Title: Personalized Feedback Programs for College Students

NCT #: NCT04975191

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Document Type: Protocol

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Print Close

View: SF - Study Identification

HM20022611 - Danielle Dick
Personalized Feedback Programs for College Students

Study Identification

1. * **Select the Principal Investigator:**
   Danielle Dick

2. * **Study Title:**
   Personalized Feedback Programs for College Students

3. * **Is this a student or trainee project in which activities will be carried out by that individual under your supervision (for example, dissertation or degree-required projects):**
   - ○ Yes
   - ● **No**

4. * **Please select the primary department or center that this study is being conducted under:**
   Psychology

5. [redacted]

6. [redacted]

[redacted]

7. * **Select one of the following that applies to the project (selection will branch to new pages):**
Note: VCU IRB offers guidance for many types of studies, including secondary data analysis studies, internet research, registries, EFIC, HUD, and Emergency Use protocols.
See *https://research.vcu.edu/human_research/guidance.htm*

- (●) **Research Project or Clinical Investigation [*most exempt, expedited, and full board research studies]**
- ( ) Exception from Informed Consent (EFIC) for Planned Emergency Research
- ( ) Humanitarian Use of Device for Treatment or Diagnosis
- ( ) Humanitarian Use of Device for Clinical Investigation
- ( ) Emergency Use of Investigational Drug, Biologic or Device
- ( ) Treatment Use (Expanded Access to Investigational Product for Treatment Use)
- ( ) Center or Institute Administrative Grant Review
- ( ) Request for Not Human Subject Research Determination (i.e. request a letter confirming that IRB review is not required)

View: SF2 - Federal Regulations

Federal Regulations

1. * **Is this a FDA regulated study?**

FDA regulated research includes all clinical investigations involving a test article and a human subject(s) that has been submitted for approval to the FDA or may be submitted in the future.
Check Yes if
- **the study involves an IND/IDE, abbreviated IDE, IND/IDE exemption, HUD, expanded access, or is otherwise subject to 21 CFR 56,**
- **the study involves a test article being administered or dispensed to subjects NOT according to a clinicians' medical judgment but rather, per the study protocol, OR**
- **the study does not involve a test article but intends to provide safety or efficacy data to the FDA.**

( ) Yes (●) **No**

2. * **Is this study supported by the Department of Defense (DoD):**

- ○ Yes
- ● **No**

3. * **Check if any of the following funding sources apply to this research (including Direct and/or Indirect funding):**

- ☐ Department of Education
- ☐ Department of Justice
- ☐ Environmental Protection Agency
- ☑ **None of the above**

View: SF2 - IRB Panel Setup

IRB Panel Setup

1. * **To which IRB is this study being submitted for review?**

- ● **VCU IRB**
- ○ WCG IRB
- ○ NCI Central IRB
- ○ Advarra IRB
- ○ Other IRB

2. * **Is this study transitioning to review by another IRB?**

- ○ Yes - transitioning from VCU IRB to an external IRB (WCG, CIRB, Other)
- ○ Yes - transitioning from an external IRB (WCG, CIRB, Other) to VCU IRB
- ● **No or not applicable**

View: SF2 - Review Setup

Review Setup

1. * **Select which study type best describes the majority of the study. Your response will help determine which IRB panel should review this.**
   - ○ Bio-Medical Research
   - ● **Social/Behavioral/Education (SBE) Research**

2. * **Which option(s) best describe the way(s) this study's procedures will be conducted? (Select all that apply.) This information may be used by the IRB in triaging studies during an emergency.**
   - ☐ In-person interactions / interventions with participants
   - ☑ **Remote interactions / interventions with participants**
   - ☐ Secondary data/specimen analyses and no contact with study participants

3. * **Does this study involve greater than minimal risk:**
   - ○ Yes ● **No**

4. * **Review type requested: (subject to IRB approval):**
   - ○ Full Board
   - ● **Expedited**
   - ○ Exempt

The IRB has determined that the selected types of anticipated individual and social benefit apply to this study

The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study. This information may be used by the IRB in triaging studies during an emergency situation.

There are no items to display

The following information applies to studies being reviewed by the VCU IRB.

The IRB has determined that the selected Exempt and/or Expedited categories apply to this study.

The below information is read-only to investigators, and the categories are set by the IRB during review. All

categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study or the study is being reviewed by an external IRB.

5. **For Expedited Studies:**
   There are no items to display

View: SF2 - Initial Setup Complete

Initial Setup Complete

Protocol Progress:
❶ **INITIAL SETUP**
② BACKGROUND, RATIONALE & GOALS
③ RESEARCH PLAN
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

View: SF2 - Background, Rationale and Goals

Background, Rationale and Goals

1. * **Describe the study's background and what is currently known from the scientific literature, including citations, or upload a citation list in document upload. Use lay language whenever possible.**

   College represents a unique opportunity to intervene and have positive life-course altering health benefits for a significant, rapidly growing (Dick et al., 2018), and increasingly diverse portion of the population (Dick & Hancock, 2015; Dick, 2018). Post-secondary enrollment is expected to grow to >24 million individuals by 2024, and college is now considered a “pervasive” American experience (Dick, 2018). College students are entering a critical developmental period for the establishment of health behaviors that persist into adulthood (Dick et al., 2018, Dick & Hancock, 2015), and college represents one of the few times in an individual’s life where all primary activities – social, career, health, and safety – are concentrated and controlled within a single setting. Accordingly, effective programs to promote health behaviors in the college setting are needed.

   Risky substance use among college students remains one of the most widespread challenges, with 39% of students

reporting that they binge drink (Substance Abuse and Mental Health Services Administration, 2011) and 36% of students reporting illicit drug use in the past year (Kilmer & Geisner, 2013). College students use alcohol at higher rates than their non-college-attending peers (Schulenberg et al., 2017) and nearly half (47%) of all students meet criteria for an alcohol or marijuana use disorder at least once in the first three years of college (Caldeira et al., 2009). Importantly, problematic substance use is associated with serious consequences, including unwanted sexual encounters, legal consequences, assault, injury, and suicide (Arria et al., 2013; Hingson, Zha, & Weitzman, 2009).

The current “gold standard” for reducing risky substance use among college students is the use of brief motivational interventions (BMIs) (Larimer & Cronce, 2002; Lee, Neighbors, Kilmer, & Larimer, 2010). BMIs aim to reduce harmful drinking practices by providing students with information about how their drinking compares to others, recognizing possible consequences associated with excessive alcohol use, and encouraging students to undertake new strategies to monitor their drinking, set limits, and reduce risk. BMIs are widely used on college campuses, with one national study finding that 62% of schools report utilizing empirically supported alcohol prevention BMI programming (Nelson, Toomey, Lenk, Erickson, & Winters, 2010).

Despite their widespread use and current status as the most effective available resource, a meta-analysis combining individual participant-level data from 6,713 individuals from 17 randomized clinical trials underscored the small effect sizes associated with BMIs and indicated a “need for the development of more effective intervention strategies" (Huh et al., 2015). Further, a review of interventions for college student drinking noted that “significant enhancement of personalized feedback intervention efficacy has not been observed in over 15 years of study” (Miller, Meier, Lombardi & Leffingwell, 2015). A second major limitation is that prevention and intervention programs for college students historically focused exclusively on alcohol. Rates of anxiety and other mental health challenges have also been rising in college students and it is inefficient to have programs that do not comprehensively address mental health. A challenge for college student mental health providers is that college students rarely want to engage in “prevention programming”. Resources on college campuses often go under-utilized. We propose to develop a program for college students that will capitalize on the element of current prevention programming that appears to be most critical to effectiveness: the delivery of personalized feedback to stimulate change (Cronce, Bittinger, Liu & Kilmer, 2014). However, rather than focusing feedback on current patterns of alcohol use, we will provide personalized feedback on underlying dispositional factors known to be related to substance use and other mental health challenges, along with personalized recommendations and resource information tailored to the individual’s profile(s). In this way, we will utilize findings from the basic epidemiological literature about the key personality pathways that influence substance use and mental health to create a Personalized Feedback Program for each student. Importantly, each of the personality-related dimensions for which we will give feedback has positive features in addition to potential challenges. Our intervention will shift the focus from the provision of information about relative levels of substance use (what is currently provided), and provide information about personality profiles that can contribute to health and wellness. This will help students understand the potential strengths associated with their personalized profiles, along with potential challenges and give them personalized resources. In this way, we aim to address several limitations of the current literature, by focusing on something likely to be of greater interest to students (personality) in order to provide information about resources that can support them in their college experience.

Citation list uploaded.

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
The primary aim of this randomized controlled trial (RCT) is to preliminarily evaluate the efficacy of the Personalized Feedback Program (PFP) as compared to an assessment only control group, a computer-delivered intervention based on brief motivational intervention (BMI) content/principles, and a combined PFP+BMI condition.

Hypothesis 1: Students who receive the PFP will demonstrate significantly lower rates of substance use and related problems in comparison to students in the control condition and the BMI group at the 30-day and 3-month follow-ups.

Hypothesis 2: Students in the PFP+BMI condition will display significantly lower rates of substance use than students in either the PFP or BMI conditions.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
The primary aim of this proposal is to conduct a preliminary test of efficacy of our newly developed innovative prevention intervention, the Personalized Feedback Program (PFP) for college students. The PFP provides feedback about students' unique personality-related traits and how these factors relate to wellness, general college success, and substance use, along with personalized recommendations and resources. Preliminary efficacy will be evaluated through a randomized controlled trial (RCT) comparing four conditions: assessment only controls, PFP, computer-delivered intervention based on brief motivational intervention (BMI) content/principles, and PFP+BMI.

4. * **Describe the scientific benefit or importance of the knowledge to be gained:**

Serving the students that are part of our university community is a critical task to ensure student success. At present, Brief Motivational Interventions (BMIs) are implemented widely on college campuses but have demonstrated very small effects. Accordingly, if the hypotheses in the present study are confirmed, the Personalized Feedback Program intervention provides a substantial addition to the existing knowledge base concerning interventions for college students. In addition, because the intervention is being implemented during college, potential benefits include the prevention of the severe academic functioning difficulties, including school dropout. Accordingly, developing programming to serve our students will contribute to the Quest for Distinction goal of improving student retention.

5. * **Describe any potential for direct benefits to participants in this study:**
The benefits of this study may be quite substantial. The potential benefits to the subjects of this study include a better understanding of their unique risk profile and how that relates to their potential for problematic drinking and substance use and impairment. Additionally, participants will be given personalized recommendations for VCU-based resources according to their profiles. Thus, they may benefit through being connected with university services early in their college career rather than waiting for problems to arise. It cannot be promised, however, that the subjects will directly benefit from the assessments or feedback provided through the interventions. Nominal payments will be provided for participation in the intervention and completion of the outcome measures.

6. * **Describe any potential for direct social impact in this study . For example, any engagement with specific communities to respond to community-identified needs, or ways the study will strengthen the well-being of the specific communities if applicable:**
There is great potential for impact on college student well-being. Risky substance use among college students is widespread and associated with significant adverse consequences. Current prevention intervention programs have limited effects, underscoring the need for innovative new ways to prevent college alcohol and other drug use. Our findings have great potential to enhance the effectiveness of college student substance use prevention programming and improve college student wellbeing.

7. **Upload a supporting citation list if applicable:**

View: SF2 - Study Population

Study Population

1. * **Provide the maximum number of individuals that**

1. May participate in any study interaction or intervention (Including screening, consenting, and study activities)
AND/OR

2. You obtain any data/specimens about (regardless of identifiability)

at VCU and at other sites under the VCU IRB's oversight. See the help text for additional guidance.
400

2. If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
The proposed study aims to enroll a random sample of 400 freshman college students in a randomized controlled trial (RCT). The RCT will have 4 conditions, each with 100 participants. We plan to present the study to freshmen ages 18 and older participating in the Spit for Science Baseline Survey being conducted in the Fall 2021 semester. We have determined a limit of 400 participants to account for future study attrition in order to reach our desired sample size of N=300 at each stage of the trial. We have previously been successful recruiting similarly sized samples of freshmen for web-based alcohol intervention studies.

