi [participant name]". Only the first name of the participant was used. | 4/28/2020 | 5/5/2020 |
| Amendment 5 submitted by us | ▪ Updated screener survey<br>▪ Updated recruitment materials (new Recruitment email and text reminders added at Houston site for participants who have been determined eligible via the screening survey but have not yet scheduled an appointment<br>▪ Addition of a brief consent form to the screener survey (Houston site; Version 1, 8/20/20)<br>▪ Include additional items to all surveys in order to measure the impact of COVID on participants (BIDR at baseline, WHO and Conway COVID items in post-intervention and 3 follow-up surveys)<br>▪ Addition of the Balanced Inventory of Desirable Responding Short Form to baseline surveys<br>▪ Updated Mental Health Safety Plan and participant resource list. | 8/27/2020 | 9/24/2020 |
| Revisions requested by IRB | ▪ Requested addition of protocol # (1906002478) and PI's names or other contacts to all recruitment materials | 9/10/2020 | 9/24/2020 |

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| | ▪ Requested to remove "Paid" from subject line of UH Recruitment and that Reminder Emails will include in the email text that Brown is a research partner in the study and that it was "approved by the Brown University IRB"<br>▪ Requested to remove emphasis on compensation line "Earn $115" in flyers for Brown<br>▪ Requested copies of parallel version of recruitment materials (e.g., flyers) for UH (in lieu of this request, study team decision was made to remove flyers as recruitment materials for UH)<br>▪ Recommended: two updated scheduling templates have been provided, which remove the location and provide a link to the Zoom call<br>▪ Requested submission of screenshots of what scheduler page looks like to participants<br>▪ In 12B ineligible text, IRB requested we add that participants may remove their information from the student database at any time by contacting [provide contact info]<br>▪ Recommended: confirm whether the added "How would you best describe your situation this semester" question will also be administered to UH students (answer: yes. Study team decision was made that UH students doing either remote or in-person instruction are eligible, while only Brown students doing in-person instruction will be eligible)<br>▪ Recommended: clarify if Question 11 ("Have you been in a study involving…") only applies to Brown students? (clarification: yes, the question is asked in UH surveys just with no study examples)<br>▪ Requested an updated Mental Health Safety Plan<br>▪ Personal Impact of COVID-19 and WHO Survey Tool are now added to the mental health safety plan)<br>▪ The statement "**These assessments will not be reviewed immediately**. Everyone participating in this research study will receive a list of contacts if they want to speak to someone about any health concerns or abuse" is now added on the first and last assessments. | | |
| Reportable event 2 | ▪ On 12/2/2020, an appointment reminder via text message was sent to the appropriate party including the participant's first name and appointment time. However, due to a subsequent copy and paste error, an additional appointment reminder text was then sent to this same participant's phone number with an incorrect first name and appointment time. | 12/2/2020 | 12/9/2020 |
| Amendment 6 submitted by us | ▪ Sharing deidentified data between Brown and University of Houston using a secure DropBox folder shared only with study personnel directly involved with | 12/18/2020 | 1/14/2021 |

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| | the project (principal investigators and the project manager at each site)<br>▪ Addition of Edward James as a research assistant | | |
| Revisions requested by IRB | ▪ Proof of investigator CITI training and request that Dr. Neighbors be added as a COI (Appendix G was sent to display that he was included on the original submission) | | |
| Amendment 7 submitted by us | ▪ Addition of a question to all assessments time points (baseline, 1-, 3-, and 6-month follow ups) asking about COVID vaccination status<br>▪ Addition of alternate recruitment announcements and language at the Brown site only. | 2/18/2021 | 3/02/2021 |
| Amendment 8 submitted by us | ▪ addition of alternate recruitment announcements to recruit more male participants at the Brown site<br>▪ Corresponding update to Recruitment Materials (pp. 2-3), which include edits to Today@Brown subject lines<br>▪ Use of Microsoft OneDrive to store deidentified study data at the Houston site | 4/23/2021 | 5/6/2021 |
| Administrative Acceptance 1 submitted by us | ▪ Request for the substitution of a new contact person at the Brown and Houston sites in the Consent form<br>▪ Corresponding change in Online Recruitment Materials at the Brown site | 8/11/2021 | 8/19/2021 |
| Amendment 9 submitted by us | ▪ Revised procedures to remove Microsoft TEAMS for remote participation<br>▪ Corresponding revised HRPP Consent Form for the Houston site | 8/26/2021 | 9/2/2021 |
| Reportable Event NOT submitted by us | ▪ Event description: On 09/20/2021 a participant at our Houston site expressed feeling distressed after completing baseline questionnaires. This participant explained that the questions made her realize how poor her current mental health was and gave specific examples of current (and recent) stressors. The participant did not endorse the intent or impulse to self-harm, and noted that she is under the current care of a Psychiatrist, with whom she has an appointment this week. The participant was given a NAMI resource guide as well as a campus-specific mental health resources list at the conclusion of the session.<br>▪ This Event was deemed not an unanticipated adverse event by Brown IRB, and the PIs decided not to pursue this issue further. | 9/20/2021 | |
| Administrative Acceptance 2 | ▪ Request to change the University of Houston designee at the Houston site on our Data and Safety Monitoring Board Plan who will take responsibility for distinguishing serious adverse events from non-serious adverse events. | 9/27/2021 | 9/29/2021 |
| Protocol closed | Submitted closure form to Brown IRB | 4/26/2023 | 4/27/2023 |

## 13. REFERENCES


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**APPENDIX A. Recruitment Materials and Participant Communications at both sites (pre-COVID)**

**UH Registrar Recruitment Email + Follow up emails**

1. **UH Recruitment Email:**

Subject line: Paid Online Heath Behaviors Study at UH

Dear <<student name>>,

The Psychology Department on campus is inviting University of Houston students to participate in a confidential, multi-part research study called "RAVEN" that examines campus health beliefs and behaviors.

Please take a brief, 3-minute online survey to see if you qualify for a study that could earn you up to $115 in Amazon gift cards.

Please visit <<SURVEY LINK>> to complete this mobile-friendly survey.

Participation is voluntary and your answers will be kept confidential.

For any related questions or concerns, please contact Dr. Clayton Neighbors at 713-743-3301 or by emailing raven@central.uh.edu.

This study was approved by the Institutional Review Board.

Thank you!

Clayton Neighbors, Ph.D. & the UH Project RAVEN Team,

**We cannot guarantee the confidentiality of email communication.*

**2. UH Reminder Screening Emails**

Subject Line: REMINDER: Paid Online Heath Behaviors Study at UH

Dear <<student name>>,

Greetings from Project RAVEN! We recently invited you to participate in Project RAVEN, a confidential, multi-part research study being conducted through the Psychology Department on campus that examines campus health beliefs and behaviors. This is just a reminder to let you know that there is still time to participate in our survey!

Please take our brief, mobile-friendly, online survey to see if you qualify for a study that could earn you up to $115 in Amazon gift cards.

<<SURVEY LINK>>

Participation is voluntary and your answers will be kept confidential.

For any related questions or concerns, please contact Dr. Clayton Neighbors at 713-743-3301 or by emailing raven@central.uh.edu.

This study was approved by the Institutional Review Board.

Thank you,

Clayton Neighbors, Ph.D. & the UH Project RAVEN Team

**We cannot guarantee the confidentiality of email communication.*

**3. UH Confirmation of Registration Email**

Subject Line: Project RAVEN Appointment Confirmation

Greetings from the Project RAVEN team,

Thank you for taking part in our study! You are scheduled for an in-lab session on <<TIME/DATE>> in the Fred J. Heyne Building (H), Room 208. Please contact our office at 713-743-3301 if you have questions. We look forward to seeing you.

Thank you,

Clayton Neighbors Ph.D. & the UH Project RAVEN team

**We cannot guarantee the confidentiality of email communication.*

Electronic Communications with Participants (Brown)

Drafts of electronic communications with participants.

All study emails will come from the ProjectRAVEN@brown.edu or RAVEN@central.uh.edu email addresses issued to this project. The following templates were developed for use at Brown and will be adapted for use at UH.

**4. Brown Project RAVEN Baseline Email 1:**

Subject Line: Project RAVEN Study Appointment

Dear Student,

Thank you for your interest in the Project RAVEN research study! Your on-campus appointment is scheduled for DATE @ TIME in LOCATION. This appointment should take about 75-90 minutes, and your $25 Amazon e-gift card will be emailed to you upon completion of the appointment. Please remember to bring your student ID. If you have any questions, please feel free to email us at ProjectRAVEN@brown.edu. We look forward to meeting you!

