

Official Title of Study: Alcohol PBS and Thinking about the Past

NCT Number: Not Assigned

Unique Protocol ID: IRB20201070D

Date of Document: 09/10/2021

IRB Application (Human Research) (Version 1.7)

1.0 General Information

***Please enter the full title of your study:**

Alcohol Protective Behavioral Strategies and Thinking about the Past

***Please enter a reference or other description for this study. This field is required, but will not be referenced by the staff. It is for your use:**

Alcohol PBS - CF

* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

2.0 Add Department(s)

2.1 List departments associated with this study. If the study is funded, please associate it with the correct A&M System member.:

Primary Dept?	Department Name
<input checked="" type="radio"/>	TAMU - College of Liberal Arts - Psychology
<input type="radio"/>	TAMU - TAMU - Psychology
<input type="radio"/>	TAMU - Texas A&M University - Not Specified

3.0 Assign key study personnel (KSP) access to the project

3.1 *Please add a Principal Investigator for the study:

Smallman, Rachel

3.2 If applicable, please select the Research Staff personnel. Please note if you do not find the personnel needed, please contact the iRIS support line at 845-4969. IRB Note: These personnel will need to sign off on the initial application submission.

A) Additional Investigators

Fields, Sherecce A
Co-Investigator

B) Research Support Staff

Arthur, Kianna
Grad Student
Bechtel, Alexis
Research Assistant
Hamdan, Hadeel
Research Assistant
Harrell, Ava
Research Assistant
Hill, Rebecca

Research Assistant
Lowe, Jessica
Grad Student
Mayrant, Dawson
Research Assistant
Rives, Dalton
Research Assistant
Rodriguez, Anahi
Research Assistant
Zepeta Mendez, Melissa
Research Assistant

3.3 *Please add a Study Contact:

Smallman, Rachel

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 If applicable, please add a Faculty Advisor:

3.5 Please select the Designated Department or Supervisor Approval(s)(not required for Animal Use Protocol):

Lench, Heather
Department Chair

For **IRB*** and IBC, add the name of the individual authorized to approve and sign off on this protocol from your Unit (e.g. the Department Chair or Dean). *REQUIRED*

4.0

Request to the Human Research Protection Program :: Please Select **ONE of the options below.**

Version 03.30.2021

4.1 I am conducting Human Subjects Research, and I want to proceed to the regular application.

☒ Yes ☐ No

Which IRB reviews your research?

☒ TAMU IRB
☐ Dentistry IRB

4.2 I am requesting a determination - is my project human subjects research?

☐ Yes ☐ No

4.3 I am requesting a determination to see if my research falls into an EXEMPTION category.

☐ Yes ☐ No

4.4 I am requesting to defer to an external IRB (that is not IRB TAMU or IRB Dentistry).

☐ Yes ☐ No

4.5 I am requesting a "Delayed Onset" of human subjects research determination.

☐ Yes ☐ No

5.0 Study Personnel Qualifications

5.1 Study Personnel Qualifications

Select the Study Personnel from the list created earlier in the application. Then provide the qualifications and role information for that study personnel selection as applicable to this study.

Study Personnel	Qualifications	Role in Study and Duties delegated by PI
Smallman, Rachel	PhD social psychology	Advisor and PI
Arthur, Kianna	PhD student, supervised by Dr. Smallman	running participants online.
Lowe, Jessica	PhD student, supervised by Dr. Smallman	Running participants online.
Fields, Sherecce A	PHD clinical psychology	Co-Investigator

5.2 External Site or Study Personnel Please list the study personnel on your study who are not associated with Texas A&M. Additional documentation and agreements may be needed for these individuals.

Will an external site review the research?

☐ Yes ☒ No

If yes, what is the name of the external site?

Name	Institution	Telephone	E-mail	Role
No External Personnel has been added to this Study				

Name (from above)	Briefly describe how the person will participate in human subjects research activities	Experience, training, education for these activities	Most recent CITI /alternative training date
No records have been added			

The IRB only needs education or CITI certificate for external personnel if there is no other IRB reviewing the research or if they are a part of the TAMU team.