4. * **List the study inclusion criteria:**
Consent: Voluntary consent must be provided.
Age: Students over the age of 18 may participate.
Year in college: Newly enrolled freshmen.
Enrollment status: Only full-time VCU students will participate.

5. * **List the study exclusion criteria:**
Age: Under the age of 18
Year in College: A sophomore, junior or senior
Enrollment Status: Enrolled part-time

6. * **Will individuals with limited English proficiency be included in or excluded from this research?**

- ○ Included
- ○ Excluded - safety concerns if participants are unable to communicate with the study team
- ○ Excluded - instruments/measures only validated in English
- ○ Excluded - no prospect of direct benefit to individual participants
- ● **Excluded - minimal risk study**
- ○ Excluded - lack of budget/resources for translation and interpretation [provide an explanation in next question]
- ○ Excluded - other reason [provide an explanation in next question]

7. Justify the inclusion and exclusion criteria if you are either targeting, or excluding, a particular segment of the population / community. Provide a description of the group/organization/community and provide a rationale.
The focus of the present (minimal risk) study is to conduct a preliminary test of efficacy of our newly developed innovative prevention intervention, the Personalized Feedback Program (PFP) for college students. As such, participants will only be included in the present study if they are a full-time college student. Alcohol intervention programming is generally designed for traditional college students attending school full-time. This is not problematic since close to 80% of the incoming freshman class each year registers for at least 9 credits and is considered full-time. Currently the intervention is being developed with VCU students in mind and the resources provided are specific to VCU; thus, only VCU students will be eligible to participate. We are limiting the study to college freshmen on the premise that a college student's first year is the most effective time to intervene given the variability in quantity and

frequency of substance use among freshmen and the fact that the proportion of people who report drinking rises steadily across the college years. On most college campuses, substance prevention programs are delivered to incoming freshmen, before they are exposed to increased risk following the transition. Accordingly, we want to focus activities and outcome evaluation on freshmen to increase the potential for generalization to other college campuses. In addition, incoming freshmen are at greatest risk for problematic alcohol use and associated consequences. Our own work in Spit for Science and that of a previous study following a cohort of incoming freshmen also found that variables measured at entry to university are among the strongest predictors of substance use and problems. These findings underscore the importance of early intervention aimed at incoming freshmen, which is why we focus on this population. Students who are considered freshmen based upon credits (e.g., withdrew from courses during first year and did not meet credit requirements to be considered sophomores), will not be eligible, as they would comprise a unique group of likely high risk students. We will limit enrollment to freshmen over the age of 18. This should not be difficult because 98% of incoming VCU freshmen are 18-19 years of age.

View: SF2 - Background, Rationale & Goals Section Complete

Background, Rationale & Goals Section Complete

Protocol Progress:
❶ **INITIAL SETUP**
❷ **BACKGROUND, RATIONALE & GOALS**
③ RESEARCH PLAN
④ CONSENT PLAN
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⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
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⑧ DOCUMENTS

Click Continue below to go to the next section

View: SF2 - Study Procedures

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
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2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
The primary aim of this proposal is to conduct a preliminary test of efficacy of our newly developed innovative prevention intervention, the Personalized Feedback Program (PFP) for college students. The PFP provides feedback about students' unique personality-related traits and how these factors relate to wellness, general college success, and substance use, along with personalized recommendations and resources. Preliminary efficacy will be evaluated through a randomized controlled trial (RCT) comparing four conditions: assessment only controls, PFP, computer-delivered intervention based on brief motivational intervention (BMI) content/principles, and PFP+BMI.

3. * **Choose all types of recruitment materials that may be used and upload them below:**

- [x] **E-mail invitations**
- [ ] Phone Solicitation scripts (i.e. cold calls or random-digit-dialing)
- [ ] Flyers, Mailed Letters or Newspaper/TV/Radio Ads
- [ ] TelegRAM announcements
- [ ] Website text
- [ ] Study-specific web sites (provide the design and text)
- [ ] Social Media
- [ ] EPIC MyChart Patient Portal research study descriptions
- [ ] Psychology Research Participant Pool (SONA) study descriptions
- [ ] Scripts for announcements made to groups
- [ ] Other recruitment material
- [ ] No recruitment materials

4. * **Describe the study procedures/methods for identifying and recruiting participants. Address the following three aspects of recruitment in your response.**

1. Identification of potentially eligible participants or secondary data/specimens of interest.
- What database(s) will be queried to identify secondary data/specimens
- How potential participants' contact information will be obtained

2. Recruitment procedures to invite participation in the study (when applicable):
- How each of the written or verbal recruitment materials and reminders (selected above) will be used
- Who will contact or respond to potential participants
- Locations where recruitment procedures will take place
- The timing and frequency of recruitment attempts

3. Eligibility screening prior to consent and how those activities will be carried out (when applicable)

See the help text for additional guidance.
Participants will be identified by self-selection during the Spit for Science baseline survey being conducted in the Fall 2021 semester. As part of the baseline survey, participants will be asked a yes/no question about their interest in learning more about the current spin-off study. Participants are informed that if they indicate 'yes' that their data and contact information will be shared with the Personalized Feedback Programs for College Students study (see document named: Spin-Off Invitation through S4S Baseline Survey). Spit for Science assigns randomly generated coded spin-off IDs for each participant. For participants that indicate ‘yes’ to the spin-off study interest question asked within the Spit for Science baseline survey, this spin-off ID is provided to the study project coordinator as part of the ‘turnover’ data, which includes email addresses, permanent address, phone number(s) and text permission if provided. The information will also include responses to the baseline measures. This data sharing will occur through a VCU approved file sharing application (like REDCap Send-It), a conditional Data Access Group (DAG) in the S4S baseline REDCap Project and/or through a shared, 'user-assigned' Participant Tracking REDCap Project.

When participants enter our study consent, they will be asked to provide their VCU email address, which will be used to match the participant back to the information provided by Spit for Science, including the spinoff ID. The spin-off ID will then be used throughout the course of the study procedures to link survey record IDs, survey data, and study data. Should they participate in the study, all survey data will be kept separate from identifiable information. The connection between a student email address and a particular record ID number is maintained behind the scenes in the REDCap system and on a password-protected secure server accessible only to select study staff. This key will be kept indefinitely on a secure server. All identifiable information from students who participate in the study will be deleted at the end of the study.

Once the study team receives the list of potential participants, the study team will randomize the participants across the four conditions. All participants have an equal chance of being randomized into each of the four conditions. The study team will then send these potential participants the “Study Enrollment Email.” This email will contain further details about the study along with a link to this study's consent in REDCap. They will be asked to enter their VCU email address as part of the consent process. Once they consent to participate, they will be automatically redirected to their condition’s program. These programs are outlined in the Study Procedures section. At the conclusion of their participation in their condition, additional contact information may be requested. Specifically, participants will be asked to confirm their VCU email address and phone number where they can be contacted to participate in the follow-up assessments. Additionally, if information that allows the study to carry out compensation steps was not provided previously (e.g. the participant’s permanent address) it will be requested at this time. While the email and mailing address questions will be required, students are able to decline to share their phone number.

The study survey will have a response limit of 400 respondents. Participants will be invited on a rolling basis (in batches according to when they complete the baseline survey) until we have reached 400. Once 400 participants have completed participation, the baseline survey will provide a message to subsequent interested participants indicating that: "Thank you for your interest in the personalized feedback program. This study is currently full. If the study opens enrollment in the future, we may contact you at that time to see if you are still interested. In the meantime, please keep an eye out for more emails from Spit for Science with other opportunities to participate in research!" The study staff will inform Spit for Science once the response limit is approaching/met and Spit for Science will remove (or alter the information presented indicating study enrollment is full) in the baseline survey to help ensure that unnecessary ascertainment and data sharing is avoided.

Starting one week after the initial invitation email is sent, eligible students who have not yet enrolled in the RCT will be sent email or text (if permission given) reminders. Reminders will be sent weekly for three weeks or until we have achieved our desired N.

All participants will be invited to complete follow-up assessments at two timepoints: 30 days after their initial participation (T2) and 3 months after their initial participation (T3). At each timepoint, they will be contacted by the study coordinator via the email address they provided on the initial survey (for content see “Intro Email/Reminder T2” and “Intro Email/Reminder T3”). The emails will contain a link to the T2 Survey and T3 Survey respectively. The reminder schedule will mirror the reminders for initial entry into the study. That is, starting one week after the invitation

email is sent, participants who have not yet completed the T2 (and later T3) survey will be sent email reminders. In addition to emails, students who shared their phone numbers in the initial survey at T1 will receive reminders via text. Reminders will be sent weekly for three weeks for each survey (for content see “Text Reminders”).

5. * **Does this study have a separate protocol document (i.e. a multisite or sponsor's protocol) that contains a detailed description of the study's methodology?**

   ○ Yes

   ● **No**

6. * **Since a separate protocol document is not uploaded, describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include:**

   1. A statement explaining the study design
   2. A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated
   3. A description of all research measures/tests/interventions that will be used (if applicable)

   See the help text for additional guidance
   Study Design: We will conduct a preliminary test of efficacy of our newly developed Personalized Feedback Program through a randomized controlled trial (RCT; target N = 400 freshman college students) comparing four conditions (N = 100 in each): an assessment only treatment as usual control group, Personalized Feedback Program (PFP), a computer-delivered intervention based on brief motivational intervention (BMI) content/principles, and a combined PFP+BMI condition.

   Study Procedure:
   Generally, participation begins during the Spit for Science baseline survey deployment. At the end of the baseline survey, participants are provided with a brief introduction to this study and asked if they are interested in participation and informed that if they indicate ‘yes’ that their information will be shared with the study staff so that the staff may contact them to complete study enrollment. The first 400 participants to respond “yes” to this question will be randomly assigned to one of the four conditions outlined below. Based on previous enrollment rates for similar studies, we believe this will allow us to reach our desired sample size of N=300 for each stage of the trial (timepoint).
   Participants will be sent invitations from the study coordinator to their university e-mail account provided on the Spit for Science baseline survey, with an embedded link to participate, which redirects students to the on-line study description and consent. The consent outlines the study procedures for three timepoints: one at the time of initial consent (T1), another 30 days after their initial participation (T2; 1-month follow-up), and a final follow-up approximately 3 months after their initial participation (T3; 3-month follow-up). Upon completion of the on-line consent in REDCap, participants will be redirected to the program to which they were randomly assigned. A description of the procedure at T1 for each condition is outlined below.

   Assessment only controls (to participants in this condition, this condition will be called the ‘Resources Program’): Upon acceptance of the consent document in REDCap, participants in the control condition will be directed to a REDCap survey. The first page of the survey will consist of a list of resources that they can utilize as a student at VCU containing links to the web pages associated with those resources (details on control group resource content can be found in Description of Measures and Interventions subsection). They will then be asked to answer questions pertaining to their future intentions regarding campus resource use, and alcohol and drug use. They will then be asked to provide their contact information, which will be used to contact them for the remaining follow-up surveys in the study and provide them with their compensation. Once participants complete the survey in REDCap they will automatically be emailed the resource list from the Resources Program should they wish to revisit any information provided. Participation for this group at T1 is expected to take ~10 minutes, but the exact length of time will vary according to how long they spend exploring the website links for the resources provided.