Best,

Study Staff: Melissa Hatch, BA

Project RAVEN Study

**5. Brown Project RAVEN Baseline Email 2 (Reminder):**

Subject Line: REMINDER: Project RAVEN Study Appointment

Dear Student,

As a reminder, your research study appointment is tomorrow DATE @ TIME in LOCATION. This appointment should take about 75-90 minutes, and your $25 Amazon e-gift card will be emailed to you upon completion of the appointment. Please remember to bring your student ID and check in at the front desk in the lobby (if in the School of Public Health location). If you have any questions, please feel free to email us at ProjectRAVEN@brown.edu. We look forward to meeting you tomorrow!

Best,

Study Staff: Melissa Hatch, BA

Project RAVEN Study

**APPENDIX B. Recruitment Materials and Participant Communications at both sites (post-COVID)**

**UH Registrar Recruitment Email + Follow up emails**

1. **UH Recruitment Email:**

**Subject line:** Paid Online Heath Behaviors Study at UH
Dear **<<student name>>**,

The Psychology Department on campus is inviting University of Houston students to participate in a confidential, multi-part research study called "RAVEN" that examines campus health beliefs and behaviors. This study can be completed remotely and is entirely online!

Please take a brief, 3-minute online survey to see if you qualify for a study that could earn you up to $115 in Amazon gift cards.

Please visit <<SURVEY LINK>> to complete this mobile-friendly survey.

Participation is voluntary and your answers will be kept confidential.
For any related questions or concerns, please contact Dr. Clayton Neighbors at 713-743-3301 or by emailing raven@central.uh.edu.

This study was approved by the Institutional Review Board.

Thank you!

Clayton Neighbors, Ph.D. & the UH Project RAVEN Team,

*WE CANNOT GUARANTEE THE CONFIDENTIALITY OF EMAIL COMMUNICATION.

**2. UH Reminder Screening Emails**
**Subject Line:** REMINDER: Paid Online Heath Behaviors Study at UH
Dear **<<student name>>**,

Greetings from Project RAVEN! We recently invited you to participate in Project RAVEN, a confidential, multi-part research study being conducted through the Psychology Department on campus that examines campus health beliefs and behaviors. This is just a reminder to let you know that there is still time to participate in our survey!

Please take our brief, mobile-friendly, online survey to see if you qualify for a study that could earn you up to $115 in Amazon gift cards.
<<SURVEY LINK>>
Participation is voluntary and your answers will be kept confidential.
For any related questions or concerns, please contact Dr. Clayton Neighbors at 713-743-3301 or by emailing raven@central.uh.edu.

This study was approved by the Institutional Review Board.

Thank you,

Clayton Neighbors, Ph.D. & the UH Project RAVEN Team

**We cannot guarantee the confidentiality of email communication.*

**3. UH Confirmation of Registration Email**
**Subject Line:** Project RAVEN Appointment Confirmation
Greetings from the Project RAVEN team,
Thank you for taking part in our study! You are scheduled for an online session on <<TIME/DATE>> . Please contact our office at 713-743-3301 if you have questions. We look forward to seeing you.
Thank you,
Clayton Neighbors Ph.D. & the UH Project RAVEN team
**We cannot guarantee the confidentiality of email communication.*

**4. Brown Electronic Communications with Participants**
Drafts of electronic communications with participants.
All study emails will come from the ProjectRAVEN@brown.edu or RAVEN@central.uh.edu email addresses issued to this project. The following templates were developed for use at Brown and will be adapted for use at UH.

**5. Brown Project RAVEN Baseline Email 1:**
Subject Line: Project RAVEN Study Appointment
Dear Student,
Thank you for your interest in the Project RAVEN research study! Your Zoom appointment is scheduled for DATE @ TIME in LOCATION. This appointment should take about 75-90 minutes, and your $25 Amazon e-gift card will be emailed to you upon completion of the appointment. Please remember you will need access to a computer with Zoom, a video camera and a quiet space for 90 minutes. Please have your student ID to display. If you have any questions, please feel free to email us at ProjectRAVEN@brown.edu. We look forward to meeting you!
Best,
Study Staff: Melissa Hatch, BA
Project RAVEN Study

**6. Brown Project RAVEN Baseline Email 2 (Reminder):**
Subject Line: REMINDER: Project RAVEN Study Appointment
Dear Student,
As a reminder, your Zoom research study appointment is tomorrow at DATE @ TIME. This appointment should take about 75-90 minutes, and your $25 Amazon e-gift card will be emailed to you upon completion of the appointment Please remember you will need access to a computer with Zoom, a video camera and a quiet space for 90 minutes. Please have your student ID to display. If you). If you have any questions, please feel free to email us at ProjectRAVEN@brown.edu. We look forward to meeting you tomorrow!
Best,
Study Staff: Melissa Hatch, BA
Project RAVEN Study

**7. Brown Email for participants who do not show up for scheduled baseline session:**
Subject Line: Reschedule Project RAVEN Appointment
Dear Student,
We missed you today and are sorry you couldn't make your scheduled Project RAVEN Zoom session. We hope you are still interested in participating! If so, please visit <scheduling link> to re-schedule your research appointment at a time that works better for you. We would still love the opportunity to get your input on these health promotion programs!
If you no longer wish to participate, we understand, but please reply to this email in order to let us know, and we will remove you from our list.
Best,
Study Staff: Melissa Hatch, BA
Project RAVEN Study

**APPENDIX C. Intervention scripts (PNF & CAA)**

**Remote (Zoom) Baseline Sessions Post-COVID Scripts**

Remote Baseline Session Protocol

This protocol is to be used in the circumstance that a participant cannot come into the lab for an in-person baseline session.

Pre-Baseline

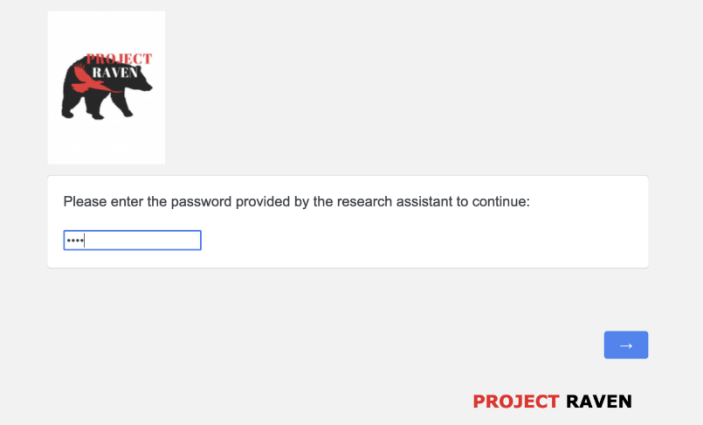
a. When a participant schedules a session, create a Zoom meeting using the information in the confirmation email.
    i. Log into The UH Project RAVEN Zoom account
    ii. Click "meetings" tab on the left, then "Schedule a new meeting"
    iii. Topic: "Project RAVEN Research Session"
    iv. Description: "This appointment should take about 60-90 minutes, and your $25 Amazon e-gift card will be emailed to you upon completion of the appointment. Please note that to participate in this study remotely you will need internet access, a computer with videoconferencing capabilities and a quiet, private space for 1.5 hours where you feel comfortable discussing your health behaviors with a research assistant. If you do not have access to these resources, please contact us and we will discuss scheduling an in-person session when classes resume in the fall."
    v. When: Enter date and time selected on Setmore
    vi. Duration: 1hr 30 min
    vii. Meeting ID: Generate Automatically
    viii. Meeting Password: Check "Require meeting password" and enter their participant ID
    ix. Video: Host: on; Participant on
    x. Audio: Telephone and computer audio
    xi. Meeting Options: Enable join before host
    xii. Save
b. Email the participant the Zoom Invitation email template. Include their individualized Zoom link.
c. 10 minutes prior to their scheduled time, email the participant the Zoom Reminder email template (see below) which should include their individualized zoom link and a link to the Qualtrics baseline survey

Orientation to Session and Consent

1. Begin the Zoom meeting and confirm that you and the participant can see and hear each other
2. Ask the participant about their environment. "Okay, before we begin our session, I need to make sure you're in an appropriate environment for our call. Could you tell me where you are?" "Okay, is this somewhere private where you feel comfortable discussing your health behaviors with me?"
3. Record the participant's responses in the tracking excel sheet. If the participant is in a public location or a location with too many distractions, ask that they reschedule their appointment for another time when they can arrange for a more private space.

a. Instruct them to open the survey link included in their confirmation email.

i. What the participant sees:

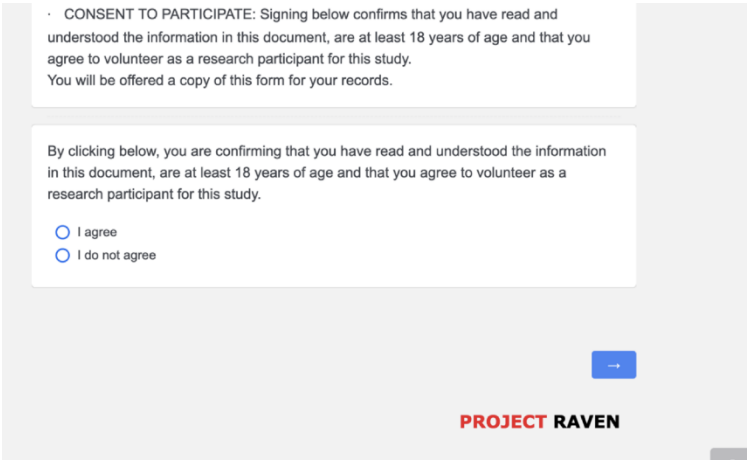



1. Instruct the participant to enter the password 1540 and then click the blue arrow. Ask them to follow along on their screen as you outline the main points from the Consent Form:

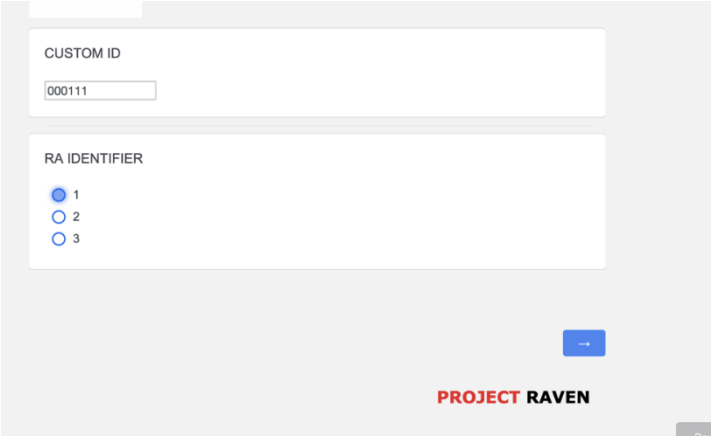
- This consent form describes your rights as a participant and what participation in this study entails
- The purpose of this study is to compare health promotion activities for college students
- Participants in this study are asked to answer several questionnaires and then are randomly assigned to 1 of 3 conditions, two of which entail brief activities
- If you are asked to participate in an activity condition today, the activity will take about 20-30 minutes and will be recorded to ensure that *I am* following the appropriate study procedures
- This study has been approved by Brown University's Institutional Review Board
- Your participation is *voluntary*, you may withdraw at any point without penalty
- For completing today's session you will receive a $25 amazon gift card code via email
- If you complete all parts of the study (Including the follow-up questionnaires) you will receive a total of $115 in amazon credit
- Do you have any questions about the study?

2. Once all questions are answered, ask that the participant click "agree" to certify that they understand and agree to participate in the study then
3. Ask them to click the next arrow

i. What the participant sees:



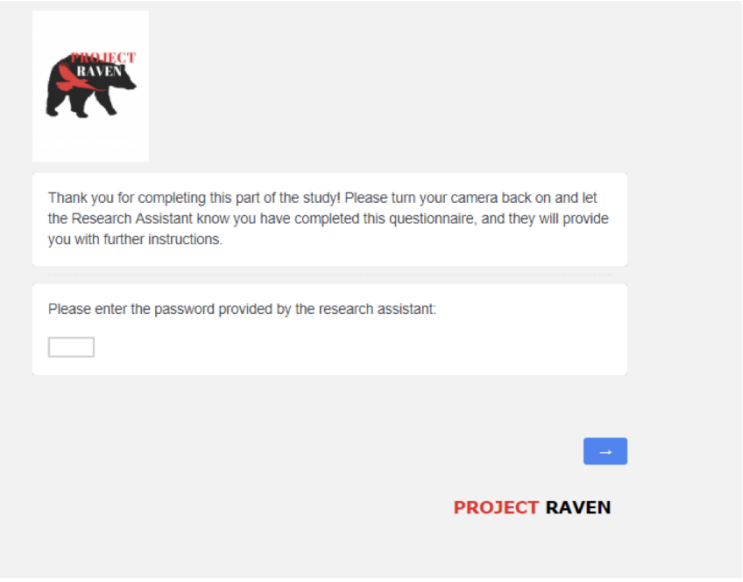
1. "We'll get you started by filling out a set of questionnaires that'll take about 30-45 minutes. Let's turn off our cameras while you respond to the survey, but I'll remain on the call to answer any questions you have. When you reach the end of the survey, let me know and we can go over the next part of the study"
2. Ask them to click the blue arrow and enter their Participant ID (with an 9 representing a remote participant (e.g., 91040) and select RA Identifier [1 = PNF, 2 = CAA, 3 = Control; based on condition]
    i. What the participant sees:




1. Turn off your camera and have the participant do the same if they like, but leave the Zoom call on in the background while the participant answers baseline in case they have any questions.
2. When the participant informs you that they have completed their session, proceed based on condition:

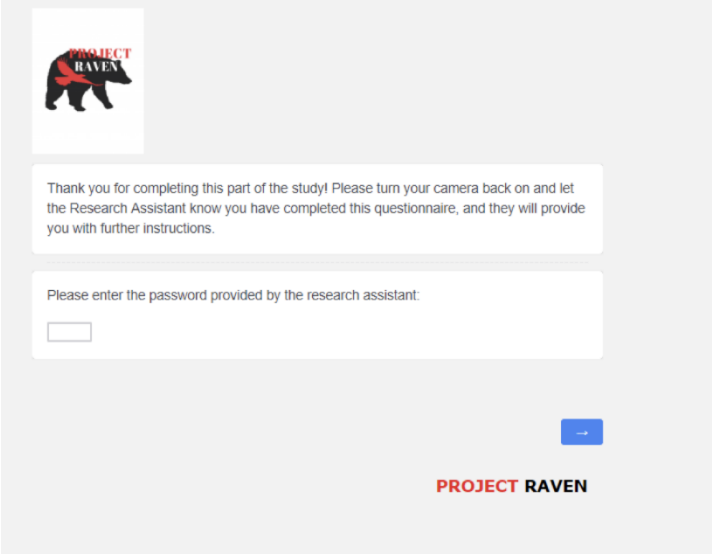
CAA Condition

1. When the participant reaches the end of the baseline survey and the password page appears, say "Okay, let's turn our cameras back on and I'll explain the next part of the study".
    i. What the participant sees:



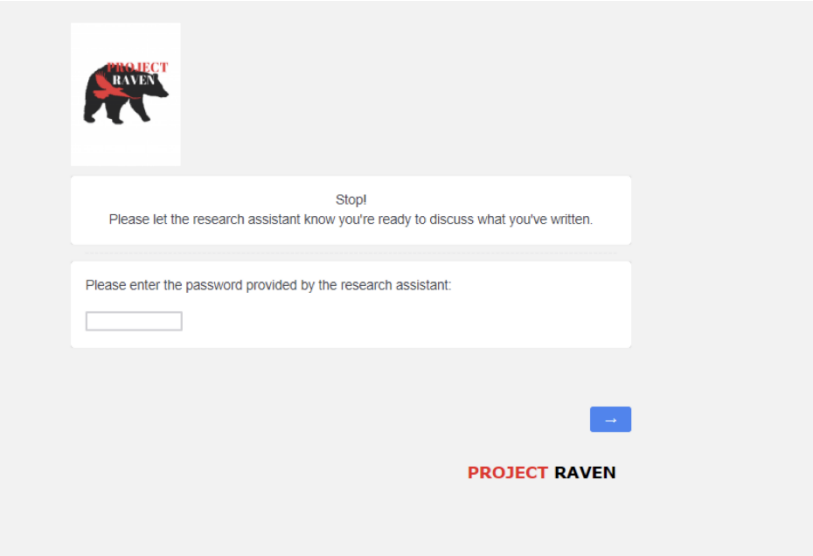
1. Explain the CAA activity to the participant:
- Thank them for completing survey, "now we will ask you to do a brief writing activity that reflects student perspectives on campus health and safety issues"
    - Choose one of three topics
    - At least 15 minutes to write

    - Instruct them to type “raven” into the textbox and click the blue arrow.



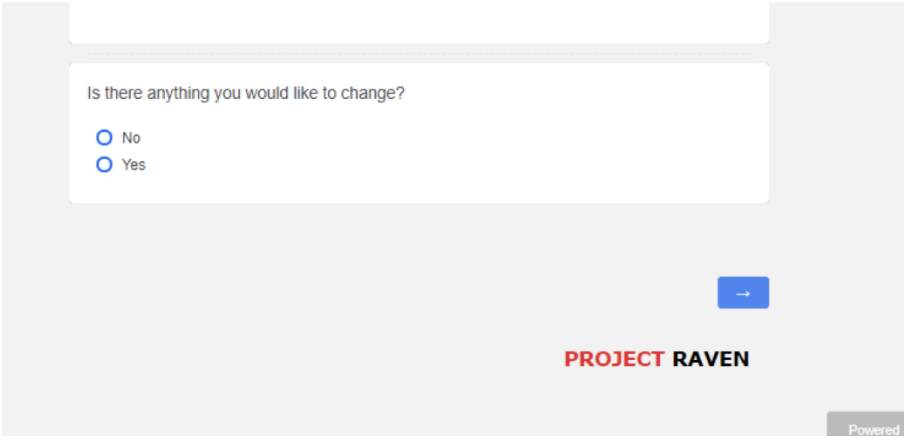

- I’m going to turn the camera off. Let me know when you're finished writing & we'll discuss it to make sure I understand what you've written”
2. Turn the camera off while the participant does the writing activity
3. When the participant tells you that they have completed the writing activity,
“Okay, let’s turn our cameras back on so that we can discuss what you wrote. What do you see on your screen?”
4. If they are not on the password page yet, instruct them to click the blue arrow to proceed. Next ask them to type “houston” in the RA Identifier box and click next.
    i.