6.0 Texas A&M University Human Research Protection Program

Project Application Form

Study Introduction

6.1 Application Checklist

The following checklist is a guide for researchers regarding supporting documents that must be considered for and/or uploaded with this application for review and approval before use.

- Informed Consent Document
- Information Sheet
- Waiver of HIPAA Authorization
- Parental Permission Form/Minor Assent Form
- Recruitment materials (i.e. flyers, emails, advertisements, telephone scripts, social media posts)
- Site Authorization Letter (for study conduct and/or access to administrative records)
- Survey/Questionnaire/Data Collection/Abstraction Forms
- Grant Applications (cover to cover), required if funded or grant submitted
- Instructions
- Protocol Investigator's Brochure (for clinical trials only)
- Case report form (for clinical trials only)
- Device Manual (if using an approved or investigational device)
- Thesis/dissertation proposal
- Waiver of parental permission/minor assent form
- Letter of cultural evaluation for international research (link to SOP)
- IRB approvals from collaborating institutions
- Any other documents related to the research
- CVs for all investigators when proposed activities are more than minimal risk
- CITI training for all personnel

6.2 Proprietary Information

This protocol includes confidential and/or proprietary information to be protected from disclosure.

☐ Yes ☒ No

6.3 Is this research funded?

Please identify your funding source, if applicable.

View Details	Sponsor Name	Sponsor Type	Funding Through	Contract Type:	Project Number	Award Number
No Sponsor has been added to this Study						

Please provide the name of the PI on the funding/grant if it is different from this IRB application.

Will funds from Qatar be used to fund this research?

☐ Yes ☒ No

*** If the response to this question is Yes, then approval by an IRB in Qatar may also be required.**

6.4 Has an entity conducted a scientific peer-review of this research?

☐ Yes ☒ No

If Yes, please specify:

6.5 Fee for Service Information

Is a company providing contract services associated with this research in which no company personnel are considered collaborators in the research (will not receive professional recognition or included in presentations or publications about the research)?

☐ Yes ☒ No

If yes, please provide the name of the company and the contact name.

If a contract exists for this study, was the fee for service information included in the primary award information?

☐ Yes ☐ No

If yes, please provide a copy of the contract.

Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.						

6.6 Is this project part of a dissertation, thesis, or record of study?

☐ Yes ☒ No

If available, please attach the proposal under Other Study Documents at the conclusion of the application.
If not yet available, submit it as an amendment form when available.

7.0 Study Scope

7.1 Research Classification

Select all that apply:

- ☒ Social/Behavioral
- ☐ Biomedical
- ☐ Both
- ☐ Clinical Trial
- ☐ Other, specify

For Social/Behavioral Research, select all that apply.

- ☒ Questionnaire/Survey
- ☐ Observation (investigator observing participants)
- ☐ Retrospective study of records existing at time of this application
- ☐ Exposure to some type of stimulus or intervention (includes device or substance)
- ☐ Participant observation (investigator acts as participant)
- ☐ Interview
- ☐ Focus Group
- ☐ Other, specify

7.2 Vulnerable Populations

Identify any vulnerable populations that will be included in the study:

- ☐ Children (for example, in Texas, under 18)
- ☐ Pregnant women, human fetuses, neonates
- ☐ Individuals with physical disabilities
- ☐ Individuals with cognitive disabilities
- ☐ Economically or educationally disadvantaged persons
- ☐ Prisoners
- ☐ Other (for example, individuals with psychiatric disorders, emotional/social impairments, depression, etc.)
- ☒ No Vulnerable Populations will be included.

If Other, then please explain:

Describe additional safeguards planned to protect the rights and welfare of vulnerable subjects:

If a subject transitions into one of the vulnerable populations (pregnant women or cognitively impaired), will the study procedures place them at any additional risk?

☐ Yes ☒ No

If a subject becomes incarcerated (including awaiting sentencing, court-mandated treatment, or in prison), contact the IRB immediately.

Please justify the use of vulnerable/special populations.