PFP: Upon acceptance of the consent document in REDCap, participants in the PFP condition will be directed to the Personalized Feedback Program (PFP) using an embedded link in the survey (details on PFP content can be found in Description of Measures and Interventions subsection). Immediately following completion of the PFP, students will be directed back to REDCap to answer a brief set of survey questions related to their experiences with the program (details on T1 post-program survey can be found in Description of Measures and Interventions subsection) and then to provide their contact information, which will be used to contact them for the remaining follow-up surveys in the study and provide them with their compensation. Once participants complete the survey in REDCap they will automatically be emailed their PFP results from REDCap should they wish to revisit any information provided. Participation for this group at T1 is expected to take ~20-30 minutes.

BMI: Upon acceptance of the consent document in REDCap, participants in the BMI condition will be directed to a computer-delivered intervention based on brief motivational intervention (BMI) content/principles using an embedded link in the survey (details on BMI content can be found in Description of Measures and Interventions subsection). Participants will be able to download their BMI feedback directly to their device. Immediately following completion of the modified BMI program, students will be directed back to REDCap to answer a brief set of survey questions related to their experiences with the program (details on T1 post-program survey can be found in Description of Measures and Interventions subsection) and then to provide their contact information, which will be used to contact them for the remaining follow-up surveys in the study and provide them with their compensation. Participation for this group at T1 is expected to take ~20-30 minutes.

PFP+BMI: Upon acceptance of the consent document in REDCap, participants in the PFP +BMI condition will be directed to the Personalized Feedback Program (PFP) using an embedded link in the survey (details on PFP content can be found in Description of Measures and Interventions subsection). Immediately following completion of the PFP, students will be directed back to a page in REDCap thanking them for completing the PFP and introducing them to the BMI. This page will direct participants to a computer-delivered intervention based on brief motivational intervention (BMI) content/principles using an embedded link. Participants will be able to download their BMI feedback directly to their device. Immediately following completion of the BMI, students will be directed back to REDCap to answer a brief set of survey questions related to their experiences with the programs (details on T1 post-program survey can be found in Description of Measures and Interventions subsection) and then to provide their contact information, which will be used to contact them for the remaining follow-up surveys in the study and provide them with their compensation. Once participants complete the survey in REDCap they will automatically be emailed their PFP results from REDCap should they wish to revisit any information provided. Participation for this group at T1 is expected to take ~40-50 minutes.

Approximately 30 days and 3 months post-intervention (post-intervention=after their initial participation at T1), all enrolled participants, regardless of their initial condition, will be invited via email and reminded via email and text by the study coordinator to complete the online Timepoint 2 (T2) and Timepoint 3 (T3) follow-up assessments. All students, regardless of their condition will be directed to the T2 survey at T2 and the T3 survey at T3 via a link in the invitation email and/or text (details on follow-up survey content can be found in Description of Measures and Interventions subsection). At T2, participants will go through the survey, completing all the questions. Upon completion of the survey, participants will be asked to provide their contact information, which will be used to contact them for the remaining follow-up survey in the study and provide them with their compensation. At T3, participants will go through the survey, completing all the questions. Upon completion of the survey, participants will be asked to provide their contact information, which will be used to provide them with their compensation. Each survey is expected to take 15-20 minutes to complete.

Description of Measures and Interventions
Control group resource list: After providing their consent to participate, participants randomly assigned to the treatment as usual control group will be presented with a list of resources available to them as VCU students (e.g. Writing Center, Recreation and Well-Being, Rams Connect), etc. Each resource will link out to its respective web page. The resources listed will match those provided throughout the Personalized Feedback Program (PFP). See attached document “Resources for control group” for full list.

PFP: In the PFP, students will answer items from the short UPPS-P Impulsive Behavior Scale (SUPPS-P; Lynam, 2013) which will measure impulsivity facets and the Big Five Inventory (BFI, John & Srivastava, 1999) which will estimate participant levels of extraversion vs introversion, conscientiousness vs. lack of direction and neuroticism vs. emotional stability. Based on their responses to these items, they will receive personalized feedback and campus resources to help them succeed during college. Further interactive elements in the program allow them to consider their goals, what could help them achieve those goals, and what may interfere. They are then guided through four sample scenarios where they can select different choice options and view their outcomes. See attached document "PFP" for the text included in the program.

BMI: In the computer-delivered intervention based on BMI content/principles, students will answer items from the Brief Alcohol Screening and Intervention for College Students (BASICS FLv3*) survey (currently used by the VCU Division of Student Affairs) regarding their levels of alcohol consumption over a typical two-week period, their levels of alcohol consumption on a peak occasion in the past three months, their experiences when they drink, things that have happened to them in the past year as a result of their drinking, their harm reduction strategies regarding alcohol, the money they spend on alcohol, and their demographics. They will answer further items from the Alcohol Use Identification Test (AUDIT; Bohn, Babor, & Kranzler, 1995) regarding their alcohol consumption and its ramifications on their lives. Participant responses to these questions will be used to generate a personalized feedback report showing them where their consumption levels fall in comparison to other VCU students, providing a summary of their drinking habits and alcohol-related spending habits, and details on how their alcohol use may impact their sleep and nutrition. They are provided with their typical and peak blood alcohol content, calculated using the U.S. Dept. of Transportation, National Highway Traffic Safety Administration's formula (National Highway Traffic Safety Administration, 1994). They are given a risk score based on the alcohol-related harms they've experienced calculated using the Brief Young Adult Alcohol Consequences Questionnaire (Kahler, Strong, & Read, 2005) as well as their score on the AUDIT. Finally, they are given an opportunity to think through their intentions regarding future use and the support available to them

*The survey and feedback reports at Columbia University, University of Washington, University of Northern Texas, and University of Vermont have served as models for this intervention. Version 3.0 (2017) was developed by Nancy Reynolds, MSPH, BASICS Director at Ithaca College, with generous input from the entire community of BASICS professionals. The VCU BASICS survey is available at

T1 Post-Program Survey:
Control: The T1 post-program survey will ask questions pertaining to participants' satisfaction and experiences with the Resources Program. They will then be asked questions pertaining to their future intentions regarding campus resource use, and alcohol use and drug use, as well as their risk comprehension. See attached document "Immediate Post-Survey Control".
PFP: The T1 post-program survey will ask questions related to participants' satisfaction and experiences with the Personalized Feedback Program. They will then be asked questions pertaining to their future intentions regarding campus resource use, and alcohol use and drug use, as well as their risk comprehension. See attached document "Immediate Post-Survey PFP".
BMI: The T1 post-program survey will ask questions related to participants' satisfaction and experiences with the BMI Program. They will then be asked questions pertaining to their future intentions regarding campus resource use, and alcohol use and drug use, as well as their risk comprehension. See attached document "Immediate Post-Survey BMI".
PFP+BMI: The T1 post-program survey will ask questions related to participants' satisfaction and experiences with both the Personalized Feedback Program and the BMI Program. They will then be asked questions pertaining to their future intentions regarding campus resource use, and alcohol use and drug use, as well as their risk comprehension. See attached document "Immediate Post-Survey PFP+BMI".

T2 Survey: The T2 survey will be the same as the T3 survey. It will include items from the following validated measures: Mental Health Continuum-Short Form (MHC-SF; Keyes, 2009), Semi-Structured Assessment for the Genetics of Alcoholism (SSAGA; Bucholz et al., 1994), Alcohol Use Disorder Identification Test (AUDIT; Bohn, Babor, & Kranzler, 1995), Symptom Checklist-90 (SCL-90; Derogatis, Lipman, & Covi, 1973), and Alcohol: Stages of Change (Short Form) (Laforge, Maddock, & Rossi, 1998). These items will assess well-being, alcohol use/problems, drug use, current anxiety/depressive symptoms, and additional questions will be asked pertaining to utilization of campus

resources and risk comprehension. Additional items will be included to assess program usefulness.

T3 Survey: The T3 survey will be the same as the T2 survey. It will include items from the following validated measures: Mental Health Continuum-Short Form (MHC-SF; Keyes, 2009), Semi-Structured Assessment for the Genetics of Alcoholism (SSAGA; Bucholz et al., 1994), Alcohol Use Disorder Identification Test (AUDIT; Bohn, Babor, & Kranzler, 1995), Symptom Checklist-90 (SCL-90; Derogatis, Lipman, & Covi, 1973), and Alcohol: Stages of Change (Short Form) (Laforge, Maddock, & Rossi, 1998). These items will assess well-being, alcohol use/problems, drug use, current anxiety/depressive symptoms, and additional questions will be asked pertaining to utilization of campus resources and risk comprehension. Additional items will be included to assess program usefulness.

Secondary Data Elements: Answers to the Spit for Science baseline survey will be incorporated as study baseline data as well. Data sharing will follow the same secure options previously described.

7. * **The IRB only reviews research activities, so indicate which of the study activities are:**

   - Being performed exclusively for research purposes (i.e. they would not otherwise be done apart from this study) VERSUS.
   - Alterations of routine activities/procedures (e.g. the study is altering the timing, frequency, method, location, amount, etc.) VERSUS.
   - Being done for other purposes and whose data/results will be used secondarily in the study (e.g. standard medical or psychological tests, routine education practices, quality improvement initiatives, etc.).
   This study is being performed exclusively for research purposes, though we anticipate that the findings will have important implications for substance use prevention on college campuses. The primary aim of this proposal is to conduct a preliminary test of efficacy of our newly developed innovative prevention intervention, the Personalized Feedback Program (PFP) for college students. Preliminary efficacy will be evaluated through a randomized controlled trial (RCT) comparing four conditions: assessment only controls, PFP, computer-delivered intervention based on brief motivational intervention (BMI) content/principles, and PFP+BMI.

8. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**

9. **Upload any supporting tables or documents (e.g. protocol documents, figures/tables, data collection forms, study communications/reminders):**

   Upload ALL instruments/guides that will be used or that participants will experience (i.e. see, hear, complete), including measures, scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc,:

   Upload ALL recruitment and screening materials, including such as ads, flyers, telephone or in-person scripts, letters, email invitations, TelegRAM announcements, and postcard reminders, screening scripts, screening forms, and screening measures:

View: SF2 - Project Details

Project Details

1. * **Select all of the following types of interventions that apply to this study (selections will branch):**
   - [x] **Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations**

- [ ] Deception (misleading participants through false or incomplete information)
- [ ] Drug(s) / Biologics / Supplement(s) / Other Compounds (investigational products or products whose administration is dictated by the study protocol and not per the physician's clinical judgment)
- [ ] Placebos
- [ ] Safety and/or effectiveness evaluation of Bio-Medical Device(s), including in-vitro diagnostic devices/assays, mobile medical apps, and HUDs used in clinical investigations
- [ ] Washout Periods
- [ ] Expanded Access - Treatment Use of an Investigational Product
- [ ] Medical or Surgical Procedures (eg: physical exam, clinical procedures, scans, etc)
- [ ] Specimen/biological sample collection
- [ ] None of the Above

2. * **Select all of the following types of interactions that apply to this study (selections will branch):**

- [x] **Surveys / Questionnaires /Written responses to questions (including data entry)**
- [x] **Active Internet data collection (i.e. using the internet to interact or intervene directly with research participants)**
- [ ] Interviews / Focus Groups / Verbal responses to questions
- [ ] Audio / Video recording or photographing participants
- [ ] Observations
- [ ] Passive Internet data collection (i.e. passively observing online behavior)
- [ ] Educational Settings/Assessments/Procedures
- [ ] None of the Above

3. * **Select all types of secondary information and/or specimens that apply to this study (selections will branch): See the help text for definitions.**

- [x] **Individually Identifiable Health Information (PHI or RHI)**
- [ ] Secondary data/specimens NOT from a research registry or repository
- [x] **Information/specimens from a research registry or repository (Usage Protocol)**
- [ ] Information/specimens originally collected for a previous research study
- [ ] Publicly available information/specimens
- [ ] Government-generated or collected information that was or will be obtained for nonresearch activities [only applicable to research conducted by or on behalf of a Federal department or agency]
- [ ] No secondary data/specimens will be used

Behavioral Intervention Details

1. * **Describe the duration of the social/behavioral intervention, task, or environmental manipulation:**
   The randomized controlled trial (RCT) will compare four conditions:

   Assessment only controls will not receive a social/behavioral intervention. They will receive a list of resources at VCU (e.g. Writing Center, Recreation and Well-Being, Rams Connect) with hyperlinks to their respective websites, but they are not required to engage with them in any way.

