Decreasing the Temporal Window in Individuals with Alcohol Use Disorder (RP1B)

NCT04128761

02/24/2024

INSTRUCTIONS:

- *Use this "TEMPLATE PROTOCOL (HRP-503)" to prepare a study protocol outlining your research plan.*
- *Depending on the nature of your study, some major sections might not be applicable to your research. If so, simply mark as "N/A." For example, a simple survey might have many sections with "N/A." For subsections (e.g., 1.x or 8.x) you can mark as "N/A"if you are certain that the subsection is not applicable.*
- *Once the IRB/HRPP approves your submission, your latest approved version of the protocol will be stored in the IRB Protocol Management online system.*
- *If your research plan changes and you need to modify the protocol, please submit an amendment to Protocol Management with the requested modifications. Download your current protocol from Protocol Management and indicate the changes/revisions using the track changes feature in order to make review of the modifications easier to follow. If you are unable to use track changes, please create a new paragraph wherever you need to make a change, and indicate "Amendment: Date" before making a change to any section. Protocol management will store the older versions of your protocol if the IRB or HRPP staff need to compare them during the review.*

PROTOCOL TITLE:

Include the full protocol title.

Scarcity narratives and AUD

PROTOCOL NUMBER:

Include the number assigned in Protocol Management (verify this has been added before submitting protocol to HRPP).

23-621

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VERSION NUMBER/DATE:

Include the version number and date of this protocol. Versions should start at 1.0.

Version 6.0 - 02/26/2024

REVISION HISTORY:

Use this table to keep track of changes. Add more rows as needed.

Revision #	Version Date	Brief Summary of Changes (i.e., the different sections)	Consent Change?
1	07/21/2023	Updated the criteria for group randomization; updated inclusion and exclusion criteria; updated data management	No
2	08/18/2023	Updated compensation	Yes
3	08/25/2023	Included that we will collect W-9 for payment	Yes
4	11/13/2023	Change in the scarcity narrative used for Session 2	No
4	02/26/2024	Changed eligibility criteria to lower the AUDIT requirement	No

Table of Contents

1.0	Study Summary	4
2.0	Objectives	4
3.0	Background	5
4.0	Study Endpoints	6
5.0	Study Design and Statistical Analysis Plan	7
6.0	Setting	7
7.0	Study Intervention(s)/Investigational Agent(s)	8
8.0	Procedures Involved	10
9.0	Data and Specimen Long Term Storage and Use	13
10.0	Sharing of Results with Subjects	16
11.0	Study Timelines	16
12.0	Inclusion and Exclusion Criteria	16
13.0	Vulnerable Populations	17
14.0	Number of Subjects	18
15.0	Recruitment Methods	19
16.0	Withdrawal of Subjects	21
17.0	Risks to Subjects	22
18.0	Potential Benefits to Subjects	23
19.0	Data Management and Confidentiality	24
20.0	Provisions to Protect the Privacy Interests of Subjects	26
21.0	Provisions to Monitor the Data to Ensure the Safety of Subjects	28
22.0	Compensation for Research Related Injury	29
23.0	Economic Burden to Subjects	30
24.0	Consent Process	30
25.0	Process to Document Consent in Writing	33
26.0	Resources Available	34
27.0	Multi-Site Research	35

1.0 Study Summary

Study Title	Scarcity narratives and AUD
Study Design	Adults with Alcohol Use Disorder (AUD) will be enrolled in the study and complete two online sessions where the effects of exposure to scarcity narratives on delay discounting and alcohol demand will be investigated. Participants will be randomly assigned to one of two scarcity narrative groups (active or control), balanced by discounting rate and sex. Delay discounting and alcohol demand will be evaluated pre and post exposure to the narratives.
Primary Objective	The primary objective is to test the theory of Reinforcer Pathology via manipulation of the temporal window with exposure to a scarcity narrative. The primary outcome measures of this study are the extent to which scarcity narratives decrease an individual's temporal window and increase their alcohol valuation, compared to baseline.
Secondary Objective(s)	Investigate the effects of scarcity narratives on delay discounting and demand in individuals with AUD
Study Population	Individuals with Alcohol Use Disorder (AUD)
Sample Size	112
Research Intervention(s)/ Investigational Agent(s)	Participants will complete two online surveys that will last approximately 1h each. The survey will collect data on AUD severity, demographics, patterns of alcohol consumption, DD, and alcohol demand pre and post exposure to scarcity narrative.
Study Duration for Individual Participants	The study will have a duration of two online sessions of approximately 1h each.
Acronyms and Definitions	AUD = Alcohol Use Disorder SUD = Substance Use Disorder DD = Delay Discounting RP = Reinforcer Pathology AI = Artificial Intelligence

2.0 Objectives

2.1 Describe the purpose, specific aims, or objectives of this study:

The goal of the present study is to test reinforcer pathology via manipulation of the temporal window (i.e., shorten the temporal window with exposure to a scarcity narrative). Another goal of the present study is to evaluate whether a voice recording can enhance the effects of a previously published scarcity narrative, compared to exposure to the written narrative only.

2.2 State the hypotheses to be tested:

We hypothesize a Group (Scarcity vs. Control) x Time (baseline vs. post) interaction. Specifically, we expect that participants exposed to an active scarcity narrative will present a shorten temporal view, as measured by Delay Discounting (DD), and increase demand for alcohol compared to baseline, whereas the control group would not show any changes between baseline and post intervention measures.

3.0 Background

3.1 Summarize the relevant prior research on this topic and gaps in current knowledge within the field of study:

RP suggests that substance use disorders results from a short temporal window of reinforcer integration, as indexed by a high DD rate. Data shows that DD serves as a behavioral marker for addiction and a predictor for therapeutic outcomes. Furthermore, a short temporal window increases the valuation of brief, immediate, and intense reinforcers (e.g., drugs), and decreases the value of reinforcers that are less intense and variable over time. RP has been mechanistically tested with manipulations that both increase the temporal window (i.e., decreases DD), such as episodic future thinking, or decrease the temporal window (i.e., increases DD), such as exposure to scarcity narratives. Although exposure to scarcity narratives has been shown to increase DD, few studies have investigated its effects on alcohol valuation, as measured through demand. Thus, the goal of the present study is to investigate the effects of scarcity narratives on both DD and demand in participants with AUD.