What the participant sees:




5. Remind the participants "I am going to record our discussion to confirm that I am doing my job"
6. Turn recorder on and set it on the desk near the speaker
   - "So which topic did you select?" (TOPIC is piped in at the top of the page)
   - "Okay, what more specifically were you asked to write about?"
- "So it sounds like the prompt had multiple parts, could you tell me what you wrote about the first one?"
   - "So it sounds like a good reason to avoid problems is…"
-"Okay, were you asked to write about anything else?" then, "Okay, and what did you say were some ways students could do that?"
- "Thanks. So, if I follow correctly, your advice to other students would be to… [two personally relevant, effective and feasible strategies]. Do I have that right?"
- "Great! Now you'll be given the chance to edit or add to what you wrote and then there are a few more questions for you to answer before we conclude today's session. Just let me know when you complete the survey and I'll turn the camera back on to discuss your compensation."

What the participant sees:

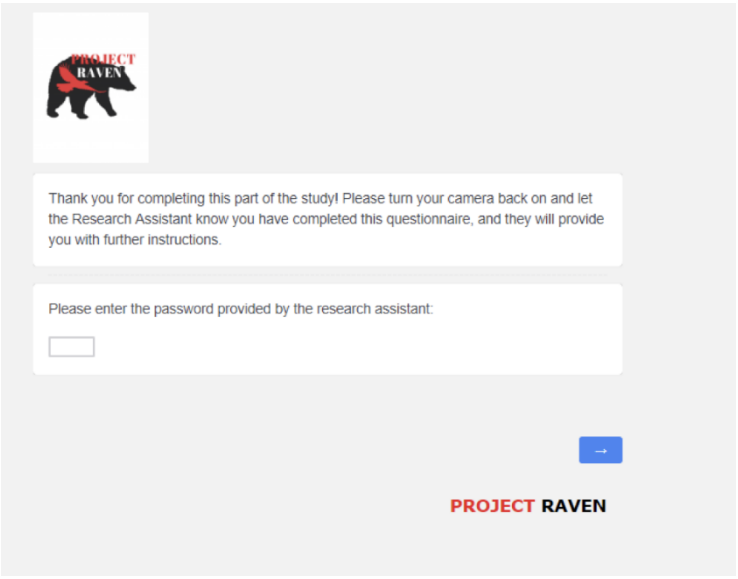



6. Turn the recorder and your camera off while the participant answers the follow-up survey

PNF Condition

1. When the participant reaches the end of the baseline survey and the password page appears, turn the camera back on and ask that the participant do the same. Explain the PNF activity to the participant
    i.

What the participant sees:




2. Let them know you will be screen sharing so that you can discuss the feedback together
3. Instruct them to type "raven" in the RA Identifier box and that another tab will open, but not to proceed while you set up the presentation.
4. Open the baseline completion email and click on the link to open the PNF in a new window (it default opens in a new tab). Move this tab to a new window, Share your screen with the participant, then make the presentation full screen. *Note that if you need to refer to the script/protocol you should have a pre-printed version* Confirm they can see your screen and the graph clearly.
5. Remind the participant "I am going to record our discussion to confirm that I am doing my job"
6. Walk the participant through the PNF activity as you would in person. At the end of each slide, ask the participant what questions/thoughts they have and ask them to let you know when they are ready to proceed. "Im going to give you a minute to look over this graph" PAUSE "What questions do you have/does this make sense/thoughts?"
7. Once you finish the PNF activity, inform the participant that they will now have the opportunity to click through the PNF *on their own* screen and then continue on to finish a few more questions. End the screenshare and turn your camera off.
8. Ask them to let you know when they complete the survey and you'll turn the camera back on to discuss their compensation.
9. While the participant finishes viewing the PNF and completes the post-intervention survey: Save their PNF slides as PDFs and combine the files into one. Do this by right clicking each PNF page and selecting "Print", then "Save as PDF". Save as "RAVEN Feedback_ID_page#" on the server.

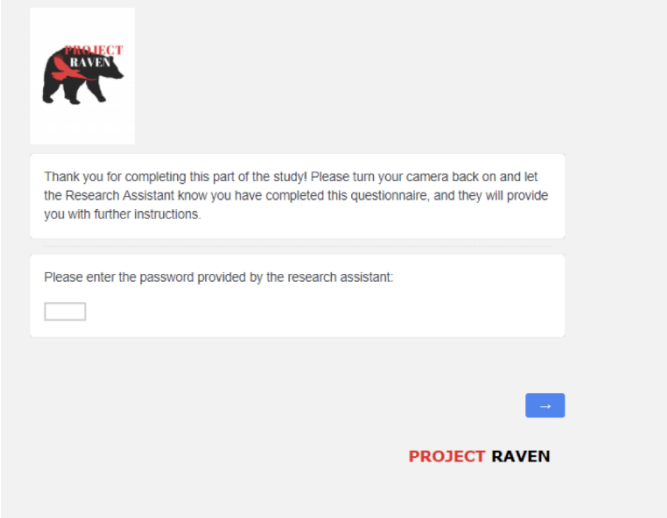
10. Once saved, merge the three PNF PDF pages together in Adobe and add the composite file to the debrief email to send the participant upon completion.

Control Condition

1. When the participant reaches the end of the baseline survey and the password page appears, turn the camera back on and explain that there are just a few more questions for them to answer. Ask them to type "raven" in the RA Identifier box to proceed. Tell them to let you know when they complete the survey and you'll turn the camera back on to discuss their compensation.

i. What the participant sees:

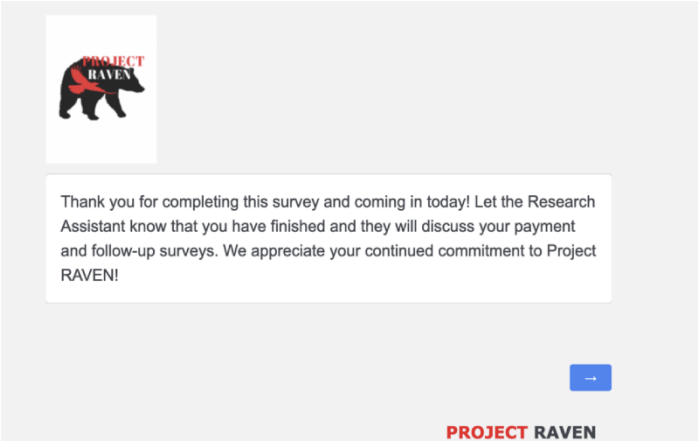
| After finishing the questionnaire |
|---|




Debrief

1. Ask the participant to click the blue arrow and ensure that their screen reads "We thank you for your time spent taking this survey. Your response has been recorded."

i. What the participant sees:



1. Verbally confirm their preferred email address

"You will be contacted in around 1-,3- and 6-months from now to complete follow-up surveys, for which you will receive $25, $30 & $35 to Amazon, respectively, for completing. These surveys are much shorter than the one you completed today and should take less than 20 minutes. Do you have any questions about the study?"

2. Tell them that you will email them a resource list now that we give to all participants along with our contact information in case they have any questions about the study
3. Thank them for participating in the study and close out the Zoom call
4. Email the participant the debrief email template, the resource list and the PNF PDF if applicable. Bcc the other RA on this communication, as a back up record in case the tracking document glitches.
5. Fill out the "Appt. Notes" column, if applicable (i.e. notable remarks, demeanor, late arrival, suggestions. Record any questions the participant asked and how you responded here, as well as in "Participant Question List and CAA Notes" on the DropBox)
6. Upload and save the recording on the *server* here: ('Z:\Project Raven\audio files' on the NeighborsLab$ drive) with the ID, Condition, your initial and the date recorded (e.g. 1000_CAA_AW_11.13.2019)

# APPENDIX D. Consent Forms

## In-person consent form pre-COVID at UH

BROWN

**CONSENT FOR RESEARCH PARTICIPATION**
Project RAVEN Study
Version 2, 10/21/2019

You are invited to take part in a research study that is jointly sponsored by Brown University and the University of Houston (UH). Your participation is voluntary.