   Personalized Feedback Program (PFP) condition: All participants in this condition will complete the PFP. The PFP is estimated to take approximately 20 minutes, though exact time will depend on the extent to which the participant wishes to engage with each section of the program.

   Brief Motivational Intervention (BMI) condition: All participants in this condition will complete a computer-delivered intervention based on BMI content/principles. The BMI is designed to be similar in time to the PFP and is estimated to take approximately 20 minutes to complete.

   PFP+BMI condition: All participants in this condition will complete both the PFP and the BMI. The PFP is estimated to take approximately 20 minutes, though exact time will depend on the extent to which the participant wishes to engage with each section of the program. The BMI is designed to be similar in time to the PFP and is estimated to take approximately 20 minutes to complete. Thus the total duration expected is 40 minutes.

2. * **Describe any potential harms or discomforts that participants could experience during the intervention:**
   There is no more than minimal risk associated with participation in this study. Potential risks may be psychological in nature as associated with participation in the Personalized Feedback Program and/or the computer-delivered intervention based on brief motivational intervention content/principles. However, we believe that potential for this kind of distress is minimal. Subjects will be advised to complete the programs only when they have sufficient privacy and they will be reminded regularly that participation is voluntary and they can withdraw from the study at any time during the process.

   All information gathered is treated under the Human Subjects Review Board guidelines of confidentiality of patient records. This study's utilization of questionnaires to evaluate psychopathology, functioning, and substance use poses a minimal risk to participants. Rating scale measures such as the ones proposed for this study are frequently used in studies of college students. One possible complication from administration of these measures is boredom or symptoms of anxiety surrounding the disclosure of personal information. A second potential risk is that confidentiality could be breached; we take extensive measures to ensure data security.

3. * **Will the intervention be physically invasive or painful?**
   - ○ Yes
   - ● **No**

4. * **Describe the impact the intervention will have on participants, including the nature and duration of any impact(s):**

If the hypotheses in the present study are confirmed, the Personalized Feedback Program (PFP) provides a substantial addition to the existing knowledge base concerning interventions to promote success and well-being in college students. Potential benefits include the prevention of harm related to higher-risk substance use, including detrimental impacts to academic success and retention. We expect that all students who participate in the PFP (either through the PFP condition or the PFP+BMI condition) will receive some benefit from learning about their traits and the strengths and challenges associated with their personality profiles. We anticipate that this will help them make more informed choices during their college years. Students will also receive information about recommended university resources for them, which could help them connect to university services and experience associated benefits. We expect that all students who participate in the BMI (either through the BMI condition or the PFP+BMI) will receive some benefit from receiving information about about how their drinking compares to others, how to recognize possible consequences associated with excessive alcohol use, and new strategies to monitor their drinking, set limits, and reduce risk. In addition, results of this study will help inform and improve the future education of college students.

5. * **In the investigator's opinion, is there any reason to think that the participants will find the intervention offensive or embarrassing? Explain why or why not.**
   There is no reason to expect the PFP intervention will be offensive or embarrassing to participants. It contains personality-related items that are routinely used in research. Additionally, we do not believe the BMI intervention will be offensive or embarrassing to participants. BMIs are mandated on college campuses across the country and are considered the current “gold standard” for reducing risky substance use among college students.

View: SF2 - Active Internet Data Collection

Active Internet Data Collection

1. * **Describe the platform/technology chosen for collecting the data and transmitting data securely over the internet. Give the rationale for selecting this technology.**
   Following participation in the Spit for Science baseline survey conducted in the Fall 2021 semester, participants will complete ratings of substance use and associated problems at 2 additional timepoints: 30 days after their initial participation (T2) and 3 months after their initial participation (T3). All the outcome measures will be completed on-line via survey using REDCAP (Research Electronic Data Capture) which significantly increases feasibility and the likelihood ratings are returned in a timely manner (i.e., as compared to mail or in-person visits). The consent for each survey will also be administered using REDCap. REDCap is a secure, web-based application designed exclusively to support data capture for research studies. REDCap provides: 1) an intuitive interface for data entry (with data validation); 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R); 4) procedures for importing data from external sources; and 5) advanced features, such as branching logic and calculated fields. The REDCap project (http://project-redcap.org/) was initiated at Vanderbilt University and includes more than 200 active institutional partners from CTSA, GCRC, RCMI funded institutions, including MUSC, and others through a collaborative international consortium. The REDCap application is currently in production use or development buildstatus for more than 11,080 studies with over 20,110 end-users spanning numerous research focus areas. REDCap was approved by the VCU Information Security Officer in 2010 as an electronic data capture (EDC) tool to collect and manage sensitive data. Accessing REDCap Database is accomplished via a secure LDAP-based web authentication process. Only VCU faculty, staff and sponsored VCU students and VCU affiliates may be granted access to REDCap Database. Off campus connectivity to REDCap database must be done via a secure VCU VPN connection. Application level security includes project level user permissions, event logging, and de-identification capabilities which facilitate the export and exchange of data in a coded manner. All REDCap data are stored on VCU University Computing Center (UCC) database servers which are backed-up and maintained following VCU best practices. REDCap will be managing the system that supports this project, the PI and research staff will be responsible for identifiable data collection, management, user rights, determining who has access and all related logistics related to data collection and reporting.

The data collected will be secured via REDCap on a secure MySQL database server at the UCC. The UCC hosts a dedicated server to store REDCap data within this MySQL database. The system will be configured to restrict access to identifiers via user permissions and resulting access controls to data entry forms, reports, and/or export functions. The identifiable data will only be available to the Registry team. Technical controls will be placed on the identifiable data and user permissions limiting access to this information (to view or export) will be in place. Access to the identifiable data will be restricted by password protection. REDCap uses LDAP (Lightweight Directory Access Protocol) authentication. A typical LDAP server is a simple network-accessible database where an organization stores information about its authorized users and what privileges each user has. Only designated registry staff will have access to the identifiable data. The UCC has implemented Tivoli Storage Manager Software to provide advanced backup capabilities for backing up of the disk and database storage. The Tivoli Storage Manager Software is a centralized, policy-based, enterprise class, data backup and recovery package. The software enables the user to insert objects not only via backup, but also through space management and archive tools. It also allows retrieval of the same data via similar restore, recall, and retrieve methods. This product is part of the IBM TotalStorage suite of products and is unrelated to Tivoli Framework. Backups will be made to a high capacity Automatic Tape Library (ATL) which is IBM software allowing servers to do backup to disk without having to re-write or replace popular tape. All backups will have the same restricted password protected access. Further, all computer data will be protected by institution and industry standard antivirus best practices will be adhered to. In addition to the VCU UCC firewalls REDCap will have GreenSQL layered between the application and the database. GreenSQL is an Open Source database firewall used to protect databases from SQL injection attacks. GreenSQL works as a proxy for SQL commands and has built in support for MySQL & PostgreSQL. The logic is based on evaluation of SQL commands using a risk scoring matrix as well as blocking known db administrative commands (DROP, CREATE, etc). GreenSQL is distributed under the GPL license. All data will have 256-bit encryption (SSL) creating a secure transmission from respondent to server. Further, Stunnel is incorporated between the application and database servers.

At T1, for those in the PFP condition, the secure REDCap consent will transfer the participant to the Personalized Feedback Program (PFP) application, passing a randomly-generated de-identified opaque handle. The PFP application will record time-stamped participant responses and interactions, and associate these with the deidentified opaque handle. Upon completion, the PFP application will return the participant to REDCap to complete the survey. All identifiable information will remain entirely within the secure REDCap application server. At no time will the PFP application store identifiable information.

At T1, for those in the BMI condition, the secure REDCap consent will transfer the participant to the computer-delivered intervention based on brief motivational intervention (BMI) content/principles, passing a randomly-generated de-identified opaque handle. The BMI application will record time-stamped participant responses and interactions, and associate these with the deidentified opaque handle. Upon completion, the BMI application will return the participant to REDCap to complete the survey. All identifiable information will remain entirely within the secure REDCap application server. At no time will the BMI application store identifiable information.

At T1, for those in the PFP+BMI condition, the secure REDCap consent will transfer the participant to the Personalized Feedback Program (PFP) application, passing a randomly-generated de-identified opaque handle. The PFP application will record time-stamped participant responses and interactions, and associate these with the deidentified opaque handle. Upon completion, the PFP application will take the participant back to REDCap. In REDCap participants will be asked to access the BMI application via an embedded link. Similarly to the PFP, the BMI application will record time-stamped participant responses and interactions, and associate these with the deidentified opaque handle. Upon completion, the BMI application will return the participant to REDCap to complete the survey. All identifiable information will remain entirely within the secure REDCap application server. At no time will the PFP or BMI applications store identifiable information.

At T1, those in the control condition will remain in REDCap for the entirety of their participation at this time.

2. * **Describe how data will be linked or unlinked to identifiers including email addresses, names, and/or IP address.**
   Obtaining Identifiers from the Spit for Science Registry:

Spit for Science assigns randomly generated coded spin-off IDs for each participant. For participants that indicate 'yes' to the Spit for Science Registry spin-off study interest question asked within the Spit for Science baseline survey launching in Fall semester 2021, this spin-off ID is provided to the study project coordinator as part of the 'turnover' data, which includes email addresses. The study will use the VCU email provided by the participant to the study to match to the Spit for Science spin-off ID. The spin-off ID will then be used throughout the course of the study procedures to link survey record IDs, survey data, and study data. Should they participate in the study, all survey data will be kept separate from identifiable information. The connection between a student email address and a particular record ID number is maintained behind the scenes in the REDCap system and on a password-protected secure server accessible only to select study staff. This key will be kept indefinitely on a secure server. All identifiable information from students who participate in the study will be deleted at the end of the study.

Spit for Science uses randomly generated coded identifiers for each participant. For those participants that say 'yes' to the study, then data related to the participant will be connected and shared with the spin-off study ID. The study will only have access to identifying information for as long as required to complete the study procedures after which they will remove or permanently delete personally identifying data and only retain a coded identifier.

Once a student completes the study survey, his/her responses are recorded and are associated with a coded number generated by the study, on a remote, secure server. Access to this server is limited to select study staff. Study staff will strip all identifying information (email address, permanent address) from the survey data and link the survey information to the de-identified dataset. Once the survey is completed, participants will be compensated electronically.

At the conclusion of all study procedures, the study will provide its dataset, with the spin-off ID, to Spit for Science. The S4S Database Administrator will replace the spin-off ID with the Spit for Science ID to allow for future de-identified data matching.

VCU investigators use computers that are in compliance with institutional policies (e.g., up-to-date software and antivirus protection), and conduct their work in private offices that would limit the opportunity for study information to be disclosed to unauthorized individuals. We reconfirm that VCU investigators will not attempt to re-identify any of the individuals who are part of the dataset being collected. All data will be kept strictly confidential. All data sent to the investigators for analysis will be de-identified. Investigators will never have access to any identifiable student information.