3.2 Describe any relevant preliminary data:

Previous online and in-laboratory studies from our group and others have shown that exposure to scarcity narratives increase DD in individuals with AUD, cocaine use disorder, smokers, overweight, and obese population. However, empirical evidence on the effects of scarcity on demand and drug valuation are scarcer.

3.3 Based on the existing literature, provide the scientific or scholarly rationale for and significance of your research and how will it add to existing knowledge:

To date, only two studies investigated the effect of scarcity narrative on DD in AUD population. Furthermore, only one of them included demand measures to assess alcohol

valuation. Thus, it is unclear how exposure to a scarcity narrative impacts both DD and alcohol valuation in AUD participants. In this study, we hypothesize that exposure to active scarcity narratives will increase DD and alcohol valuation as measured through demand compared to exposure to a control narrative. Specifically, we expect that participants exposed to an active scarcity narrative will present a shorten temporal view, as measured by Delay Discounting (DD), and increase demand for alcohol compared to baseline, whereas the control group would not show any changes between baseline and post intervention measures.

4.0 Study Endpoints

*4.1 Describe the primary and secondary **study** endpoints. See links below for discussion of study endpoints and how they may differ from study objectives. These are most common in clinical trials but are sometimes applicable to other types of biomedical research, as well as social, behavioral, or educational research. See link below for a discussion.*

https://docs.google.com/document/d/1Wocz7K7a0hCQJPPO_khh5l1SQQjhGDDGHzcOPRHR5Tw/edit?usp=sharing

Primary:
Change in Delay Discounting: Change in discounting rates will be compared within-subjects across sessions and between groups.

Change in Alcohol Demand: Change in alcohol demand will be compared within-subjects across sessions and between groups.

Alcohol craving: Change in alcohol craving will be compared within-subjects across sessions and between groups.

Subjective time perception: Change subjective time perception will be compared within-subjects across sessions and between groups.

*4.2 Describe any primary or secondary **safety** endpoints. These should be included for all studies that are greater than minimal risk. (Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*:

These procedures are not more than minimal risk.

5.0 Study Design and Statistical Analysis Plan

5.1 Describe the basic study design/approach (e.g., qualitative study using five focus groups of first year students to describe assimilation into the university community; randomized controlled trial of a behavioral change intervention to increase dietary intake of whole grains; pre- post-test evaluation of new pedagogical techniques to improve adult literacy):

The study will use a within-between design. Adults with AUD will be randomly assigned to two groups (active or control), balanced by discounting rate and sex. All participants will provide measures for all assessments pre and post exposure to the scarcity (or control) narrative.

5.2 Describe corresponding data analysis plan/approach (e.g., content analysis of focus group transcripts; descriptive analysis followed by linear regression modeling; nonparametric analysis of pre- and post-test measures):

Demographic characteristics will be summarized using descriptive statistics. We will compare outcome measures using a repeated measures ANOVA with active vs. control narratives as explanatory variables. Outcomes of interest include delay discounting and alcohol demand.

6.0 Setting

6.1 Describe the sites or locations where your research team will conduct the research. Consider each of the items listed below:

- *Identify where your research team will identify and recruit potential subjects.*
- *Identify where the team will perform the research procedures.*
- *Describe the composition and involvement of any community advisory board(s).*
- *For research conducted in other locations, describe:*
  - *Site-specific regulations or customs affecting the research at those locations.*
  - *Local scientific and ethical review structure at those locations. Examples include work in other cultures or ethnic groups (within or outside of the U.S.) and work with churches. The HRPP will provide additional guidance for international research.*

Location of Recruitment:

Participants will be recruited from our REDCap data base. Previously screened participants who have agreed to be re-contacted for other studies and that meet for the current experiment will be contacted via email with an invitation to participate in the current study.

Location of study:

The entirety of data collection will be conducted online. All participants will enroll on a voluntary basis and eletronically sign an IRB-approved consent form prior to study participation.

7.0 Study Intervention(s)/Investigational Agent(s)

7.1 Describe the study interventions (including behavioral interventions) and/or investigational agents (e.g., drugs or devices) to be used in this study. Consider each of the items listed below:

- *Drug/Device Handling: If the research involves drugs or devices, describe your plans to store, handle, and administer the drugs or devices so that they will be used only on subjects, and only by authorized investigators.*
- *Describe whether any of the following will be used: microwaves, X-rays, DEXA scans, general anesthesia, or sedation*
- *If control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference the SOP in this section.*

Active scarcity narrative:
"
There was a major hurricane in my area. My car and house have been destroyed by the storm. My family is depending on me to come up with a solution. The storm shelters are full of other hurricane victims and I will have to be separated from my family to get a bed. I have no idea when I will see them again or how I will get food."

Control scarcity narrative: "There was a minor storm in my area. Hail fell on both my house and car, and I have a small dent in the hood of my car. I contacted my insurance company, and the repair is fully covered. The earliest available appointment is next week, when the repair team will travel to me and fix my car while I am at work. My house appears to be undamaged."

7.2 List the name of all drugs (including any vitamins, supplements, herbs, or nicotine) to be used in the study. Indicate whether they have FDA approval, and list any limitations for their use:

NA

7.3 List all devices, how they will be used, their purpose in the study, and if they will be used in a manner consistent with their approved uses. If they will be used in ways that are not yet FDA approved, indicate whether they need an IDE or a determination that they are exempt from the IDE Determination. If a determination of significant risk or non-significant risk is needed for any of the devices, include the researcher's recommendation for each of those devices:

NA

7.4 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- *Identify the holder of the IND/IDE/abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

NA

8.0 Procedures Involved

8.1 Describe and explain the study design:

Adults with alcohol use disorder will be randomly assigned to one of two scarcity narrative groups narrative (active vs. control), balanced discounting rate and sex. We will enroll approximately 160 participants in order to conclude with 112 completers (56 per group).