- RESEARCHERS: Drs. Kate Carey (kate_carey@brown.edu), Angelo DiBello (angelo_dibello@brown.edu) and Clayton Neighbors (cneighbo@Central.UH.EDU) are the investigators in charge of this study.

- PURPOSE: This study seeks to compare brief health promotion activities designed for college students who drink. You are being asked to be in this study because you are a student between the ages of 18-26 and attending the University of Houston.

- PROCEDURES: This study involves 4 types of activities: (1) After reading this form, if you agree to participate, you will be asked to complete an online baseline survey. This survey will ask basic questions about you (e.g., your age, gender) and your social and health beliefs and behaviors (e.g., personality traits; alcohol and drug use; and mental health). You will be asked a few questions about alcohol consumption that must be answered to continue in the study. Answering these questions is up to you. If you choose to skip any of the required questions, you will be withdrawn from the study and receive partial compensation. You may skip any non-required questions that you do not feel comfortable answering. (2) This study will have 3 different groups of research participants. To decide which group you will be in, we will use a method of chance. This method is like rolling dice. After completing the confidential survey, you will be randomly assigned to (a) review a few pages of brief personalized feedback about yours and other students' drinking behaviors, or (b) complete a writing activity designed to share student perspectives on promoting healthy behaviors and then describe your recommendations to an RA, or (c) participate in assessment surveys only. The conversations with RA will be audiotaped to document that appropriate procedures were followed. (3) Next, you may be asked to complete a brief (~10 minute) survey sharing your thoughts and feelings about the activity/information you reviewed. (4) Approximately 1-, 3- and 6-months from your in-lab session, you will be invited to complete online follow-up questionnaires that should take about 30 minutes each.

- TIME INVOLVED: The time commitment to this study will be approximately 3 hours over a period of 6 months. Specifically, today you will be asked to complete a 40-60-minute baseline questionnaire and then you may be asked to participate in one of the student health behavior activities described above, which can take another 20-30 minutes. Then over the next 6 months you will be invited to complete three 30-minute online surveys on the following schedule: one month from today, three months from today, and the last 6 months from today.

- COMPENSATION: You can receive up to $115 for participating in this study: $25 for today's session (completing the baseline questionnaire and a health behavior activity), and $25 for completing the one- month follow-up survey, $30 for completing the 3-month follow-up survey, and $35 for completing the final 6-month follow-up survey.

Payment for participating in this study will be made using electronic gift cards to Amazon.com. Upon completion of this session, a link with your Amazon gift card will be emailed to the Brown-affiliated [UH-affiliated] email address you provided us with to schedule this appointment. Subsequent gift cards will be delivered through the same process upon completion of the brief 1-, 3- and 6-month follow-up surveys. There is information about how to use this gift card on Amazon.com and you can call [for Brown: Melissa Hatch at (401) 863-6631; for UH: Pelin Cunningham-Erdogdu at (713) 743-3301] if you have any questions regarding redeeming your gift card.

- RISKS: The risks in this study are minimal. The surveys and activities ask about your social and health behaviors and related beliefs and attitudes. It is possible that answering some of the questions in this study might cause some discomfort. You may withdraw from the study at any time without penalty. In the event that participation in this study triggers the desire to further discuss your health behaviors or other issues with a professional, a list containing contact information for confidential counseling and other student resources will be provided to all participants in this study.

- BENEFITS: We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, you will be contributing to research that may lead to better programs for future college students at institutions like Brown and UH.

- CONFIDENTIALITY: Your participation in this study and information gathered from the study will be kept confidential. This means that your answers to research questions will not be shared with anyone outside of the trained members of the research team. We take several steps to protect your privacy. For example, we will not connect your name to any research data. Instead, we will assign a code number to your information. We recommend that you respond to follow-up surveys in a private location, and upon completion you close your browser to protect your privacy. We will keep the master list that links your name to your code number separate from your questionnaire responses. At the end of the study, all personally identifying information will be erased. The data may be posted online when research results are published but it will not contain any information that could identify you or your participation in this research study.

  This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings (for example, if there is a court subpoena) without your consent. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to any person not connected with the research, you must provide consent to allow the researchers to release it.

  There are a few exceptions to confidentiality protections. Because this study is regulated by the Brown University Institutional Review Board (IRB), the IRB may choose to inspect research records that identify you. Also, we cannot refuse a request from United States Government personnel for information that is needed for auditing or evaluation of federally funded projects. Lastly, the Certificate of Confidentiality does not prevent us from disclosing to state or local authorities if you reveal any intention to hurt yourself or anyone else, or child and elder abuse.

  A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

- VOLUNTARY: The decision whether to be in this study is entirely up to you. Even if you decide to be in this study, you can change your mind and stop at any time with no penalty.

- CONTACT INFORMATION: If you have any questions about your participation in this study, you can contact Dr. Clayton Neighbors at cneighbo@central.uh.edu or 713-743-2616. Research staff can be contacted by email at RAVEN@central.uh.edu.

- YOUR RIGHTS: The Brown University Human Research Protection Program is responsible for monitoring human subjects protections for this joint study. If you have any questions concerning your rights as a research participant, you may contact them at (401) 863-3050 or email them at IRB@Brown.edu.

- CONSENT TO PARTICIPATE: Signing below confirms that you have read and understood the information in this document, are at least 18 years of age and that you agree to volunteer as a research participant for this study.

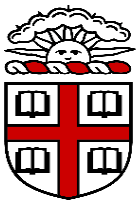
You will be offered a copy of this form for your records.

_____

Participant's Signature / Date / PRINTED NAME

**In-person consent form pre-COVID at Brown**

Appendix E: Informed Consent



BROWN

## CONSENT FOR RESEARCH PARTICIPATION

Project
RAVEN
Study
Version 2,
10/21/2019

You are invited to take part in a research study that is jointly sponsored by Brown University and the University of Houston (UH). Your participation is voluntary.

- RESEARCHERS: Drs. Kate Carey (kate_carey@brown.edu), Angelo DiBello (angelo_dibello@brown.edu) and Clayton Neighbors (cneighbo@Central.UH.EDU) are the investigators in charge of this study.

- PURPOSE: This study seeks to compare brief health promotion activities designed for college students who drink. You are being asked to be in this study because you are a student between the ages of 18-26 and attending Brown University [UH].

- PROCEDURES: This study involves 4 types of activities: (1) After reading this form, if you agree to participate, you will be asked to complete an online baseline survey. This survey will ask basic questions about you (e.g., your age, gender) and your social and health beliefs and behaviors (e.g., personality traits; alcohol and drug use; and mental health). You will be asked a few questions about alcohol consumption that must be answered to continue in the study. Answering these questions is up to you. If you choose to skip any of the required questions, you will be withdrawn from the study and receive partial compensation. You may skip any non-required questions that you do not feel comfortable answering. (2) This study will have 3 different groups of research participants. To decide which group you will be in, we will use a method of chance. This method is like rolling dice. After completing the confidential survey, you will be randomly assigned to (a) review a few pages of brief personalized feedback about yours and other students' drinking behaviors, or (b) complete a writing activity designed to share student perspectives on promoting healthy behaviors and then describe your recommendations to an RA, or (c) participate in assessment surveys only. The conversations with RA will be audiotaped to document that appropriate procedures were followed. (3) Next, you may be asked to complete a brief (~10 minute) survey sharing your thoughts and feelings about the activity/information you reviewed. (4) Approximately 1-, 3- and 6-months from your in-lab session, you will be invited to complete online follow-up questionnaires that should take about 30 minutes each.

- TIME INVOLVED: The time commitment to this study will be approximately 3 hours over a period of 6 months. Specifically, today you will be asked to complete a 40-60-minute baseline questionnaire and then you may be asked to participate in one of the student health behavior activities described above, which can take another 20-30 minutes. Then over the next 6 months you will be invited to complete three 30-minute online surveys on the following schedule: one month from today, three months from today, and the last 6 months from today.

- COMPENSATION: You can receive up to $115 for participating in this study: $25 for today's session (completing the baseline questionnaire and a health behavior activity), and $25 for completing the one- month follow-up survey, $30 for completing the 3-month follow-up survey, and $35 for completing the final 6-month follow-up survey.

  Payment for participating in this study will be made using electronic gift cards to Amazon.com. Upon completion of this session, a link with your Amazon gift card will be emailed to the Brown-affiliated [UH-affiliated] email address you provided us with to schedule this appointment. Subsequent gift cards will be delivered through the same process upon completion of the brief 1-, 3- and 6-month follow-up surveys. There is information about how to use this gift card on Amazon.com and you can call [for Brown: Melissa Hatch at (401) 863-6631; for UH: Pelin Cunningham-Erdogdu at (713) 743-3301] if you have any questions regarding redeeming your gift card.

- RISKS: The risks in this study are minimal. The surveys and activities ask about your social and health behaviors and related beliefs and attitudes. It is possible that answering some of the questions in this study might cause some discomfort. You may withdraw from the study at any time without penalty. In the event that participation in this study triggers the desire to further discuss your health behaviors or other issues with a professional, a list containing contact information for confidential counseling and other student resources will be provided to all participants in this study.