3. * **Is there an alternative method for completion of the data collection other than the internet?**

   ○ Yes

   ● **No**

4. * **Describe how individuals will be able to skip or not answer particular questions. If any questions are mandatory, provide justification.**

   In each of the post-program surveys conducted at Timepoint 1, as well as the follow-up surveys delivered at Timepoints 2 and 3, participants who do not want to answer particular questions can select the response option "I choose not to answer."

   Students will not have the option to skip anything in the Personalized Feedback Program (though there is a "neither agree nor disagree" neutral option for each question) to ensure that they complete the entire program and receive their correct personalized feedback.

   Students will not have the option to skip anything in the BMI condition to ensure that they complete the entire program and receive their correct personalized feedback.

5. **If not including children, describe any procedures used to verify that research participants are adults.**
This research will not include children. All participants will be confirmed incoming VCU freshmen who will be attending university full-time. Students must be 18 or older to participate in the Spit for Science project. Additionally, as part of their consent, participants will acknowledge that they are 18 years of age or older. 98% of incoming VCU freshmen are 18-19 years of age, so we do not foresee difficulty ensuring our sample is of the age required.

View: SF2 - Secondary Data/Specimen Details

Secondary Data/Specimen Details

1. * **Describe the source(s) and nature of the information/specimens being obtained. This response should:**

a. Identify where the data/specimens will come from (e.g., another researcher's registry, pathology lab, commercial source, medical records, etc.); and
b. List what types of specimens will be obtained (when applicable); and/or
c. List all data elements that will be obtained (when applicable). A data collection form or other documentation may be uploaded and referenced here.
Participants will be identified by self-selection during the Spit for Science baseline survey being conducted in the Fall 2021 semester. As part of the baseline survey, participants will be asked a yes/no question about their interest in learning more about the current spin-off study (the contents of this question can be found in the attached document "Baseline Survey Interest Question"). Participants are informed that if they indicate 'yes' that their contact information will be shared with the Personalized Feedback Programs for College Students study. The contact information and spin-off IDs will be provided to the study coordinator by the Spit for Science Registry. This data sharing will occur through a VCU approved file sharing application (like REDCap Send-It), a conditional Data Access Group (DAG) in the REDCap Project and/or through a shared, 'user-assigned' Participant Tracking Project. Additionally, the study will make use of participants' survey responses on the Spit for Science baseline survey being conducted in the Fall 2021 semester. Data will be shared with the present study in accordance with Spit for Science Registry's Standard Operating Procedures. Spit for Science will provide access to the de-identified phenotypic (survey) dataset.

2. * **Describe whether any agreement exists between you and data/specimen provider that states you will never have access to the ability to identify the participants (i.e. access to identifiers or the code key) and that you will not attempt to re-identify individuals.**
Investigators will complete the de-identified data-sharing agreement, following the Spit for Science protocol. After the DSA has been approved, the investigators will be granted access to the de-identified dataset for participant ID selection.

The de-identified Spit for Science data contains a participant or registry ID that will be used for participant selection. All participants from which the selection will be drawn are part of the Registry and have completed the Spit for Science baseline (parent) consent and survey conducted in the Fall 2021 semester. Spit for Science then assigns these participants a second randomly generated unique ID called a spin-off ID. This spin-off ID will be used to track participation outcomes and acts as an indirect identifier that Spit for Science can link back to the participant within the registry. The contact information and the spin-off IDs of individuals who indicate they are interested in participating in or learning more about the study will be shared (using a secure file sharing application, like VCU FileLocker or a participant tracking project within REDCap) with the study project coordinator. Following the conclusion of study procedures, identifiable information is not retained by the study nor does the study have the mechanism to match Spit for Science generated IDs back to identifiable information. Furthermore, the PI of the spin-off study will sign an Agreement that indicates they will not have access to names or other participant identifying information.

3. * **When the information/specimens were originally collected, did individuals provide consent for secondary research use of their data/specimens (i.e. consent to another research study or to a research registry)?**
   - (●) **Yes**
   - ( ) No

4. * **Provide name(s) of the registry/repository being accessed.**
   Spit for Science Registry

5. * **Site having responsibility for the management of this registry/repository:**
   - (●) **VCU**
   - ( ) Non-VCU

6. **If the registry / repository is located at VCU, provide the IRB number for the registry / repository.**
   HM13352

7. * **Is the original consent form that participants signed upon entry into the registry /repository available?**
   - ( ) Yes
   - (●) **No**

8. **If NO above, describe in detail the allowed uses of the data information/specimens as outlined in the registry / repository consent. Be sure to describe any stipulations or limitations on the use.**
   The data information we will be collecting for this study will come from the Spit for Science Baseline Survey to be conducted in Fall 2021. This baseline study is currently awaiting IRB approval for an amendment, and thus the consent document has not been delivered to participants or approved by the IRB as of yet. We will upload the baseline consent to this application as soon as it is IRB approved.

View: SF2 - Costs to Participants

Costs to Participants

1. * **Select all categories of costs that participants or their insurance companies will be responsible for:**
   - [x] **Participants will have no costs associated with this study**
   - [ ] Study related procedures that would be done under standard of care
   - [ ] Study related procedures not associated with standard of care
   - [ ] Administration of drugs / devices

- [ ] Study drugs or devices
- [ ] Other

View: SF2 - Compensation

Compensation

1. * **Describe any compensation that will be provided including:**
   1. **total monetary amount**
   2. **type (e.g., gift card, cash, check, merchandise, drawing, extra class credit)**
   3. **how it will be disbursed**

   T1:
   All participants who complete the condition they have been assigned to and post-program survey at time point 1 (T1; beginning of fall semester 2021) (resources program, Personalized Feedback Program (PFP), brief motivational intervention (BMI), or PFP+BMI) will receive a $25 Amazon e-gift card.

   T2:
   All participants who complete the follow-up assessment at time point 2 (T2; 30 days post initial participation) will receive a $20 e-Amazon gift card.

   T3:
   All participants who complete the follow-up assessment at time point 3 (T3; approx. 3 months post initial participation) will receive a $20 Amazon e-gift card.

   Bonus:
   All participants who complete all 3 surveys will receive an additional $20 Amazon e-gift card at the conclusion of their participation at T3.

2. **If compensation will be pro-rated, explain the payment schedule.**

3. * **Will Social Security Numbers be collected for compensation purposes only?**
   - ○ Yes
   - ● **No**

View: SF2 - Contingency Plan

Contingency Plan

This page will be used by the IRB in the event that an institution-wide emergency situation arises that requires contingency plans.

A contingency plan describes the alternative procedures that a study would want to use in case of an emergency that prevented normal study activities from occurring. It is a form of adaptive protocol. It enables the VCU IRB to quickly approve alternative study activities along with criteria for when those activities would or would not be put into effect. For example, in 2020, some studies had a COVID-19 Contingency Protocol approved that described alternative remote procedures that they would switch to whenever the University restricted in-person research activities.

In all studies, investigators are strongly encouraged to plan prospectively and build flexibilities into their regular protocols (regardless of whether an emergency situation exists) as well as think about what they would do in an emergency situation. For example, windows for timed study visits, ranges instead of exact values, flexibilities in inclusion criteria, etc. Flexibility and adaptations that are built into the protocol will reduce the number of changes that have to be submitted to the IRB and should reduce the number of incidents of deviations and noncompliance by investigators.

Further instructions and smartform questions on this page will be released from the IRB in the event of such an institution-wide emergency situation.

View: SF2 - Research Plan Complete

Research Complete

Protocol Progress:
❶ **INITIAL SETUP**
❷ **BACKGROUND, RATIONALE & GOALS**
❸ **RESEARCH PLAN**
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

View: SF2 - Consent Process

Consent Process

1. * **List all consent groups:**

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
View	All participants	None of the Above (select waiver below)	Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)	N/A: Requesting Waiver of Consent		Not using electronic signature platforms	In the baseline Spit for Science Survey delivered in the Fall semester of 2021, participants will be asked if they are interested in participating in our study. Those who say "Yes" to the interested question will be asked if their information can be shared with our study. Those who say "Yes" to the data sharing question will receive the "Study Enrollment Email" from our study coordinator. This email contains a link to the Study Consent document. Participants are able to review the consent, close the	Participation in this study is voluntary. All interested participants will be reminded in the consent document that their participation is voluntary and that they can withdraw from the study at any time without penalty. Consent will only be done electronically, thereby further reducing participants' chances of feeling coerced. The consent document will be presented online at the time and place desired by each individual. Each individual is able to review the consent, take time to consider it and/or ask any questions,	The study consent process is conducted on-line, meaning participants can take as much time as they need to make a decision.	

Group	Types Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
					window, and open it again at any time prior to their participation. Participants will not be able to participate in any of the programs or answer any survey items without giving consent to participate in the study. If participants do not consent to participate after reading the consent, they will not be contacted about the study again. Once participants do consent to participate in the study, they will be automatically taken to the program to which they have been randomized followed by the brief set of follow-up questions (Post-Program Survey).	and return to the document to provide their consent or not.		

2. Upload any consent / assent documents:

View: SF2- Waiver of Documentation of Consent

Waiver of Documentation of Consent

Consent groups that require a waiver of documentation (i.e. consent form not signed):

Group	Types	Waivers	Roles	Roles - Other	Consent	Decision	Status Change
All participants	None of the Above (select waiver below)	Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)	N/A: Requesting Waiver of Consent		In the baseline Spit for Science Survey delivered in the Fall semester of 2021, participants will be asked if they are interested in participating in our study. Those who say "Yes" to the interested question will be asked if their information can be shared with our study. Those who say "Yes" to the data sharing question will receive the "Study Enrollment Email" from our study coordinator. This email contains a link to the Study Consent document. Participants are able to review the consent, close the window, and open it again at any time prior to their participation. Participants will not be able to participate in any of the programs or answer any survey items without giving consent to participate in the study. If participants do not consent to participate after reading the consent, they will not be contacted about the study again. Once participants do consent to participate in the study, they will be automatically taken to the program to which they have been randomized followed by the brief set of follow-up questions (Post-Program Survey).	The study consent process is conducted on-line, meaning participants can take as much time as they need to make a decision.	

1. * Select which of the following applies to the consent groups used in this study:

- ☐ (1) The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern
- ☑ **(2) The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context**

☐ (3) The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained

2. * **Explain how your selection above applies to this study:**
The proposed consent process occurs completely online and the online consent protocol provides potential participants the opportunity to take the time they need to read the consent and decide whether or not they want to provide consent/participate in the study. An online consent process also decreases participant burden for a study that is ultimately completed online.

Before enrolling in the study, participants will be provided full consent information online. Participants will then be asked if they understand and are willing to participate in this research. They must indicate their consent and confirm their consent before being able to participate in the study.

This research involves no procedures for which consent is typically required outside the research setting. This study consists mostly of surveys in which students answer questions about themselves, their substance use, their behavioral and emotional wellbeing, and their college experiences. Outside the research setting, surveys are not typically something for which consent is required.

The Personalized Feedback Program is also minimal risk. There is no reason to expect the intervention will be offensive or embarrassing to participants. It contains personality-related items that are routinely used in research. Additionally, we do not believe the BMI intervention will be offensive or embarrassing to participants. BMIs are mandated on college campuses across the country and are considered the current “gold standard” for reducing risky substance use among college students.