The procedure will include two sessions. During the first session, participants will complete all the assessments via an online survey without any independent variable. After the first session, participants will be randomized to one of two groups. During the second session, participants will be initially exposed to one of the scarcity narratives (active vs. control). They will be asked to read the narrative while also listening to the narrative on audio. They will listen to either a male or female voice. The voice will be matched based on sex. They will be asked to vividly imagine that this narrative applies to them. Next, participants will complete the assessments in the presence of these narratives.

All dependent variables will be measured pre and post exposure to the scarcity narrative for all participants. Thus, narrative effects will be measured within-subject. Comparisons between active and control narratives will conducted between groups.

8.2 Provide a description of:

- *All research procedures being performed*
- *If the study has more than one procedure, session, and/or subject population, describe each procedure, session, and/or study population separately. For complex studies, you are encouraged to include a figure or chart.*

Participants in our REDCap database will be contacted if they have given prior permission to be contacted for future studies. Participants will be screened again for eligibility for the current study using a Qualtrics online survey.

Eligible participants will complete two online surveys on Qualtrics. The first survey will serve as the baseline. In the second survey, they will be exposed to one of the scarcity narratives and then they will answer the survey.

8.3 Describe:

- *Procedures or safeguards intended to reduce the probability and magnitude of risks. (For example: Reducing the risk of injury in a virtual reality study either by having the subjects sit during the study or by providing an obstacle-free space for walking.)*
- *Be sure to describe all drugs and devices used in the research, when they will be administered or used, and their purpose.*
- *Methods used to collect data about subjects. Please upload all data collection forms to Protocol Management. Some common examples are:*
  - *Screening questionnaires*
  - *Survey(s), including online surveys*
  - *Demographic questionnaire(s)*
  - *Interview guide(s), e.g., questions or pool of questions for semi-structured interviews*
  - *Focus group guide(s)*
  - *Other documents used to collect data*

Delay Discounting: Assesses money and alcohol (matched on utility) rewards devaluation as a function of delay by presenting hypothetical choices between smaller, sooner and larger, later rewards at a range of delays.

Alcohol Purchase Task: Assesses alcohol demand, where participants report the quantity of standard alcoholic drinks they would consume across various prices.

Alcohol Relative Reinforcement Schedule: Measures substance-related and substance-free reinforcement.

Alcohol Urges Questionnaire: Assesses alcohol craving.

Alcohol Withdrawal Symptoms: Assesses alcohol withdrawal.

Temporal perception scale: Measures the subjective perception of future proximity

Contemplation Ladder: Measures readiness to change substance use

The Holmes Rahe Life Stress Inventory: Assesses occurrence of stressful life events
Obsessive Compulsive Alcohol Use Scale: Measures alcohol craving during the past week

Reward Responsiveness Scale: Assesses reward sensitivity

Stress Appraisal Measure: Assesses cognitive appraisal of an anticipatory stressful event

Expectancies and attitudes: Measures expectancies regarding intervention group membership assessed

Experiment/Experimenter Attitudes Rating Scale: Assesses participants' attitudes and a tendency to confirm arbitrary experimental hypotheses.

8.4 What data will you collect during the study and how you will obtain them? Please include descriptions of electronic data collection, database matching, and app-based data collection:

All of the survey and questionnaire data will be collected using Qualtrics, an online survey platform used to develop, administer, and collect participant data in a secure password-protected database. Only study personnel will have access to the survey and collected data.

8.5 Who will transcribe or code audio and/or video recordings?:

NA

8.6 Include a description of any deception to be used in the study. Include justification for the use of deception (why the deception is necessary), describe the debriefing process, and describe how the study meets <u>all</u> the following criteria for alteration of consent (deception is considered an alteration of informed consent):

- *The research involves no more than minimal risk to the subjects*
- *The alteration will not adversely affect the rights and welfare of the subjects*
- *The research could not practicably be carried out without the alteration/deception*
- *(Optional but encouraged in most cases) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception)*

NA

8.7 If the study involves long-term follow-up (once all research related procedures are complete), describe what data will be collected during the follow up period and when it will occur:

NA

9.0 Data and Specimen Long Term Storage and Use

9.1 If you will store data or specimens for future use, describe where you will store the data or specimens, how long they will be stored, and how and by whom the data or specimens will be accessed:

All participant data, including electronic data, will be stored in secure places to protect confidential participant information. Secured places will include locked filing cabinets, locked rooms accessible only to study personnel, and/or password-protected databases. Moreover, all data will be quality controlled in preparation for data analyses. All discrepancies in data entry will be checked against the raw data source, and the correct data entry will be used. All data entered into spreadsheets and databases will be coded by participant ID number and not by name (i.e., first and last name), stored in a master ID log. The master ID log will be stored in REDCap and Qualtrics, which are HIPAA compliant. Additionally, all entered data will be backed up on secure password-protected servers. Computers used in the studies will also be password protected, and accessible only by study personnel. Computers and password-protected servers used for this study are Virginia Tech secured and managed. We will provide certification of IRB approvals of the study protocol to NIDA prior to enrolling study participants. VT IRB regulations will be strictly adhered to in the conduct of the proposed research. Specifically, prior to implementation of any protocol changes, amendments will be submitted to the IRB for approval. Data will be stored for three years following publication in accordance with NIH policy. Individuals on the IRB approved protocol will have access to data in long term storage.

9.2 For specimens, list the data to be stored or associated with each specimen:

NA

9.3 Describe the procedures to release data or specimens outside of the research team, including the process to request a release, approvals required for release, who can obtain data or specimens, and what data will be provided with specimens:

Investigators will adhere to all NIH requirements regarding data sharing. Participant data collected in this project will be de-identified and made available if requested. We will also share the analysis results. As part of this process, all investigators will be required to agree to the following conditions: 1) will adhere to the reporting responsibilities; 2) will not redistribute the data beyond the requesting individual and named collaborators; 3) will give appropriate acknowledgement; 4) will not use the data for commercial purposes; and 5) will obtain appropriate ethical approvals.