- BENEFITS: We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, you will be contributing to research that may lead to better programs for future college students at institutions like Brown and UH.

- CONFIDENTIALITY: Your participation in this study and information gathered from the study will be kept confidential. This means that your answers to research questions will not be shared with anyone outside of the trained members of the research team. We take several steps to protect your privacy. For example, we will not connect your name to any research data. Instead, we will assign a code number to your information. We recommend that you respond to follow-up surveys in a private location, and upon completion you close your browser to protect your privacy. We will keep the master list that links your name to your code number separate from your questionnaire responses. At the end of the study, all personally identifying information will be erased. The data may be posted online when research results are published but it will not contain any information that could identify you or your participation in this research study.

  This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative,

or other proceedings (for example, if there is a court subpoena) without your consent. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to any person not connected with the research, you must provide consent to allow the researchers to release it.

There are a few exceptions to confidentiality protections. Because this study is regulated by the Brown University Institutional Review Board (IRB), the IRB may choose to inspect research records that identify you. Also, we cannot refuse a request from United States Government personnel for information that is needed for auditing or evaluation of federally funded projects. Lastly, the Certificate of Confidentiality does not prevent us from disclosing to state or local authorities if you reveal any intention to hurt yourself or anyone else, or child and elder abuse.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

- VOLUNTARY: The decision whether to be in this study is entirely up to you. Even if you decide to be in this study, you can change your mind and stop at any time with no penalty.

- CONTACT INFORMATION: If you have any questions about your participation in this study, you can contact Dr. Kate Carey at kate_carey@brown.edu or (401) 863-6558, [or Dr. Clayton Neighbors at cneighbo@central.uh.edu or 713-743-2616]. Research staff can be contacted by email at ProjectRAVEN@brown.edu [RAVEN@central.uh.edu].

- YOUR RIGHTS: The Brown University Human Research Protection Program is responsible for monitoring human subjects protections for this joint study. If you have any questions concerning your rights as a research participant, you may contact them at (401) 863-3050 or email them at IRB@Brown.edu.

- CONSENT TO PARTICIPATE: Signing below confirms that you have read and understood the information in this document, are at least 18 years of age and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form for your records.

---

Participant's Signature / Date / PRINTED NAME

## Virtual consent form post-COVID at UH (via Qualtrics)

BROWN

**CONSENT FOR RESEARCH PARTICIPATION**
Project RAVEN Study Version 4, 8/4/2020

You are invited to take part in a research study that is jointly sponsored by Brown University and the University of Houston (UH). Your participation is voluntary.

RESEARCHERS: Drs. Kate Carey (kate_carey@brown.edu), Angelo DiBello (angelo_dibello@brown.edu) and Clayton Neighbors (cneighbo@Central.UH.EDU) are the investigators in charge of this study.

PURPOSE: This study seeks to compare brief health promotion activities designed for college students who drink. You are being asked to be in this study because you are a student between the ages of 18-26 and attending the University of Houston.

PROCEDURES: Participation in this study requires that you have secure internet access and access to a computer with a video camera. You will be using video conference software (Zoom at Brown, Microsoft TEAMS at UH), which may require the download of software to enable the videocall. Appointments should be scheduled during a time where you will have access to these resources and a private location for 90 minutes.

This study involves 4 types of activities, all conducted via online survey and video conference: (1) After reading this form, if you agree to participate, you will be asked to complete an online baseline survey. This survey will ask basic questions about you (e.g., your age, gender) and your social and health beliefs and behaviors (e.g., personality traits; alcohol and drug use; and mental health). You will be asked a few questions about alcohol consumption that must be answered to continue in the study. Answering these questions is up to you. If you choose to skip any of the required questions, you will be withdrawn from the study and receive partial compensation. You may skip any of the non-required questions that you do not feel comfortable answering. (2) This study will have 3 different groups of research participants. To decide which group you will be in, we will use a method of chance. This method is like rolling dice. After completing the confidential survey, you will be randomly assigned to (a) review a few pages of brief personalized feedback about yours and other students' drinking behaviors, or (b) complete a writing activity designed to share student perspectives on promoting healthy behaviors and then describe your recommendations to an RA, or (c) participate in assessment surveys only. The conversations with the RA will be conducted by video conference and audiotaped to document that appropriate procedures were followed. (3) Next, you may be asked to complete a brief (~10 minute) survey sharing your thoughts and feelings about the activity/information you reviewed. (4) Approximately 1-, 3- and 6-months from your initial study session, you will be invited to complete online follow-up questionnaires that should take about 30 minutes each.

TIME INVOLVED: The time commitment to this study will be approximately 3 hours over a period of 6 months. Specifically, today you will be asked to complete a 40-60-minute baseline questionnaire and then you may be asked to participate in one of the student health behavior activities described above, which can take another 20-30 minutes. Then over the next 6 months you will be invited to complete three 30-minute online surveys on the following schedule: one month from today, three months from today, and the last 6 months from today.

COMPENSATION: You can receive up to $115 for participating in this study: $25 for today's session (completing the baseline questionnaire and a health behavior activity), and $25 for completing the one-month follow-up survey, $30 for completing the 3-month follow-up survey, and $35 for completing the final 6-month follow-up survey.

Payment for participating in this study will be made using electronic gift cards to Amazon.com. Upon completion of this session, a link with your Amazon gift card will be emailed to the Brown-affiliated [UH-affiliated] email address you provided us with to schedule this appointment. Subsequent gift cards will be delivered through the same process upon completion of the brief 1-, 3- and 6-month follow-up surveys. There is information about how to use this gift card on Amazon.com and you can call Alyssa Rice at (713) 743-3301 or email aarice2@cougarnet.uh.edu if you have any questions regarding redeeming your gift card.

RISKS: The risks in this study are minimal. The surveys and activities ask about your social and health behaviors and related beliefs and attitudes. It is possible that answering some of the questions in this study might cause some discomfort. You may withdraw from the study at any time without penalty. In the event that participation in this study triggers the desire to further discuss your health behaviors or other issues with a professional, a list containing contact information for confidential counseling and other student resources will be provided to all participants in this study.

BENEFITS: We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, you will be contributing to research that may lead to better programs for future college students at institutions like Brown and UH.

CONFIDENTIALITY: Your participation in this study and information gathered from the study will be kept confidential. This means that your answers to research questions will not be shared with anyone outside of the trained members of the research team. We take several steps to protect your privacy. For example, we will not connect your name to any research data. Instead, we will assign a code number to your information. We recommend that you respond to follow-up surveys in a private location, and upon completion you close your browser to protect your privacy. We will keep the master list that links your name to your code number separate from your questionnaire responses. At the end of the study, all personally identifying information will be erased. The data may be posted online when research results are published but it will not contain any information that could identify you or your participation in this research study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings (for example, if there is a court subpoena) without your consent. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to any person not connected with the research, you must provide consent to allow the researchers to release it.

There are a few exceptions to confidentiality protections. Because this study is regulated by the Brown University Institutional Review Board (IRB), the IRB may choose to inspect research records that identify you. Also, we cannot refuse a request from United States Government personnel for information that is needed for auditing or evaluation of federally funded projects. Lastly, the Certificate of Confidentiality does not prevent us from disclosing to state or local authorities if you reveal any intention to hurt yourself or anyone else, or child and elder abuse.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

VOLUNTARY: The decision whether to be in this study is entirely up to you. Even if you decide to be in this study, you can change your mind and stop at any time with no penalty.

CONTACT INFORMATION: If you have any questions about your participation in this study, you can contact Dr. Kate Carey at kate_carey@brown.edu or Dr. Clayton Neighbors at cneighbo@central.uh.edu or 713-743-2616. Research staff can be contacted by email at RAVEN@central.uh.edu.

YOUR RIGHTS: The Brown University Human Research Protection Program is responsible for monitoring human subjects protections for this joint study. If you have any questions concerning your rights as a research participant, you may contact them at (401) 863-3050 or email them at IRB@Brown.edu.

CONSENT TO PARTICIPATE: Signing below confirms that you have read and understood the information in this document, are at least 18 years of age and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form for your records.

By clicking below, you are confirming that you have read and understood the information in this document, are at least 18 years of age and that you agree to volunteer as a research participant for this study.

- ○ I agree
- ○ I do not agree

# Virtual consent form post-COVID at Brown (via Qualtrics)

**CONSENT FOR RESEARCH PARTICIPATION**

Project RAVEN Study Version 3, 3/16/2020

You are invited to take part in a research study that is jointly sponsored by Brown University and the University of Houston (UH). Your participation is voluntary.

· RESEARCHERS: Drs. Kate Carey (kate_carey@brown.edu), Angelo DiBello (angelo_dibello@brown.edu) and Clayton Neighbors (cneighbo@Central.UH.EDU) are the investigators in charge of this study.