8.0

Project Overview - Protocol Section Begins Here

8.1 Project Summary

In the space below, provide a summary of the project. Include information about background and rationale for the study including preliminary data, purpose, objectives, specific aims, and research questions. Character limit: 5,000 (applies to first box).

Background

Individuals often think of how a situation or outcome could have turned out differently -- if only something was different or something had changed, then the outcome could have been better or worse. This is a common type of thinking, known as counterfactual thinking, that often takes the form of "if only" statements. These thoughts are frequent after negative events, but have also been found to occur after positive events and 'near misses'. Research has shown that their evaluative nature elicits a variety of consequences, such as biased decision making, changes in an event's meaningfulness, heightened positive or negative affect, and future behavioral changes (such as intentions, motivation, persistence/effort; for review, see: Epstude & Roese, 2008; Roese & Epstude, 2017). Specifically, many areas of research involving counterfactuals have often looked into key elements that are often discussed in other health behavior literature, such as self-efficacy, motivation, and intentions (Tal-Or, Boninger, & Gleicher, 2004; Wong, 2007; Smallman & Roese, 2009). One such area that incorporates these elements is health promotion literature, such as Protective Behavioral Strategies (PBS) and alcohol consumption

(Dvork, Pearson, Neighbors, Martens, & Stevenson, 2016; Dvorak, Pearson, Neighbors, & Martens, 2015). The objectives of this study are laid out as such: First, to further explore the role counterfactuals play in increasing an individual's intentions toward behavioral change. Second, to further elucidate the inner and outer workings of Protective Behavioral Strategies for increasing positive health behaviors. Finally, to address the applicability of a counterfactual intervention on promoting intentions to use PBS.

Procedure

All data will be collected on qualtrics. Interested individuals will sign up using the online subject pool, SONA. Part 1 will be completed online, either in the lab or at their own personal computer. After electronically confirming consent (using the provided informed consent sheet from TAMU Research Compliance and Biosafety), participants will complete demographics, followed by the Alcohol Use Disorder Identification Test, a measure of perceived behavioral control, a measure of delay-discounting, the Daily Drinking Questionnaire-Revised, the Young Adult Alcohol Consequences Questionnaire, Protective Behavioral Strategies (PBS), the Personal Assessment of Responsible Drinker Identity Scale, Alcohol Use Contemplation/Intention measure. After these measures have been completed, participants will then be randomly assigned to one of four conditions. In one condition, participants will be asked to only write about a negative drinking event. In the second condition, participants will be asked to write about a negative drinking event in addition to recalling facts about the same event. In the third condition, participants will be asked to write about a negative drinking event and will then complete a counterfactual task. The task will ask the individuals to list three counterfactual strategies about the negative event, future situations these strategies could be used, as well as obstacles to using the strategies. The task will wrap up by asking these participants to indicate intention to use those strategies in the future. In the fourth condition, participants will be asked to complete the Personalized Normative Feedback (PNF). Participants in all conditions will complete perceptions of protective behavioral strategy norms questions, the Alcohol Use Contemplation/Intentions measure, a measure of perceived behavioral control as well as intentions to use protective behavioral strategies.

All follow up parts will be either online or in the lab, one week apart. Participants will indicate, for each day the previous week (Sunday, Saturday, Friday, Thursday, Wednesday, Tuesday, Monday), what they were doing, their general location, if they consumed alcohol that day, and the extent to which they experienced a list of situations. Following this, all participants will then indicate the extent that they used the list of PBS. For those who had been randomly assigned to the counterfactual condition in Part 1, they will complete additional measures: indicating the use of the counterfactual strategies that the participant came up with in Part 1 and their intention to use these counterfactual strategies over the next week. Finally, all participants will complete a measure of perceived behavioral control, rate intentions to use PBS in the next week, and answer the protective behavioral strategy norms questions. In follow up sessions 4 and 6, participants will also complete the Personal Assessment of Responsible Drinker Identity Scale and the delay discounting task. Email information will be completed at the end of each part. A page displaying additional resources will also be displayed. All participants will finish the study by completing a debriefing task after the final follow up.