Results from research conducted will be shared and disseminated, including: regular project meetings, annual meetings, symposia, workshops, and/or conferences for related groups. Manuscripts will be written and submitted for publication in peer-reviewed journals/conferences, following the NIH Public Access Policy guidelines. All necessary ethical approvals will be obtained.

Raw data will be made available upon request after the dissemination of results.

Access Criteria:

Data requests will be reviewed by the principal investigators and data will be shared with the expectation of acknowledgment of funding source and primary study team.

9.4 Describe the identifiers to be included with stored data or specimens, as well as any key or code that could be used to make them identifiable. Describe where the code will be stored, who will have access to it, and when it will be destroyed:

All screened participants are assigned study IDs that are thereafter associated with all collected data. The electronic de-identified data is stored on the Bickel shared server which is password protected and only accessible to members of the research team on the VT IRB approved protocol.

Study ID and identifiers (i.e., name, email, age, and demographics) will be available together electronically only in the pre-screener in Qualtrics. Specifically, we will use a pre-screener survey in Qualtrics to collect demographic and other screening criteria to decide the participant's eligibility to enroll in the study. After completing the pre-screener, the participant will be assigned an ID. If eligible to enroll in the study, they will receive that ID by email together with the link to the surveys. They will use this ID to

authenticate their access to the two surveys of the study. They will not have to provide any PII during the surveys following the pre-screen. Throughout the remaining of the study, the only personal information linked to their ID will be their email which will be needed to send the survey links and process the payments. Data will be stored in Qualtrics and only authorized people will have access to the data in Qualtrics.
If data need to be downloaded from Qualtrics, those data will be stored in password-protected folders and only the participant's ID will be included in the file. No other PII will be stored together with the participants' responses to the surveys.

9.5 Please select the identifiers you will obtain (whether directly from participants or from another source), including but not limited to:

☒	*Name*
☒	*Geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and equivalent geocodes (note, the initial three digits of a zip code are not considered identifiable)*
☒	*Elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and single year of age over 89 and all elements of dates (including year) indicative of such age (note, such ages and elements may be aggregated into a single category of age 90+)*
☐	*Phone numbers*
☐	*Fax numbers*
☒	*Electronic mail addresses (e-mail)*
☒	*Social Security numbers*
☐	*Medical record numbers*
☐	*Health plan beneficiary numbers*
☐	*Account numbers*
☐	*Certificate/license numbers*
☐	*Vehicle identifiers and serial numbers, including license plate numbers*
☐	*Device identifiers and serial numbers*
☐	*Web Universal Resource Locators (URLs)*
☒	*Internet protocol (IP) address numbers*
☐	*Biometric identifiers, including finger and voice prints (audio recording)*
☐	*Full face photographic images and any comparable images (including video recording)*
☐	*Student record number or identification number*
☐	*User name for online or computer accounts*

☐	*Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data):* Click here to explain.

10.0 Sharing of Results with Subjects

10.1 Describe whether you will share results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) with subjects or others (e.g., the subject's primary care physician). If so, describe how you will share the results and include this information as part of the consent document. Upload materials you will use to explain the results to subjects:

We will not share any results with the study participants. In the event of incidental findings, we will follow the established protocol highlighted in the NIDA Data and Safety Monitoring Plan (DSMP) for the R01 associated with this project.

11.0 Study Timelines

11.1 Describe:

- *The duration of an individual subject's participation in the study (for example, 1 hour, 2-4 weeks, 3-5 years).*
- *The amount of time expected to enroll all study subjects (weeks, months, years, etc.)*
- *The amount of time expected for the investigators to complete this study including primary data analyses.*

The study will last two online sessions of approximately 1h each.

12.0 Inclusion and Exclusion Criteria

12.1 Describe how you will screen individuals for eligibility. When will screening occur and what procedures will you use? Upload any screening scripts or surveys to Protocol Management:

We will use a study-specific pre-screening online survey that will occur prior to enrolling participants into the study, in order to effectively decrease attrition in our studies by ensuring that participants meet all inclusion/exclusion criteria prior to enrolling into the randomized study.

12.2 Describe the eligibility criteria that define who will be included and who will be excluded from enrollment for each procedure of your study. Include any geographic criteria (e.g., Virginia Tech undergraduate students, a national sample of adults with engineering degrees, minors aged 8-12 in the New River Valley, university faculty in Virginia and Paris, France):

Inclusion criteria will require that participants:
(1) demonstrate high-risk or harmful drinking (AUDIT>15; i.e., 16 or higher); (2) be 21 years old or older, (3) have a desire to quit or cut down on their drinking, but do not have proximate plans to enroll in treatment for AUD during the study period

Exclusion criteria include: (1) having a current unmanaged psychotic disorder, (2) reporting current pregnancy or lactation, (3) having dementia

12.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of these populations as subjects in your research unless you indicate them in the description of your subject population.)

- *Minors, as defined by state law where the study is performed (infants, children, teenagers)*
- *Pregnant women (can be included in minimal risk studies by mentioning in section 13.1)*
- *Prisoners (including all incarcerated individuals)*
- *Adults not capable to consent on their own behalf*

Vulnerable subjects, such as individuals with cognitive impairments, minors, prisoners, and pregnant women will be excluded.

13.0 Vulnerable Populations

13.1 If the research involves individuals who are vulnerable to coercion or undue influence, please describe additional safeguards you will include to protect their rights and welfare. Consider the applicable items listed below:

- *If the research involves Virginia Tech students, indicate whether these are students of any of the investigators. If so, describe whether*

the activities will take place during class time as part of the curriculum and the steps you will take to reduce the possibility that students feel obliged to participate in order to improve their course grade. The HRPP can provide further guidance as needed. Describe whether you will request access to student records (e.g., SAT, GPA, GRE scores).