· PURPOSE: This study seeks to compare brief health promotion activities designed for college students who drink. You are being asked to be in this study because you are a student between the ages of 18-26 and attending Brown University.

· PROCEDURES: Participation in this study requires that you have secure internet access and access to a computer with a video camera. You will be using video conference software (Zoom), which may require the download of software to enable the videocall. Appointments should be scheduled during a time where you will have access to these resources and a private location for 90 minutes.

This study involves 4 types of activities, all conducted via online survey and video conference: (1) After reading this form, if you agree to participate, you will be asked to complete an online baseline survey. This survey will ask basic questions about you (e.g., your age, gender) and your social and health beliefs and behaviors (e.g., personality traits; alcohol and drug use; and mental health). (2) This study will have 3 different groups of research participants. To decide which group you will be in, we will use a method of chance. This method is like rolling dice. After completing the confidential survey, you will be randomly assigned to (a) review a few pages of brief personalized feedback about yours and other students' drinking behaviors, or (b) complete a writing activity designed to share student perspectives on promoting healthy behaviors and then describe your recommendations to an RA, or (c) participate in assessment surveys only. The conversations with the RA will be conducted by video conference and audiotaped to document that appropriate procedures were followed. (3) Next, you may be asked to complete a brief (~10 minute) survey sharing your thoughts and feelings about the activity/information you reviewed. (4) Approximately 1-, 3- and 6-months from your in-lab session, you will be invited to complete online follow-up questionnaires that should take about 30 minutes each.

· TIME INVOLVED: The time commitment to this study will be approximately 3 hours over a period of 6 months. Specifically, today you will be asked to complete a 40-60-minute baseline questionnaire and then you may be asked to participate in one of the student health behavior activities described above, which can take another 20-30 minutes. Then over the next 6 months you will be invited to complete three 30-minute online surveys on the following schedule: one month from today, three months from today, and the last 6 months from today.

· COMPENSATION: You can receive up to $115 for participating in this study: $25 for today's session (completing the baseline questionnaire and a health behavior activity), and $25 for completing the one-month follow-up survey, $30 for completing the 3-month follow-up survey, and $35 for completing the final 6-month follow-up survey.

Payment for participating in this study will be made using electronic gift cards to Amazon.com. Upon completion of this session, a link with your Amazon gift card will be emailed to the Brown-affiliated email address you provided us with to schedule this appointment. Subsequent gift cards will be delivered through the same process upon completion of the brief 1-, 3- and 6-month follow-up surveys. There is

information about how to use this gift card on Amazon.com and you can call Melissa Hatch at (401) 863-6631 if you have any questions regarding redeeming your gift card.

· RISKS: The risks in this study are minimal. The surveys and activities ask about your social and health behaviors and related beliefs and attitudes. It is possible that answering some of the questions in this study might cause some discomfort. You may withdraw from the study at any time without penalty. In the event that participation in this study triggers the desire to further discuss your health behaviors or other issues with a professional, a list containing contact information for confidential counseling and other student resources will be provided to all participants in this study.

· BENEFITS: We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, you will be contributing to research that may lead to better programs for future college students at institutions like Brown and UH.

· CONFIDENTIALITY: Your participation in this study and information gathered from the study will be kept confidential. This means that your answers to research questions will not be shared with anyone outside of the trained members of the research team. We take several steps to protect your privacy. For example, we will not connect your name to any research data. Instead, we will assign a code number to your information. We recommend that you respond to follow-up surveys in a private location, and upon completion you close your browser to protect your privacy. We will keep the master list that links your name to your code number separate from your questionnaire responses. At the end of the study, all personally identifying information will be erased. The data may be posted online when research results are published but it will not contain any information that could identify you or your participation in this research study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings (for example, if there is a court subpoena) without your consent. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to any person not connected with the research, you must provide consent to allow the researchers to release it.

There are a few exceptions to confidentiality protections. Because this study is regulated by the Brown University Institutional Review Board (IRB), the IRB may choose to inspect research records that identify you. Also, we cannot refuse a request from United States Government personnel for information that is needed for auditing or evaluation of federally funded projects. Lastly, the Certificate of Confidentiality does not prevent us from disclosing to state or local authorities if you reveal any intention to hurt yourself or anyone else, or child and elder abuse.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

· VOLUNTARY: The decision whether to be in this study is entirely up to you. Even if you decide to be in this study, you can change your mind and stop at any time. There will be no penalty if you decide not to be in the project or withdraw from the project later.

· CONTACT INFORMATION: If you have any questions about your participation in this study, you can contact Dr. Kate Carey at kate_carey@brown.edu or (401) 863-6558. Research staff can be contacted by email at ProjectRAVEN@brown.edu.

· YOUR RIGHTS: The Brown University Human Research Protection Program is responsible for monitoring human subjects protections for this joint study. If you have any questions concerning your rights as a research participant, you may contact them at (401) 863-3050 or email them at IRB@Brown.edu.

· CONSENT TO PARTICIPATE: Signing below confirms that you have read and understood the information in this document, are at least 18 years of age and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form for your records.

By clicking below, you are confirming that you have read and understood the information in this document, are at least 18 years of age and that you agree to volunteer as a research participant for this study.

○ I agree

○ I do not agree

Appendix E. Data Safety Monitoring Plan (DSMP)

| National Institute on Alcohol Abuse and Alcoholism | Version: DSMP V1 |
|---|---|
| | Effective Date: 01JUN17 |
| NIAAA Data and Safety Monitoring Plan (DSMP) | |
| PI Name: **Carey, Kate** | Grant Number: **1R01AA025043-01A1** |
| Approval Date: **LEAVE BLANK** | **LEAVE BLANK** |

Instructions: At a minimum, the DSMP must include the following critical elements as outlined on the NIAAA website and provided below. Please provide an answer addressing each critical element. If one of the elements does not apply to your study, please respond N/A.

1. A description of the entity(ies) responsible for monitoring the trial (e.g., an independent monitoring group or person, DSMB, etc.) and procedures for monitoring subject safety.

Dr. Carey, Contact PI, will have primary responsibility for monitoring the trial assisted by the other PIs who will meet as a team biweekly, as well as the DSMB that convenes twice per year.

The project coordinator will download and review all data on a monthly basis. Our data management plan contains periodic data quality checks, early generation of analysis variables, and interim data summaries to provide a check on completeness of study data. The full analysis plan will be executed on collected data at the end of the RCT to ensure that we have correct variables and fix errors so final analyses can be completed quickly.

The screening survey will be completed anonymously, and screening data are unlinked to contact information obtained in the scheduler, so that we will not know the identities of students who complete the screener. During the RCT, face-to-face contact with participants is limited to the baseline/intervention session; research staff will be trained to identify adverse events (defined below) and report the to the site-specific contact. Similarly, any safety concerns raised by participants through study-related electronic/phone communications will be reported by research staff to the site-contacts, who will be prepared to provide referrals to their respective campus counseling centers. Finally, electronic surveys completed by participants will not be monitored at an individual basis, because of assurances that responses to questions will not be associated with names, but each will end with a list of counseling centers and alcohol and drug services, as well as the number for a 24-hour crisis hotline.

## A. DSM BOARD PLAN

Because this multisite prevention study involves a relatively low risk protocol and a non- clinical participant pool, we propose to rely on the standing DSMB that meets monthly at the Center for Alcohol and Addiction Studies. The members will consist of **3 faculty members** with experience in conducting clinical trials, who have no conflict or role with the current study. This project will be reviewed **every 6 months**, and at these meeting the DSMB will evaluate the progress of the trial, review recruitment and retention rates, and examine any factors that may affect outcome. The DSMB reviews compliance with eligibility criteria and adherence to protocol safety rules. The DSMB will also review the rates of adverse events and serious adverse events to determine any changes in participant risk. DSMB members will be local to the prime site, permitting rapid communication with both research teams and IRB and the ability to convene quickly on issues related to participant safety or other problems, if necessary.

## B. CONFLICT OF INTEREST

Before being asked to serve on the DSMB, the PI will ensure that members do not have a conflict of interest. The PI will also check that members are not in conflict prior to all Board meetings in case something with respect to their status has changed

## C. PROTECTION OF CONFIDENTIALITY

Participants will only be identified by number during review of study progress by the DSMB. We are not collecting data requiring that confidentiality be breached.

## D. COMMUNICATION PLAN

A report will be submitted by the investigators **to the DSMB** twice a year, containing the following categories:

i. Brief description of the trial
ii. Baseline sociodemographic characteristics
iii. Recruitment rates
iv. Retention and disposition of study participants
v. Q.A. and data monitoring Issues
vi. Summary of AEs and SAEs and actions taken
vi. Summary of changes to participant risk and to protocol

The report submitted **after each DSMB** meeting to the IRB and NIAAA PO will include:

i. Brief description of the trial
ii. Summary of discussion
iii. DSMB recommendations/action items
iv. signature of DSMB members

2. Name of the responsible party (e.g., Principal Investigator, Study Physician if different than PI) who will distinguish a serious adverse event (SAE) from a non-serious adverse event (AE) and provide attributions (causality and severity). Provide a detailed accounting of how SAEs, AEs, and unanticipated problems will be managed consistent with local IRB guidelines (e.g. reporting requirements).