View: SF2 - Consent Plan Complete

Consent Plan Complete

Protocol Progress:
❶ **INITIAL SETUP**
❷ **BACKGROUND, RATIONALE & GOALS**
❸ **RESEARCH PLAN**
❹ **CONSENT PLAN**
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

View: SF2 - Risks, Discomforts, Potential Harms and Monitoring

Risks, Discomforts, Potential Harms and Monitoring

1. * **Describe the risks of each research procedure to participants or others. For each identified risk, provide an assessment of the anticipated seriousness and likelihood of the risk. Some examples of possible risks include but are not limited to:**

    - **Physical risks (e.g. bodily harms or discomforts, side effects, etc.)**
    - **Psychological risks (e.g. emotional, mental, or spiritual harms or discomforts, changes to thoughts, beliefs, or behaviors, etc.)**
    - **Research data risks (e.g. loss of confidentiality and privacy)**
    - **Social or legal risks (e.g. impacts on relationships or reputation, legal or criminal justice actions for self or others, etc.)**
    - **Financial risks (e.g. impacts on income, employability, or insurability, loss of services, etc.)**
    - **Other risks (e.g. unforeseeable risks of experimental procedures, risks related to particular study designs (randomization, washout, placebo, withholding care/services, deception), etc.)**

    See the help text for additional guidance.

    There is no more than minimal risk associated with participation in this study. Potential risks may be psychological in nature as associated with participation in surveys and personality-related assessments. However, we believe that the potential for this kind of distress is minimal. Subjects will be advised to complete the surveys, and if applicable, the Personalized Feedback Program and/or the computer-delivered intervention based on Brief Motivational Intervention (BMI) content/principles only when they have sufficient privacy and they will be reminded regularly that participation is voluntary and they can withdraw from the study at any time during the process. Should participants experience emotional distress and/or concerns about their emotional health or substance use while completing the surveys, Personalized Feedback Program or the computer-delivered intervention based on BMI content/principles, they will be given the contact information for University Counseling Services at 828-6200. There is someone on call all day, every day, all year long.

    There are no more than minimal risks involved in this study, however all research participation might involve loss of privacy or confidentiality. Standard practices will be used to protect participant confidentiality and personal information, including removing identifiers from all survey and program data collected, using only numbers to identify participant data, and keeping all data files securely stored.

    Students may decline to participate given the sensitive nature of the questionnaire items (i.e., voluntary disclosure of recent alcohol consumption in spite of being underage for consuming alcohol; however, we note that the content of the questionnaires is generally similar to the content of the Spit for Science project, which has successfully been employed with >12,000 VCU students).

    Loss of confidentiality: With all research participation, there is a risk that personal information obtained from research participants will be mishandled, and confidentiality may be compromised. Participation in this study is voluntary.

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
    It is explicitly stated in the consent document that the subject can choose to withdraw or not to participate at any point

in the study. Subjects will also be fully informed of the potential risks involved prior to soliciting formal consent to participate. The goal of this project is to ensure that all college students who complete the prevention program will receive adequate feedback and information about relevant university resources. Participants will be encouraged to reach out to their university counseling/health services if they experience distress during the study. Standard practices will be used to protect participant confidentiality, including removing identifiers from all data collected, using only numbers to identify participant data, and keeping all data files when not in use in a locked filing cabinet behind a locked office. REDCap, the survey tool that will be utilized for this project, has many security measures in place to prevent against the inappropriate release of survey data and information. REDCap will be used to contact participants via email, collect survey responses, and record survey completion. To provide an additional layer of protection to participants, the collection of direct identifiers (VCU email address, permanent address) will be assessed separately from the general surveys. All identifiable information will only be saved on a Monroe Park campus-based VCU approved secure server (the server is HIPAA compliant for security set up, the shared folder will only be browseable and accessible by the authorized registry personnel, each authorized person has their own account to log on server through VCU Web VPN then work on the shared folder). The key will be password protected. Only the study project coordinator and select project staff will know the password.

At T1, for those in the PFP condition, the secure REDCap consent will transfer the participant to the Personalized Feedback Program (PFP) application, passing a randomly-generated de-identified opaque handle. The PFP application will record time-stamped participant responses and interactions, and associate these with the deidentified opaque handle. Upon completion, the PFP application will return the participant to REDCap to answer a brief set of survey questions related to their experiences with the program. All identifiable information will remain entirely within the secure REDCap application server. At no time will the PFP application store identifiable information.

At T1, for those in the BMI condition, the secure REDCap consent will transfer the participant to the computer-delivered intervention based on brief motivational intervention (BMI) content/principles, passing a randomly-generated de-identified opaque handle. The BMI application will record time-stamped participant responses and interactions, and associate these with the deidentified opaque handle. Upon completion, the BMI application will return the participant to REDCap to answer a brief set of survey questions related to their experiences with the program. All identifiable information will remain entirely within the secure REDCap application server. At no time will the BMI application store identifiable information.

At T1, for those in the PFP+BMI condition, the secure REDCap survey will transfer the participant to the Personalized Feedback Program (PFP) application, passing a randomly-generated de-identified opaque handle. The PFP application will record time-stamped participant responses and interactions, and associate these with the deidentified opaque handle. Upon completion, the PFP application will take the participant back to REDCap. In REDCap participants will be asked to access the BMI application via an embedded link. Similarly to the PFP, the BMI application will record time-stamped participant responses and interactions, and associate these with the deidentified opaque handle. Upon completion, the BMI application will return the participant to REDCap to answer a brief set of survey questions related to their experiences with the programs. All identifiable information will remain entirely within the secure REDCap application server. At no time will the PFP or BMI applications store identifiable information

At T1 those in the control condition will remain within the secure REDCap application server for the entirety of their participation at this timepoint.

All participants regardless of their initial condition will remain within the secure REDCap application server for the entirety of the follow-up surveys at T2 and T3.

3. * **Describe any potential risks or harms to a community or a specific population based on study findings (e.g. information that could be stigmatizing or derogatory):**
We do not believe the study poses any additional risks to any specific population. The study investigators initially took a number of steps to ensure that all study materials would be acceptable to multiple groups and populations, and we will continue to make every effort to reduce any potential risks or harms to our participants. Our research team has extensive experience working with young adults and presenting findings in a manner that is useful to the population

being studied. Additionally, Co-I Trisha Saunders, Associate Director of the Health and Wellness Promotion Center ("The Well", changing to RecWell this upcoming year) at VCU, was instrumental in designing both the Personalized Feedback Program and the computer-delivered intervention based on BMI content/principles and selecting their language. She will continue to play a role in presenting the findings in a positive and empowering way to students. She has worked with students for over 5 years in the Well at VCU, worked in a similar role for 5 years at another university, and is highly adept at working with and conducting outreach for this population.

Within the Personalized Feedback Program, the names of all personality types were specifically chosen to reduce any stigma traditionally associated with that trait. All personality types start with "the good" things about them, and we emphasize that there are pros and cons associated with each of the different types. While we will be informed by students' generated personality types when looking at differences in response to the intervention and behavior changes following the intervention, we will not be presenting these findings in a derogatory way.

We intend for our recruitment methods to ensure we have a diverse sample of students with varying traits.

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
   The goal of this project is to ensure that all college students who complete the Personalized Feedback Program will receive adequate feedback and information about university resources that can support them. Participants will be encouraged to reach out to their university counseling/health services if they experience distress during the study.

5. * **Describe criteria for when the investigator would withdraw an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:**
   Participants will be withdrawn from the study if they do not follow the instructions outlined in the protocol and informed consent form. Additionally, students can withdraw at any time by contacting the study coordinator (either via email or phone) and request this. This staff will verify what level of withdrawal they desire at the time of withdrawal (e.g. do they want their past data removed or do they just not want to participate in assessments at future time points). After a student has withdrawn completely, they will never be contacted by this study again.

6. * **Summarize any pre-specified criteria that would trigger the investigator/sponsor/monitoring committee to stop or change the study protocol due to safety concerns:**
   None. This study assesses aspects of behavior that are routinely assessed. We do not collect any information that might necessitate stopping the study protocol.

   Data and Safety Monitoring
   Data and safety monitoring is a system for checking the study's data at regular intervals over the study period to identify and address issues that could affect the safety of research participants. This requirement is in accordance with 45 CFR 46.111.

   The purpose of data and safety monitoring plan is to set forth study team procedures for monitoring/addressing:
   - Participant safety (physical, psychological, etc.)
   - Data validity
   - Early stopping (termination) based upon changes in risks and benefits.

7. * **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all greater than minimal risk studies]**
   - [ ] DSMB
   - [ ] DSMP
   - [x] **No DSMB/DSMP [Note: This response is not applicable for greater than minimal risk studies]**

Privacy

Privacy refers to an individual's right to control how others view, record, or obtain information about them. When privacy is violated it can involve such things as

- Being asked personal questions in a public setting;
- Being publicly identified as having a particular characteristic or diagnosis;
- Being seen entering a place that might be stigmatizing;
- Being photographed, videotaped or observed without consent;
- Disclosure of personal information to unauthorized people

Privacy is not the same as confidentiality because privacy protections apply to people, and confidentiality protections apply to data. Confidentiality protections should be described on the Data Confidentiality page of this form, not here.

Instructions for this page:

Select all the applicable ways that the research team will protect participants' privacy throughout the course of the study. Not all will be applicable to every study.

To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections when conducting one-on-one in-person interventions or interactions (for groups see Q2 below):**
   - ☐ Conducting study activities in locations that maximize privacy (limited people around, closing doors, drawing drapes around beds, monitoring voice volume, etc.)
   - ☐ Verifying identity before discussing personal information.
   - ☐ Asking the participant if they are comfortable answering questions in that location
   - ☐ Asking the participant if they are comfortable with having other people present (if any)
   - ☐ Moving away from other people when conducting activities in public spaces or offering a private space
   - ☐ Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing) if uncomfortable verbally responding

- [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
- [ ] Other protections not listed in this question – describe below
- [x] **N/A – study has no in-person interventions or interactions with participants**

2. * **Protections when conducting group interventions or interactions:**

- [ ] Conducting study activities in locations that maximize privacy (limited people passing by, closing doors, monitoring voice volume, etc.)
- [ ] Moving to a more private area to answer questions or to discuss concerns
- [ ] Discussing privacy with the participants and the importance of not talking outside the group about what other people say during the group session
- [ ] Allowing participants to use a pseudonym or limiting use of individuals' names during the group activity
- [ ] Asking everyone in a public group setting (e.g. classrooms, workshops) to turn something in (blank or filled) so participants do not have to self-identify when turning in materials
- [ ] Collecting paper forms in a closed box or envelope rather than passing to others or leaving in an open area
- [ ] Limiting participant identifiers that would be visible on paper documents (i.e. using study IDs instead of direct identifiers)
- [ ] Allowing people to distance themselves from other participants during group activities
- [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing instead of speaking)
- [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Other protections not listed in this question – describe below
- [x] **N/A – study has no group interventions or interactions**

3. * **Protections when conducting remote interventions or interactions (e.g. phone, text, video-conference, tele-health, online, etc.):**

- [x] **Conducting study activities in locations where study staff can maximize their own privacy (limited people around, closing doors, monitoring voice volume, etc.)**
- [ ] Leaving/sending generic messages that avoid using study and participant identifiers, such as names, study titles, clinics, study topics, etc.
- [x] **Obtaining permission prior to sending text messages**
- [ ] Advising the participant to move to a location where they are comfortable answering questions and will not be overheard
- [x] **Advising online participants to complete the activity at a time and location where they will be comfortable answering questions**
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos

- [ ] Offering other options of ways to complete the activity (i.e. online, paper, phone) if more privacy is desired
- [x] **Offering a way to save and return later to the online activity if privacy is compromised**
- [ ] Other protections not listed in this question – describe below
- [ ] N/A – study has no remote interventions or interactions with participants

4. * **Protections when mailing study materials to/from participants:**

- [ ] Obtaining permission to mail study materials
- [ ] Confirming/verifying the accuracy of addresses before mailing items
- [ ] Ensuring the participant is able to personally receive mailed materials and has a way to protect their own privacy if they do not want others to know they are receiving research communications (i.e. notifying participants of when to expect it)
- [ ] Using return address labels and document headers that avoid study identifiers, such as study names, clinics, study topics, etc.
- [ ] Avoiding or limiting use of participant identifiers and health information on mailed documents (i.e. using study IDs instead of direct identifiers)
- [ ] Providing a return mailing address label or pre-addressed envelope to ensure returned items are sent to the correct address
- [ ] Communicating receipt of mail from participants and/or asking them to notify you when they mail it to ensure study documents are not lost in transfer
- [ ] Offering other options of ways to complete the activity (i.e. by phone or online) if desired
- [ ] Other protections not listed in this question – describe below
- [x] **N/A – not mailing any materials to/from participants**

5. * **Protections when analyzing or disseminating study data** *Applicable to all studies***:**

- [x] **Working only in locations where the study team can ensure privacy (not working in close proximity to non-study personnel, closing doors, closing/putting away documents/files before leaving, etc.)**
- [x] **Securing physical materials only in locations that ensure privacy (access limited to authorized study personnel)**
- [x] **Only sharing data/specimens in accordance with the Sharing Plan outlined in this smartform**
- [ ] Obtaining explicit parental permission before disseminating or sharing recordings or photos of children
- [ ] Blurring/redacting/hiding faces and other identifiable features/marks (tattoos, scars, birthmarks, distinctive voice, etc.) in recordings or photos prior to disseminating or sharing
- [ ] Other protections not listed in this question – describe below

6. * **If “other protections” was selected in one or more of the questions above, describe all the other way(s) that the research team will protect participants' privacy. See the help text for additional guidance.**
To protect participants’ privacy during the recruitment phase of the project, potential participants will be able to review information about the present study (including all consent documents) and decide whether they wish to participate in a setting of their choosing, at their own pace, and they will be able to contact the project coordinator by email with any further questions prior to consenting and participating on their own at a convenient time.