- *If the research involves employees of Virginia Tech or the research sponsor, describe steps you will take to ensure that the employees are freely participating and describe how their data will be protected from inspection by their supervisors.*
- *If the research involves Virginia Tech NCAA athletes, you must obtain approval from the athletic department.*
- *For research involving Montgomery County Public Schools, you must obtain county approval (after obtaining contingent Virginia Tech approval). Other locales have different requirements; please check on these and describe here. Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should be uploaded as a supporting document.*
- *If the research involves pregnant women, review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves prisoners, review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (minors), review the "CHECKLIST: Minors (HRP-416)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves cognitively impaired adults, review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information in this protocol.*

This research study will not include any vulnerable populations.

14.0 Number of Subjects

14.1 Indicate the total number of subjects to be enrolled and how this number was determined (e.g., sample size calculation [show], number of available subjects in a finite pool, number of tests funding award would allow):

In the preliminary data, we observed effect sizes ranging from ηp2 = .027 to ηp2 = .074. Thus, we selected a medium effect size (f = 0.25) to inform sample size of the current study. A total of 112 participants will complete the study (56 participants per group), assuming a type 1 error rate of 0.01 to account for multiple comparisons, 95% statistical power, and pre- and post-measure correlation of 0.25, based on an ANOVA comparing the intervention at sessions 1 and 2.

We anticipate a 70% retention rate; thus, to achieve a final sample size of 112, we anticipate consenting 160 participants.

14.2 If this is a multi-site study, indicate the number of subjects to be enrolled at this site and the total to be enrolled from all sites:

NA

14.3 If applicable, indicate the number of potential subjects you expect to screen for enrollment, and the number of subjects you will need to complete the research procedures:

We cannot accurately estimate the total number of potential participants we expect to screen. However, as described above, we anticipate enrolling 160 participants in order to complete a total of 112 participants. Additionally, the first few participants enrolled in the study may be pilots.

14.4 If the study has more than one procedure, indicate the total number of subjects to undergo each procedure separately:

All participants will undergo all sessions unless they withdraw from the study.

15.0 Recruitment Methods

15.1 Describe when, where, and how you will recruit potential subjects:

Participants will be recruited from our REDCap data base. Previously screened participants who have agreed to be re-contacted for other studies will be contacted via email with an invitation to participate in the current study.

15.2 Describe the source of subjects (for example, clinic patients with specific conditions, students in the library, community members at a gathering, or members of a local gym):

Participants will be recruited from our REDCap database. Previously screened participants who have agreed to be re-contacted for other studies will be contacted via email with an invitation to participate in the current study.

15.3 Describe the methods that you will use to identify potential subjects:

We will check our current REDCap database, composed of participants that have screened in REDCap for other studies in our lab, and look for participants who: 1) have agreed to be re-contacted for future studies, and 2) reported alcohol use. We will then send out an email about the new study with a new REDCap screener link. All prospective participants will be required to fill out the new screener before enrolling for the current study to assure they meet all the inclusion criteria for the study.

15.4 Describe materials that you will be use to recruit subjects. Attach copies of these documents with this protocol in Protocol Management and be sure to include the IRB protocol number on each document.

- *For flyers, attach the final copy of printed flyers.*
- *For Virginia Tech News, Facebook postings and ads, newspaper ads, websites, MTurk/SONA/online survey systems, etc., attach the final wording and graphics to be used.*
- *For email recruitments, please include the subject line.*
- *For advertisements meant for audio broadcast, please submit the wording of the advertisement prior to taping (to avoid having to re-record with approved language) and submit the final recorded version for IRB review before use.*
- *Describe any compensation to subjects. Separate compensation into appropriate categories, such as: reimbursement for expenses, time and effort, and additional incentives for study participation. For each category, specify the amount (including any pro-rated amount), schedule, and method of payment.*

A template of the invitation email is attached.

Compensation. Participants will be compensated for each survey completed and will receive a study completion bonus if they complete both sessions. Compensation will be provided via online gift cards. Participants will be required to complete an online W-9 form in order to receive the payment.

Session 1: $15
Session 2: S20
Study completion bonus: $5

16.0 Withdrawal of Subjects

16.1 Describe circumstances under which you anticipate subjects could be withdrawn from the research without their consent:

Participants may be withdrawn from the research without their consent if they become ineligible based on inclusion/exclusion criteria or learning of a contraindication for continuing, or if they demonstrate inconsistent responding during baseline assessment.

16.2 If applicable, describe any procedures for orderly termination (e.g., discontinuation of a study drug or debriefing after a behavioral intervention):

If a participant is withdrawn from the study, he or she will be informed that we have collected all the data required from their participation. If a participant is withdrawn or voluntarily discontinue, their compensation for the study will be pro-rated accordingly.

16.3 Describe procedures that you will follow when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection (e.g., participant declines to continue with regular blood draws, but continues with periodic behavioral questionnaires):

If a participant is withdrawn or discontinued, they will be withdrawn from the entire study.

17.0 Risks to Subjects

17.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include for the IRB's consideration a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, privacy, and economic risks. Do not indicate "No risk" or "N/A." Instead, for studies with very low risk (e.g., anonymous online questionnaire on a mundane topic) indicate "The investigators are not aware of any risks from participation in this study." or "No more than risks than are found in everyday life." The example consent form presents a tabular method for risk information, which you can also use here. Common risk types include:

- *Physical (e.g., potential for pain, discomfort, infection)*
- *Psychological (e.g., potential for stress, discomfort, and/or embarrassment)*
- *Social (e.g., potential for discrimination or stigmatization and disruption of personal and family relationships)*
- *Legal (e.g., potential for disclosure of illegal activity, negligence)*
- *Privacy (e.g., potential for personal information being accessed, used, or disclosed without the subjects' knowledge or consent, breach of confidentiality/security)*
- *Economic (e.g., potential for individuals to lose access to economic services, employment, insurability)*

There are minimal risks involved in participation, including:

1. Adverse emotional reactions: These reactions may be related to some of the research tasks. Participants may also feel uncomfortable disclosing personal information such as drug use history.