Each site has a designee who will take responsibility for distinguishing serious adverse events from non-serious adverse events: Dr. Carey (licensed clinical psychologist) for the Brown sample and Pelin Cunningham-Erdogdu for the Houston sample. Dr. DiBello (who also holds a masters in clinical counseling) will serve as back-up for both sites, due to his familiarity with both. In the proposed study we will use the FDA definition of adverse events (AE) and serious adverse events (SAE). An adverse event is any untoward (unexpected and undesirable) physical or psychological occurrence, serious and non- serious, in a participant that may have a causal relationship with study participation.
Symptoms or conditions present at or before the assessment that manifest themselves with the same intensity or frequency after study participation will not be recorded as adverse events. Although deemed highly unlikely, research staff will be trained to observe and report any unanticipated or adverse reactions reported by participants. The baseline session represents the only instance of face to face contact with participants. All other assessments are completed remotely online. Any concerns will be immediately reported to the investigators, who will review the information and classify the relationship of the study protocol to the event as:

- *Not related*: The event is clearly related to the participant's clinical state, not with the study protocol
- *Remote*: Event was most likely related to the participant's clinical state, not with the study protocol
- *Possible:* Event follows a reasonable temporal sequence associated with participating in the study but is possibly related to the participant's clinical state.
- *Probable:* Event follows a reasonable temporal sequence associated with participating in the study and cannot be explained by the participant's clinical state.

The scale below will be used to estimate the grade of severity of the adverse event:

- *Grade 1 Mild*: Transient or mild discomfort, no limitation of activity, no or minimal intervention/therapy required.
- *Grade 2 Moderate*: Mild to moderate limitation in activity; some assistance may be needed; no or minimal intervention/therapy required.
- *Grade 3 Severe:* Marked limitation in activity; some assistance usually required; intervention/therapy required; hospitalization possible.
- *Grade 4 Life –threatening:* Extreme limitation in activity; significant assistance required; significant intervention/therapy required; hospitalization probable (SAE).

3. A description of the follow-up plans for SAE and unresolved unanticipated problems.

During the intervention phase of the study the research staff will convene separately at both sites on a weekly basis to discuss study progress and potential problems. Informed consent forms will list the contact phone numbers for site PIs so that any potential adverse events or complaints can be reported by the students directly to the site PI or designee. In addition, the consent form will include the contact phone numbers for appropriate Brown University IRB personnel so that participants can directly report any complaints or potential adverse events.

4. Risks associated with study participation.

In our previous research in similar research projects at similar venues, no adverse events have occurred; therefore, in the proposed project, we anticipate the likelihood of an adverse event to be minimal.

5. Confirmation that SAEs and unanticipated events which are considered "at least possibly related" during the treatment and follow-up phases will be reported to the local IRB and to NIAAA within 48 hours of knowledge of the SAE and all other SAEs and unanticipated events must be reported within the time period mandated by the local IRB.

Yes. In the case of a serious event, a written report will be provided to the Brown University IRB (as Brown will serve as the IRB of record for both sites), and to the NIAAA project officer within 48 hours of the initial reporting of the event. Any actions determined by the Brown University IRB as a result of any adverse event also will be reported to NIH

6. A statement confirming that the Annual Report will include the following: a summary of all AEs, confirmation of adherence to the DSMP, a summary of any data and safety monitoring issues since prior reporting period, a description of the changes in the research protocol or DSMP and all new and continuing IRB approvals.

The annual report to NIAAA will include all AEs, confirmation of adherence to the DSMP, a summary of any data and safety monitoring issues since prior reporting period, a description of the changes in the research protocol or DSMP and all new and continuing IRB approvals.

7. Study inclusion and exclusion criteria

*Inclusion criteria for RCT*:
(1) Age 18-26
(1) Male or female student at Brown University or University of Houston
(2) Past month heavy episodic drinking (for men, >5 drinks in one day, for women >4 drinks in one day)
(3) At least two self-reported negative consequences from drinking in the past month
*Exclusion criteria for RCT*:
(1) Students that have requested that the university not share information about them will not be contacted during recruitment
(2) status as a senior graduating in the next 6 months

8. A statement confirming that trained clinical staff will be present or on call when study procedures take place, based on level of risk and consistent with approved protocol, policies and guidance from the local IRB and/or other regulatory and monitoring entities. Examples include (but are not limited to) the administration of alcohol, other drugs and/or medications; invasive or other study procedures or testing; etc. The types of trained personnel (e.g.: nurse, nurse practitioner, physician assistant, physician, etc.) should be stated.

The current study involves no invasive procedures requiring trained clinical staff, as participants will be engaged in completing survey questionnaires, engaging in self-directed writing tasks and discussing them with a research assistant. Nonetheless, we will designate a responsible person at each site who can be on call in the event of an adverse event. At the Center for Alcohol and Addiction Studies at Brown, Dr. Carey, is a licensed clinical psychologist has relevant experiences in clinical research, and staff training and supervision. At Houston, the designee will be Pelin Cunningham-Erdogdu, a research staff member.

9. For studies in which alcohol is administered, provide assurance that NIAAA guidelines for the administration of alcohol will be followed. These guidelines can be found here: Alcohol Administration Human Laboratory Studies.

N/A

10. Describe the plan for referral to treatment during follow-up phases for any research participant who requires additional intervention due to significantly increased alcohol consumption or serious psychiatric/medical symptoms.

The follow-up phases of this research involve electronic communications with participants and online surveys. Data will not be monitored at the individual level for changes in clinical status. However, at the end of each online survey, participants will be provided with the phone number for a 24-hour crisis hotline, as well as a list of counseling centers and alcohol and drug resources, including ones both inside and outside of the Universities.

11. Describe procedures for data quality assurance and protecting confidentiality of participant data (e.g., Certificate of Confidentiality).

We will follow data collection, storage, and management procedures that protect participant confidentiality. All data will be identified only by a unique subject identification number, which will be stored separately from identifying information. In addition, contact information will be collected and stored separately from survey responses, and will only be accessible to trained research staff that need to use it. Assessment data are stored on a secure server with a firewall to protect the data and to prevent unauthorized access.
Databases on the server are password protected and will be accessed only by research staff who have met the Brown University or University of Houston requirement for training in Human Subjects Protections. We will not share any specific information about participants with any other departments or offices at Brown University or the University of Houston.

12. Provide a statement indicating certification of IRB approval(s) of the study protocol will be provided to NIAAA prior to screening study participants. IRB approvals should be submitted (preferably electronically) to the NIAAA Grants Management Officer (GMO) before initiating a proposed clinical trial. For multi-site studies, the Data Coordinating Center (DCC) and associated study sites must submit certification of IRB approval as well as assurance that IRB approvals have been obtained for all study sites, are on file at the clinical site and DCC, and are available to the NIAAA upon request.

We confirm that an IRB application will be submitted through Brown University. Brown University will serve as the IRB of record and an IAA has been set up between Brown University and the University of Houston indicating that Brown University is the IRB of record. No recruitment or data collection will take place prior to full IRB approval.

13. Provide the analysis plan including the power calculation(s). There should be discussion of any planned interim and/or futility analyses, including adjustments for allocating “alpha” on “multiple looks” at the data.

Sample size and power calculations. Power analyses focus on estimating a sample size large enough to detect “true” effects, thereby avoiding Type II errors. Sample size estimates were obtained for intervention contrasts. Necessary sample sizes were assessed via sample size and power equations for multi-level models using the Optimal Design software program.

Based on previous findings using CAA and PNF approaches, we anticipate intervention effects relative to the neutral control condition to be in the small to medium range but at least comparable to effects which have been reported for personalized normative feedback, which are typically in the .28 range (e.g., Dotson et al., 2015). Based on the proposed sample size of 600, given four assessment points, we anticipate the ability to detect effects of intervention contrasts and moderation effects across the small to medium range.
Considering maximum anticipated attrition rates of 15% (N=510) we will have .70, .80, and .90 power to detect effects sizes of delta = .24, .27, and .32, respectively.

14. Provide the study stopping rules part of the study protocol. Generally, stopping rules reflect one of the following conditions: 1) there is clear evidence of harm; 2) there is no likelihood of demonstrating treatment benefit (futility); 3) there is overwhelming evidence of the benefit of treatment.

There are no study stopping rules associated with the current protocol. Based on prior research, there is no reason to believe that the interventions used in this study could cause harm. Therefore, we do not plan interim analyses prior to achieving our full sample. We anticipate that the full sample will be needed to have sufficient power to detect significant group differences.