We have been automatically issued a Certificate of Confidentiality (CoC) from the National Institutes of Health to further protect the privacy of our subjects. The CoC will protect the researchers and institution from being compelled to disclose information that would identify our subjects and help achieve the research objectives and promote participation in our study by assuring confidentiality and privacy to our participants.

View: SF2 - Data Confidentiality and Storage

Data Confidentiality and Storage

Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared. It describes how the study’s research materials (data, specimens, records, etc.) are protected from unauthorized access.

Instructions for this page:
Select all the ways that the research team will keep the study materials and data confidential throughout the course of the study. Not all will be applicable to every study.
To elaborate on any response, also click the “Other Protections” checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections for paper research materials:**
   - ☐ Maintaining control of paper documents at all times, including when at an off-campus location
   - ☐ Limiting or avoiding use of participant identifiers on paper documents (i.e. using study IDs instead of direct identifiers)
   - ☐ Storing paper documents in a secure location accessible only to authorized study personnel
   - ☐ Promptly transcribing, scanning, or abstracting data from paper into electronic platforms with destruction of the paper copy
   - ☐ Proper destruction of paper records (and obtaining prior permission when required) in accordance with VCU Records Management policies
   - ☐ Other protection not listed in this question – describe below
   - ☑ **N/A – no paper research materials**

2. * **Protections for research specimens:**
   - ☐ Maintaining control of specimens at all times, including when at an off-campus location

- [ ] Storing specimens in a secure location accessible only to authorized study personnel
- [ ] Labeling specimens with subject ID or other coded information instead of direct identifiers
- [ ] Final destruction of specimens will be devoid of any identifiable information
- [ ] Other protection not listed in this question – describe below
- [x] **N/A – no research specimens**

3. * **Protections for electronic files/data - See https://ts.vcu.edu/about-us/information-security/data-management-system/**
   - [x] ***Required for all studies* Use VCU-approved methods of data storage, transmission, and transfer (see https://dms.vcu.edu)**
   - [x] **Remotely accessing VCU network storage to store data when at off-campus locations**
   - [x] **Ensuring unauthorized individuals who might share a device do not have access to study materials (e.g. individual logins, separate accounts)**
   - [x] **Using VCU-approved data collection tools and apps (e.g. REDCap) and storing exported analysis files in VCU-approved storage locations (see https://dms.vcu.edu)**
   - [ ] When using non-VCU-approved electronic data collection tools, storage locations, data transfer platforms, and mobile apps (e.g. Dropbox, Box, Survey Monkey, Fitbits, novel apps): • consulting with VCU Information Security on proper data management (see https://ts.vcu.edu/askit/essential-computing/information-security/); • advising participants about the terms of use and privacy policies of those sites/apps; • limiting or avoiding use of identifiers; and • removing data promptly from the external location after transferring it to a VCU storage location
   - [x] **De-identifying the research data by replacing subjects' names with assigned subject IDs**
   - [x] **Storing the study's linkage key in a password-protected and VCU-approved storage location (see https://dms.vcu.edu)**
   - [x] **When analyzing particularly sensitive information, using computers that are unconnected from the internet.**
   - [x] **Proper destruction of electronic records (and obtaining prior permission when required) in accordance with VCU Records Management policies**
   - [ ] Other protection not listed in this question – describe below

4. * **Protections for computers and research devices/apps provided for participant use by the study:**
   - [ ] Transferring data promptly from the device/app to a VCU storage location
   - [ ] Setting strong passwords on computers and research devices (when applicable)
   - [ ] When providing devices or mobile apps to children, informing parents about the settings and how to manage them (if applicable), internet access, and any other installed apps on the device
   - [x] **Other protection not listed in this question – describe below**
   - [ ] N/A – no computers or devices/apps being provided for participant use

5. * **Protections for email/online communications**
   - [x] **Only using VCU/VCU Health email addresses for study-related communications**

- [ ] Only using VCU/VCU Health–approved methods of teleconferencing or video conferencing (e.g. Zoom) (for studies involving HIPAA, contact VCU or VCU Health Information Security [as appropriate] about HIPAA-compliant systems)
- [ ] Other protection not listed in this question – describe below
- [ ] N/A – no email/online communications

6. * **If "other protections" was selected in one or more of the questions above, specify where this study's paper and electronic research data and/or physical specimens will be stored and how they will be secured from improper use and disclosure.**

For Q4: The Personalized Feedback Program (PFP) is a web application hosted on a publicly-accessible web server, accessed via the participant's personal web browser. The PFP web application (and associated server) does not receive or store any personally-identifying information. The PFP web application provides all (de-identified) recordings of participant interactions to the VCU-controlled REDCap server for secure storage.

For Q3: For recruitment from the Spit for Science Registry, Spit for Science will only share information with the study and vice versa using a secure file sharing application, like REDCap Send-It or VCU FileLocker or through a limited access REDCap project.

The surveys will be administered using REDCap, and email addresses and phone numbers will never be stored with subject data. All identifiable information will remain entirely within the secure REDCap application server. At no time will the Personalized Feedback Program application or the computer-delivered Brief Motivational Intervention application store identifiable information. Consent forms and surveys will be administered using REDCap. REDCap is a secure, web-based application designed exclusively to support data capture for research studies. REDCap provides: 1) an intuitive interface for data entry (with data validation); 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R); 4) procedures for importing data from external sources; and 5) advanced features, such as branching logic and calculated fields. The REDCap project (http://project-redcap.org/) was initiated at Vanderbilt University and includes more than 200 active institutional partners from CTSA, GCRC, RCMI funded institutions, including MUSC, and others through a collaborative international consortium. The REDCap application is currently in production use or development buildstatus for more than 11,080 studies with over 20,110 end-users spanning numerous research focus areas. REDCap was approved by the VCU Information Security Officer in 2010 as an electronic data capture (EDC) tool to collect and manage sensitive data. Accessing REDCap Database is accomplished via a secure LDAP-based web authentication process. Only VCU faculty, staff and sponsored VCU students and VCU affiliates may be granted access to REDCap Database. Off campus connectivity to REDCap database must be done via a secure VCU VPN connection. Application level security includes project level user permissions, event logging, and de-identification capabilities which facilitate the export and exchange of data in a coded manner. All REDCap data are stored on VCU University Computing Center (UCC) database servers which are backed-up and maintained following VCU best practices. The UCC database servers are located on the VCU Medical School Campus. This facility houses many critical campus servers in a Tier 2 level data center, which provides redundant capacity for cooling and power supply for the IT equipment. All servers are physically secured, follow appropriate multilevel access control protocols, and maintain long term data security via daily and monthly backup/restore procedures. All users are connected to a TCP/IP local area network within VCU webvpn network or customized IP registered by specific users. Desktop resources, network storage, and email systems are protected from virus attacks via antivirus software that is automatically updated weekly. Desktop PCs and campus networks are behind appropriate firewalls. Desktops and their corresponding network resources follow appropriate multilevel access protocols; network data storage availability is assured via nightly and monthly archival procedures.

We have been automatically issued a Certificate of Confidentiality (CoC) from the National Institutes of Health to further protect the privacy of our subjects. The CoC will protect the researchers and institution from being compelled to disclose information that would identify our subjects and help achieve the research objectives and promote participation in our study by assuring confidentiality and privacy to our participants.

7. * **If research data that contains any of the 18 HIPAA identifiers will be released to person(s) or group(s) outside of the VCU study team or the PI's department, identify the data recipient(s) along with their VCU department or other institutional or organizational affiliation(s).**
N/A

8. * **Select all identifiers that will be collected as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:**

- [x] **Names**
- [x] **Geographic Locators Below State Level**
- [ ] Social Security Numbers
- [ ] Dates (year alone is not an identifier)
- [ ] Ages over 89 (age under 89 is not an identifier)
- [x] **Phone Numbers**
- [ ] Facsimile Numbers
- [x] **E-mail Addresses**
- [ ] Medical Record Numbers
- [ ] Device Identifiers
- [ ] Biometric Identifiers
- [ ] Web URLs
- [ ] IP Addresses
- [ ] Account Numbers
- [ ] Health Plan Numbers
- [ ] Full Face Photos or Comparable Images
- [ ] License/Certification Numbers
- [ ] Vehicle ID Numbers
- [ ] Other Unique Identifier
- [ ] No Identifiers
- [ ] Employee V#

9. * **If the study will code (i.e. de-identify) the research data by replacing subjects' names with assigned subject IDs, explain the following aspects of the coding process:**

- The process for how subject IDs will be generated/assigned (e.g. random, sequential)

- Whether there will be a key that links the subject ID with direct identifiers.

If a key will be created, describe
- The place where the key will be stored
- The role(s) of all individuals who will have access to the key
- When the key will be destroyed

See the help text for guidance.
All students who accept the consent document will be assigned a randomly generated ID in REDCap. This ID will be linked securely within REDCap to their de-identified data and separately with their preferred email address. A copy of this key will be stored on a password protected computer only accessible to the project coordinator. The key will be destroyed at the conclusion of the study.

Spit for Science Registry staff assign a randomly generated spin-off ID to each participant associated with this study. For participants that indicate 'yes' to being interested in participating in the study, Spit for Science provides the study project coordinator with the spin-off ID as part of the 'turnover' data, which also includes email addresses, permanent address, phone number(s) and text permission if provided. The information will also include responses to the baseline measures. The spin-off ID will be used as an indirect identifier for tracking recruitment/enrollment steps and participant statuses., The spin-off ID continues to be used throughout the course of the study until all data collection is completed. At the end of data collection procedures and compensation, the study will remove/destroy identifying information from their own records. The next step is for the Spit for Science Registry to replace the spin-off ID. To accomplish this, the study project coordinator would then provide their de-identified study dataset (using a secure platform like VCU FileLocker or REDCap SEND-IT) to the Spit for Science Registry so that the Spit for Science programmer could append the Spit for Science ID (registry/participant ID) assigned to the participant when they joined the registry and remove the spin-off ID from the data. This dataset, with the updated coded identifier will be shared back to the study project coordinator using the same secure platform options. This allows the study to use the registry/participant ID to match to the existing Spit for Science data to which access has already been granted through existing data use agreements. Unless otherwise noted, Spit for Science retains all its coded identifiers indefinitely. Spit for Science does not share the key that would allow these identifiers to be merged back with personally identifying information.