2. Loss of confidentiality: The research team will employ every effort to maintain participant confidentiality, however the loss of confidentiality is a potential risk, specifically associated with the collection, storage, and transmission of data via an app.

17.2 Indicate the measures you will use to minimize risks and monitor subjects for safety. (e.g., asking a subject at regular intervals to rate how they are feeling from 1 to 10, or to slowly crouch in order to check their balance.)

NA

17.3 If applicable, indicate which procedures might have risks to the subjects that are currently unforeseeable. This will be rare, and usually applicable when testing a new drug or device or a new use of an existing drug or device:

NA

17.4 If applicable, indicate which procedures might have risks to an embryo or fetus should the subject be or become pregnant:

NA

17.5 If applicable, describe risks to others who are not subjects (e.g., collection of sensitive health data that might affect sexual partners if disclosed, mandatory reporting of abuse, DNA testing that might affect family members or relationships):

NA

18.0 Potential Benefits to Subjects

18.1 Describe the potential benefits that individual subjects might experience from participating in the research. Include the probability, magnitude, and duration of the potential benefits, as this will be useful to the IRB's risk:benefit analysis. Do not include benefits to society or others. Do not list monetary or non-monetary compensation for participation, as this is not a benefit These should be included in section 2 or 3 of this document:

Participants may benefit from education about research participation. The project involves minimal risk to confidentiality or other personal rights or to physical or emotional health. The results from this behavioral economic study will inform the development of new treatments for cocaine use. Thus, in general, the expected benefits outweigh the very minimal risks to participants.

18.2 If applicable, specify that there are no anticipated direct benefits for participants:

There are no anticipated direct benefits for participation in this study.

19.0 Data Management and Confidentiality

19.1 Describe procedures that you will use for quality control to ensure validity of collected data:

All staff involved in the conduct and/or monitoring of this study will have completed the Virginia Tech (VT) Human Subject Protection Training. Documentation of training will be maintained by the VT Institutional Review Board (IRB). VT IRB regulations will be strictly adhered to in the conduct of the proposed research. Specifically, prior to implementation of any protocol changes, amendments will be submitted to the IRB for approval. The PI will be responsible for continuous data and safety monitoring of all participants enrolled in this study.

The Co-PIs and the IRB will oversee monitoring of the data collection procedures. These procedures will be reviewed regularly in a number of settings. For instance, issues pertaining to data validity and integrity will be addressed formally during regularly scheduled study personnel meeting in which all study personnel, including the Co-PIs, will be in attendance. Issues pertaining to participant safety also will be addressed at these meetings. Moreover, the Co-PIs and the Senior Research Associate Project Manager will meet on a regular basis to discuss these topics further.

19.2 Describe any existing data or biospecimens you will obtain as part of this study. Include:

- *Variables or samples to be obtained*
- *Source of the data or specimens*
- *Your authorization to access or receive the data or biospecimens*
- *Whether the data or biospecimens are publicly available*
- *Whether the data or specimens you receive will contain identifiers*

The study will obtain existing data on participant contact information collected during screens in REDCap.

19.3 Describe the steps that you will take to handle and secure study data during data collection, storage, use, and transmission. Include

information about training of study staff, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers and data, etc.:

Access to study data will be limited to study personnel who have completed human subjects research protections and Good Clinical Practice trainings and who have been delegated the responsibility of data collection, management, or analyses by the PI.

All screened participants are assigned study IDs that are thereafter associated with all collected data, whether paper or electronic. The electronic de-identified data is stored on the Bickel shared server which is password protected. Non-electronic data that is collected is stored in participant specific binders identified only by study ID. These binders are stored in a locked file room inside a locked office within ARRC. . Study ID and identifiers (i.e., name, email, age, and demographics) will be available together electronically only in the pre-screener in Qualtrics, a widely used secure web-based application. Specifically, we will use Qualtrics to collect demographic and other screening criteria for eligibility for study enrollment. This service is password protected and has been approved by Virginia Tech IRB.

Personally identifiable information (PII) and Protected Health Information (PHI) is strongly guarded at all points in the study procedures.

All online data collection will be completed using the participant's ID, and will not require entering any PII.

As the survey is computerized, self-administered, and directly entered into the secure server, only authorized researchers will have access to assessment survey responses.

Study laptops will be password protected with an encrypted file system.

19.4 For multi-site studies, describe how data or specimens will be handled and secured for each site (e.g., central or disseminated data storage, data coordinating center):

NA

19.5 Describe the plan for data disposition following the conclusion of the study (e.g., long term maintenance of data, data destruction methods).

- *What information will be included in the long term storage of data or specimens?*
- *How long will the data or specimens be stored?*

- *Where and how data or specimens will be stored?*
- *Who will have access to the data or specimens during long term storage?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How will data or specimens be shared or transported?*
- *When and how will personal identifiers be destroyed?*

Answers to the study questions, demographic data, contact information, and primary records (i.e., PII and/or PHI) will be stored in a secure HIPAA compliant data storage environment managed by Virginia Tech for a period of 3 years after the publication of the primary data analysis in accordance with the National Institutes of Health (NIH) guidelines. The files will be deleted from storage at the designated time.

Data will be used exclusively for research purposes and will be collected online via Qualtrics. Data will be stored on Qualtrics and will be only available for download/export by people with authorized access to the surveys.

Data will be encrypted during transfer between the HIPAA compliant data storage environment and remote computers. Computers used in the study will be password-protected, and data will be accessible only by study personnel.

20.0 Provisions to Protect the Privacy Interests of Subjects

20.1 Describe the steps that you will take to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal information (e.g., collecting the minimal amount of private information required to complete the study, protecting the data once it is obtained):

Data will be collected and stored securely on the Qualtrics server, a commercial subscription service for implementing and executing tasks and questionnaires on any device with a modern Internet browser, including mobile and desktop computer devices. The computerized survey will collect only data that is needed to support analytic objectives and all results presented will be in aggregate form where no individual can be identified.