View: SF2 - Data Retention

Data Retention

1. * **Select all of the ways that individually identifiable information obtained during pre-screening and/or screening will be handled for individuals who DO NOT qualify for the study:**
   - ☐ Immediately destroy the information and identifiers (no data collected)
   - ☐ Immediately destroy the identifiers connected with the data (anonymization)
   - ☐ Store until the end of study & then destroy
   - ☐ Use as "screening failure" data by members of the study team
   - ☐ Provide to others outside of the research team (with the participant's permission)
   - ☐ Request permission from participant to maintain and use the identifiable information

- [x] **Other**
- [x] **N/A - study does not require screening procedures**

2. **If Other, explain how the information will be handled.**
   There are no eligibility requirements outside of participation in the Spit for Science baseline survey delivered in the Fall semester of 2021. All participants in the baseline survey will be eligible to participate in our study until we have reached our desired N.

3. * **Will participants be able to withdraw their data (paper, electronic, or specimens) from the study (e.g. ask that it be destroyed or returned) if they no longer wish to participate? (FDA-regulated studies should select No - see help text)**
   - (●) **Yes**
   - ( ) No

4. **If Yes , describe the process (oral, written, email, letter, etc.) that participants should use to request withdrawal of their data/specimens. Identify if there is a timepoint when withdrawal will no longer be an option and/or if the amount of data that can be withdrawn is reduced at different points in the study.**
   Participation in the current study is completely voluntary. Those who wish to participate can stop at any time. Participants are also provided with the project coordinator's study email address and can contact them at any time to withdraw participation and/or request that their data be destroyed.

5. * **What will happen to the research materials (e.g. data, specimens, documents, etc.) when the research has been completed?**
   - (●) **Stored indefinitely with identifiers removed**
   - ( ) Stored indefinitely with identifiers attached
   - ( ) Destroyed at the end of study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements
   - ( ) Destroyed when notified by sponsor but not less than the minimum time required for data retention per VCU Data Retention Policy
   - ( ) Other

View: SF2 - Sharing Plan

Sharing Plan

This page addresses times when investigators may be required to share information about participants or may desire to share their research information/specimens with the aim of advancing science. This page creates a plan for when

and how information/specimens could be shared.

Try to anticipate all reasonably foreseeable sharing so that the consent document can also reflect that information. However, it is acceptable to amend this page later and explain either how re-consent of previously and currently enrolled participants will occur or why re-consent should not be required.

The IRB reviews this page against the consent document (if one exists) to demonstrate the ethical principle of Respect for Persons by confirming that plans for sharing do not go against what participants would understand about the use of their data/specimens.

The IRB also ensures there are adequate protections for the privacy of participants and the confidentiality of participants' data/specimens when data is shared with others.

1. * **Is it likely investigators could discover information about child/elder abuse or neglect that would require mandatory reporting by the investigators or staff?**

   The Code of Virginia requires that most medical personnel and all employees of institutions of higher education report suspected child/elder abuse or neglect.

   - ○ Yes
   - ● **No**

2. * **Is it likely investigators could discover a previously unknown reportable disease or condition that would require mandatory reporting by the investigators or staff (i.e., HIV , coronavirus, hepatitis, etc.)?**

   ○ Yes ● **No**

3. * **Will the sponsor or investigator obtain a Certificate of Confidentiality for this study?**

   Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH), the FDA and CDC to protect identifiable research information from forced disclosure. All human subject research studies regardless of funding can qualify to receive a CoC. A CoC is automatically issued for research that was ongoing on December 13, 2016. or initiated after that date. For more information, see https://humansubjects.nih.gov/coc/

   - ○ No - Will not obtain CoC for this study
   - ● **Yes - CoC has been obtained or issued automatically**
   - ○ Yes - CoC request is pending
   - ○ Yes - Plan to submit request for CoC and will amend study/ICF once status of request is known

4. * **Select the way(s) that individual-level information or biospecimens (including DNA) may be used by the VCU PI or VCU study team for other future research projects (i.e. analyses beyond/apart from the aims of this study)?**
   See help text for definitions.

- [ ] Will use directly identifiable information or specimens.
('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research is treated as a registry by the VCU IRB. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. You will be asked more questions about this on a later page)

- [ ] Will use de-identified or indirectly identifiable information or specimens.
('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. When the researcher holds both the data and the key, the VCU IRB considers the subjects to be readily identifiable. Maintaining identifiable data for future research uses is treated by the IRB as a registry. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. You will be asked more questions about this on a later page)

- [ ] Will use anonymized information or specimens.
('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified, i.e. no direct or indirect identifiers or identifiable combinations of variables. The VCU IRB considers uses of anonymized data/specimens to not be human subject research.)

- [ ] Will use aggregate results (summary-level results), not individual-level information or specimens.
(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects.)

- [ ] Will contribute to an existing registry or repository
(You will be asked more questions about this on a later page.)

- [x] **Will not use information/specimens for purposes beyond this study.**

- [ ] Not sure and will submit an amendment when known

- [ ] Other use(s) of individual-level information in a way not listed above

5. * **Select the way(s) the VCU PI/study team may share <u>individual-level</u> information or biospecimens (including DNA) <u>with other researchers</u> who are not on this study team (i.e. for analyses beyond/apart from the aims of this study).**
See help text for definitions.

- [ ] Will share directly identifiable information or specimens with other researchers.
('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research uses is treated by the VCU IRB as a registry. The data recipient's use of identifiable data would require them to obtain IRB review. You will be asked more questions about this on a later page.)

- [ ] Will share de-identified or indirectly identifiable information or specimens with other researchers.
('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. The VCU researcher maintains the key but does not share it with any other researchers. The recipient's use of de-identified data/specimens may not be human subject research if there is documentation that the key will never be shared with the recipient, but they should check with their own IRB about review requirements. You will be asked more questions about this on a later page.)

- [ ] Will share anonymized information or specimens with other researchers.
('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified (i.e. no direct or indirect identifiers or identifiable combinations of variables). The VCU IRB considers uses of anonymized data/specimens by other researchers to not be human subject research, but the recipient should check with their own IRB about review requirements.)

- [ ] Will only share aggregate results (summary-level results), not individual-level information or specimens.
(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects. The data recipient should check with their own IRB about review requirements.)

- [ ] Will contribute to an existing registry or repository (You will be asked more questions about this on a later page.)
- [ ] Will submit data to an NIH genomic data repository (You will be asked more questions about this on a later page.)
- [x] **Will not share information/specimens with other researchers.**
- [ ] Not sure and will submit an amendment when known
- [ ] Other sharing of individual-level information with other researchers

6. * **The Principal Investigator certifies that after the study has been closed with the VCU IRB, the following conditions will be met whenever individual level research information and/or specimens are used or shared:**

- The identities of participants who are represented in the dataset/specimens will not be readily ascertainable or otherwise re-identifiable by the recipient;
- If a linkage/code key is created, it will be maintained at VCU and not shared with the recipient under any circumstances;
- The PI will have no knowledge that the remaining information could be used alone or in combination with any other information to identify the individuals represented in the data; and
- The PI agrees to abide by this sharing plan even after the study has been closed with the VCU IRB.

- ○ Yes
- ○ No
- ● **N/A - No sharing will occur**

7. If the Certificate of Confidentiality has been obtained by the PI, upload it here:

Pertinent and Incidental Findings

1. * **Is it likely investigators could discover a participant's previously unknown condition (e.g. pregnancy, disease, suicidal thoughts, wrong paternity, genetic results, or other findings that may be of importance to health or well-being) or if a participant is engaging in illegal or reportable activities:**
   - (●) **Yes**
   - ( ) No

2. * **Describe what possible pertinent or incidental findings stemming from research-only procedures may be discovered.**
   It is possible that participants may disclose the use of illegal substances and/or underage drinking.

3. * **Explain what actions or procedures research personnel should take to inform the PI of such a discovery :**
   Research personnel will not take any action if participants disclose the use of illegal substances or underage drinking. One aim of this study is to understand the impact of our newly developed innovative prevention intervention, the Personalized Feedback Program (PFP) on substance use among college students. Thus, the nature of the study requires that we ask participants about their current and past substance use. Participants will be encouraged to reach out to their university counseling/health services if they experience distress during the study.

4. * **Will findings be disclosed to participants and/or any other person/group outside of the study team?**
   - ( ) Yes
   - (●) **No**

5. **If pertinent and/or incidental findings will not be disclosed, explain why not:**
   One aim of this study is to preliminarily evaluate the efficacy of the Personalized Feedback Program (PFP) in reducing risky substance use among college students as compared to an assessment only control group, a computer-delivered intervention based on brief motivational intervention (BMI) content/principles, and a combined PFP+BMI condition. Thus, the nature of the study requires that we ask participants about their current and past substance use. If we were to share any incidental findings, this could jeopardize the comfort and safety of potential participants to answer the survey honestly.

Risk Benefit Complete

Protocol Progress:
❶ **INITIAL SETUP**
❷ **BACKGROUND, RATIONALE & GOALS**

Click Continue below to go to the next section

View: SF2 - Populations with Special Considerations

Populations with Special Considerations

1. * **Check all participant groups that will be either**

   a) Specifically included in this study or

   b) Discernable in the research data/specimens.

   (Selections will branch)

   - [ ] Children
   - [ ] Emancipated minors
   - [ ] Wards of the State
   - [ ] Pregnant women or fetuses
   - [ ] Neonates or Post-delivery Materials
   - [ ] Prisoners
   - [ ] Decisionally Impaired Adults
   - [x] **VCU / VCUHS students or trainees**
   - [ ] VCU / VCU Health System employees
   - [ ] Individuals with limited English proficiency
   - [ ] Active military personnel
   - [ ] Student populations in K-12 educational settings or other learning environments
   - [ ] Members of a federally recognized American Indian and Alaska Native tribe

- [ ] None of the Above

2. **Additional considerations for student populations:**
   * **Select all who will be research participants in the study:**
   - [x] **VCU Students**
   - [ ] K-12 Students
   - [ ] Parents/Guardians of Students
   - [ ] Teachers
   - [ ] Administrators
   - [ ] Other

3. **If applicable, describe any alternative activities for students (including VCU students) who choose not to participate in the research.**

4. * **Describe how the study will minimize the possibility of coercion to participate.**
   We prevent undue coercion to participate by providing participants with the opportunity to decline participating in the study even after they initiate the consent process. Recruitment will only be done electronically, thereby further reducing participants' chances of feeling coerced. In addition, participants will have the opportunity to seek additional information about participating in the study. In the electronic consent document the decision to consent or to decline consent is presented at the end of the consent document with the following statement: ‘‘I have been provided with an opportunity to read the consent form carefully. All of the questions that I wish to raise concerning this study have been answered. Do you consent to participate in this research study? ‘Yes’ or ‘No’.’ In addition, the consent document will be available and individuals will be encouraged to download a copy for their own records. The study email will be available in the consent document. Individuals who are uncertain about whether they want to participate will therefore have the opportunity to contact the coordinator with questions about the study.

View: SF2 - Populations with Special Considerations Section Complete

Populations with Special Considerations Section Complete

Protocol Progress:
❶ **INITIAL SETUP**
❷ **BACKGROUND, RATIONALE & GOALS**
❸ **RESEARCH PLAN**
❹ **CONSENT PLAN**
❺ **RISKS, PRIVACY & CONFIDENTIALITY**
❻ **POPULATIONS WITH SPECIAL CONSIDERATIONS**