The study team will comply with all Health Insurance Portability and Accountability Act (HIPAA) Health IT guidelines and policies. The study team will store participant PII (e.g., contact information) on a HIPAA compliant data storage environment that is appropriate for PHI and managed by Virginia Tech. The study staff will have access to this information, on a strictly need-to-know basis.

All online data collection will be completed using the participant's ID, and will not require entering any PII.

The online assessment data are saved automatically on secure servers. Data will be encrypted during transfer to and from the secure servers.

As the survey is computerized, self-administered, and directly entered into the secure server, only study staff will have access to assessment survey responses.

Destruction of Study Data:
Primary records (i.e., PII and/or PHI) will be stored in a secure HIPAA compliant data storage environment managed by Virginia Tech for a period of 3 years after publication of the primary 3-year data analysis in accordance with the National Institutes of Health (NIH) guidelines. The files will be deleted from storage at the designated time

Participants will have substantial control over the location where they will take the online survey.

20.2 Describe steps that you will take to make subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures (e.g., use of a same gender investigator to place sensors on the torso, a private changing area if clothing must be changed, sensitivity when discussing pregnancy testing with subjects, making it clear on surveys that participants can discontinue at any time, not asking questions about private or sensitive issues unless necessary for the research):

The survey will be completed online in a location with sufficient privacy chosen by the participant. Participants will be reminded before starting the online survey that they may stop participation at any time without penalty.

As an additional protection against the risk of loss of confidentiality, we will use only ID numbers and keep all data in password-protected databases.

20.3 Describe how you plan to access existing sources of information about the subjects (e.g., medical records, grades) and how you will protect participant privacy through the data security plan:

All data will be encrypted and stored in password-protected secure server at ARRC.

20.4 Describe any required reporting that might occur as a result of your research questions, study populations, and data collection methods. Examples for Virginia and Virginia Tech include:

- ***Any*** *suspicions (e.g., circumstantial, disclosed) of child abuse (physical, emotional, sexual) and neglect*
- *Sexual discrimination and/or sexual violence that involves a student*
- *Disclosure or signs of intention to harm oneself (i.e., suicidal ideation and/or plan)*
- *Disclosure or signs of desire to harm others (i.e., homicidal ideation and/or plan)*
- *Suspected abuse, neglect or exploitation of vulnerable adults (e.g., individuals with a disability, elderly persons)*

We will report any disclosure or signs of intention to harm oneself (i.e., suicidal ideation and/or plan). In the event of this disclosure study staff will follow ARRC's SOP related to suicidal ideation.

21.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

Safety monitoring is required when research involves greater than minimal risk and is sometimes appropriate for other studies.

21.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe (e.g., periodic reporting to the IRB, establishing a data monitoring committee, reporting data monitoring committee findings to the IRB and the sponsor).*
- *What data you will review, including safety data, unexpected events, and data that show the ability to produce the intended results.*
- *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with subjects).*
- *The frequency of data collection, including when safety data collection starts.*
- *Who will review the safety data and with what frequency.*
- *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
- *Any conditions that will trigger an immediate suspension of the research (e.g., a serious adverse event).*

Data quality assurance and confidentiality: All participant data, including electronic data, will be stored in secure places to protect confidential participant information. Secured places will include locked filing cabinets, locked rooms accessible only to study personnel, and/or password-protected databases. Moreover, all data will be quality controlled in preparation for data analyses. All discrepancies in data entry will be checked against the raw data source, and the correct data entry will be used. All data entered into spreadsheets and databases will be coded by subject ID number and not by name (i.e., first and last name), stored in a master ID log. Additionally, all entered data will be backed up on secure password-protected servers. Computers used in the studies will also be password protected, accessible only by study personnel. We will provide certification of IRB approvals of the study protocol to NIDA prior to screening study participants. VT IRB regulations will be strictly adhered to in the conduct of the proposed research. Specifically, prior to implementation of any protocol changes, amendments will be submitted to the IRB for approval.

The MPIs and the IRB will oversee monitoring of the aforementioned procedures. These procedures will be reviewed regularly in a number of settings. For instance, issues pertaining to data validity and integrity will be addressed formally each week during a weekly study personnel meeting in which all study personnel, including the MPIs, will be in attendance. Issues pertaining to participant safety also will be addressed at these meetings. Moreover, the MPIs and the Senior Research Associate Project Manager will meet on a monthly basis to discuss these topics further. In consultation with the IRB and NIDA, the study will be stopped if there is clear evidence of harm.

22.0 Compensation for Research Related Injury

22.1 If the research involves more than minimal risk to subjects, describe the available compensation in the event of research-related injury, if any:

NA

22.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury. At Virginia Tech, this is most common for sponsored research:

NA

23.0 Economic Burden to Subjects

23.1 Describe any costs that subjects might be responsible for because of participation in the research, including any uncompensated costs for items such as transportation, missed work, and childcare:

To the extent possible, we will attempt to minimize obstacles to participation by optimizing our data collection platform for both desktop and mobile devices.

24.0 Consent Process

24.1 Indicate the process by which you will obtain consent for study participation. Please upload all consent, parental permission, and assent forms, documents, and scripts referenced in this section to Protocol Management.

Describe the following:

- *Where the consent process will take place (e.g., clinic waiting area, classroom, online)*
- *The time interval between sharing the consent information with the prospective subject and obtaining consent. For lab, interview, and focus group studies, the Virginia Tech IRB prefers that subjects have at least 24 hours to review the consent form and study information before the appointment where consent will be obtained. For simple online survey studies, you can typically present the consent information immediately before subjects begin participation.*
- *If applicable, processes to ensure ongoing consent or assent (e.g., for multiple sessions; for research in which a minor will turn 18 during the study; for longitudinal research with minors who will later be asked to provide or affirm their assent).*
- *Please review "SOP: Informed Consent Process for Research (HRP-090)" for recommended procedure. Describe your process, being sure to include:*
  - *The name and role of all study personnel who will be trained and certified by the PI to conduct the consent process*
  - *The time that will be devoted to the consent discussion*
  - *Steps that you will take to minimize the possibility of coercion or undue influence*
  - *Steps that you will take to gauge or ensure the subjects' understanding*

The consent process will occur online. Participants will indicate their consent electronically prior to starting the survey. Thus, the consent process may occur at any participant-chosen location. Participants will have the opportunity to read and review the ICF document that will explain the nature of the study, its purpose, procedures,

expected duration, and the benefits and risks involved in study participation. Participants will be given ample time to carefully consider whether they want to participate.

After screening, eligible participants will receive a link via email. When following the link, the first page of the survey will display the full version of the consent and participants will be asked to check a box indicating that they consent in order to continue to the survey. Participants will be told that they should feel free to discuss participation with relatives, friends, and primary care physicians. Participants will also be informed of their right to stop participating in the study at any time without penalty. ICF will also include the contact information available to them should they have any questions throughout the study.

The electronic consent will be available at the beginning of each online survey and participants will be reminded that they may stop participating in the study at any time without penalty.

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If non-English speakers will be recruited, describe the process you will use to ensure that the oral and/or written consent information provided will be in a language that they understand.*
- *If you translate consent forms and study materials, please provide a certified translation of the form as well as the certification document.*
- *Indicate the spoken language that study personnel obtaining consent will use. Describe how you will assess fluency of personnel obtaining consent to ensure that the translation is accurate.*

NA

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

- *Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure you have provided sufficient information for the IRB to make these determinations (i.e., that it meets the criteria for a waiver or alteration of the consent process).*

NA

Subjects who are not yet adults (minors: infants, children, teenagers)

- *Describe the criteria that you will use to determine legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g., in Virginia, individuals under the age of 18 years).*
  - *For research conducted in Virginia, review "SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)" to determine which individuals in the state meet the definition of "minor."*
  - *For research conducted outside of the state, please describe the legal requirements for the definition of "minor."*
- *Describe the process for obtaining parental permission.*
  - *Permission from one parent is acceptable for studies that involve no greater than minimal risk OR involve greater than minimal risk but present the prospect of direct benefit to the minor subject.*
  - *Permission from both parents is required in all other cases (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the minor).*
- *Describe whether you will obtain permission from individuals other than parents or Legally Authorized Representatives, and if so, who will be allowed to provide permission. Describe the process you will use to determine these individuals' authority to consent to the minor's general medical care.*
- *Indicate whether you will obtain assent from all, some, or none of the minors. If you will obtain assent from some minors, indicate which minors will be required to assent. Consider chronological age and intellectual capacity when determining who will be required to provide assent (e.g., infants are unable to assent. However, teenagers are likely able to read and sign an assent form).*
- *When assent of minors is obtained, describe whether and how you will document it. Will minors sign an assent form or give verbal assent?*
- *Attach parental permission and minor assent forms or scripts in Protocol Management.*

NA

Adults Unable to Consent

- *Describe the process you will use to determine whether an individual adult is capable of consent.*
- *List the individuals from whom you will obtain permission in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and non-minor child).*
    - *For research conducted in the Virginia, review "SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)" to determine which individuals in the state meet the definition of "legally authorized representative."*
    - *For research conducted outside of Virginia, please describe the legal requirements for obtaining permission from a legally authorized representative in the state where the research will occur.*
- *Describe the process for assent of the subjects.*
    - *Indicate whether you will require assent from all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.*
    - *If you will not obtain assent from some or all subjects, please provide justification for not obtaining assent.*
    - *Describe whether and how you will document assent.*

NA

25.0 Process to Document Consent in Writing

25.1 Consult "SOP: Written Documentation of Consent (HRP-091)" for recommended procedures, and describe whether and how consent of the subject will be documented in writing:

Prior to beginning the survey, participants will electronically agree to participate in the study by checking a box after being presented with the full version of the ICF in Qualtrics.

25.2 If the research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, you can request that the IRB waive the requirement to obtain written documentation of consent (e.g., consent to participate is indicated by pressing a button for an online questionnaire – after the consent information is presented and before the questionnaire begins):

Consent to participate is indicated by pressing a button for an online questionnaire – after the consent information is presented and before the questionnaire begins.

25.3 If you will document consent in writing, attach a consent document with places for signatures. If you will obtain consent, but not document consent in writing, please attach the consent script or text. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You should use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script:

The study will obtain consent, but not document consent in writing. The consent script is attached.

26.0 Resources Available

26.1 Describe the resources available to conduct the research. For example, as appropriate:

- *Describe the PI's availability to supervise the research.*
- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
- *Describe the time that you will devote to conducting and completing the research.*
- *Describe your facilities.*
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated or unanticipated consequence of participation in the research.*
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions (e.g., training plans, detailed study notebooks).*

The PI's primary focus is overseeing research efforts and will devote sufficient time to supervise the study.

We have a history of successful recruitment of individuals in recovery from AUD. All participants will enroll on a voluntary basis and electronically sign an IRB-approved informed consent form prior to study participation. In addition, we have more than

sufficient numbers of participants in our current REDCap database to recruit an adequate number of participants for the current study.

Contact methods that were previously successful in previous studies will be used to recruit for this study. Participants will be allowed to answer the surveys at a time and location of their convenience in an attempt to minimize barriers to participation and increase retention and survey completion.

The PI's office and Virginia Tech facilities reside on the 3rd floor of the Fralin Biomedical Research Institute (FBRI) and consists of several laboratories for clinical research. Office space for the PI, co-investigators, project manager, post-doctoral associates, and graduate students is provided in the FBRI.

This is a minimal risk observational study. In the unlikely event of any medical emergencies, study representatives will call 911 regardless of whether it is related to the study. If a participant reports depression or suicidal thoughts to any study representative, the participant will be provided with information about relevant resources (i.e., suicide hotlines and/or call 911, if appropriate).

27.0 Multi-Site Research

Contact the HRPP for multi-site research (involving multiple institutions) and the details required for this section will be provided. Otherwise, indicate N/A.

NA