Procedures Involved:

In the space below, Describe and explain the study design. Provide a description of all research procedures being performed and when they are performed.

List each procedure or test and how often the procedure or test will occur for each participant.

Include a procedure schedule or table of events, if applicable - clinical studies.

Describe: All source records that will be used to collect data about subjects. This includes surveys, scripts, recordings and data collection forms; all test articles including dietary supplements, drugs and devices used in the research and the purpose of their use, and their regulatory (FDA) approval status.

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Responses will be recorded through the survey website Qualtrics. Once data collection has concluded, responses will be downloaded onto an Excel sheet and stored on a password-protected computer.

See attached for exact questions in each measure. descriptions of each task are below.

Prescreen (through Psychology Subject Pool)
AUDIT

Baseline Part 1

Pre-manipulation measures:

Task 1: Demographics
Task 2: AUDIT
Task 3: DDQ-R
Task 4: Perceived Behavioral Control
Task 5: Delay Discounting Measure
Task 6: YAACQ
Task 7: PBS-20
Task 8: PARDI
Task 9: Alcohol Use contemplation/intention measure

Manipulation

Condition 1: Negative event only
Condition 2: Negative event and Fact listing
Condition 3: Negative event and counterfactual task
Condition 4: Personalized Normative Feedback

Post-manipulation measures

Task 9: Perceived behavioral control
Task 10: PBS Intentions
Task 11: Perceptions of Protective Behavioral Strategies questions
Task 12: Alcohol Use contemplation/intention measure
Task 13: Email
Task 14: Additional Resources

Follow Up Parts 2-6

Task 1: PBS-20
Task 2: Daily indication of drinking and strategy use
Task 3: Counterfactual Behavior Use and Intentions
Task 4: Perceived behavioral control
Task 5: PBS Intentions
Task 6: Perceptions of Protective Behavioral Strategies questions
Task 7: PARDI [only follow up sessions 4 and 6]
Task 8: Delay Discounting Measure [only follow up sessions 4 and 6]
Task 9: Email
Task 10: Additional Resources
(End of Part 6): Debriefing

Demographics. A basic demographics questionnaire will collect data on participants' age, gender, ethnicity, race, language spoken, and fluency in English.

Alcohol Use Disorder Identification Test (AUDIT; Saunders, Aasland, Babor, De La Fuente, & Grant, 1993). Participants will complete the Alcohol Use Disorder Identification Test – Consumption Scale (AUDIT-C), which is a screener for alcohol consumption. Previous studies support the reliability and validity of the AUDIT-C as a measure of alcohol consumption among college students (DeMartini & Carey, 2012).

Daily Drinking Questionnaire-Revised (DDQ-R; adapted from Collins, Parks, & Marlatt, 1985) Assesses drinking habits and patterns among individuals averaged over the last 3 months.

Perceived Behavioral Control. (PBC; Cooke, Sniehotta, & Schuz, 2007; Ajzen & Sheikh, 2013) This measure is on a 7-point scale and is composed of six items: For me to avoid drinking alcohol is (difficult-easy); I am confident that, if I wanted to, I could avoid alcohol (definitely false-definitely true); How much control do you believe you have over avoiding alcohol (no control- complete control)? For me to drink less than 7(females)/10 (males) units in a single session in the next week would be (*very difficult-very easy*). If I wanted to I could drink less than 7(females)/10(males) units in a single session in the next week (*definitely false-definitely true*). How much control do you believe you have over drinking less than 7(females)/10(males) units in a single session in the next week? (*no control-complete control*).

Delay Discounting. Delay discounting will be assessed utilizing an adjusting-delay task developed by Bickel & Colleagues (see Epstein et al., 2014 for description). Participants are presented with items prompting a choice between receiving a certain amount of money (\$1000) after a specified delay (i.e., 1 day, 1 week, 1 month, 3 months, 1 year, 5 years, or 25 years) or receiving a smaller amount of money immediately. The value of the

immediate reward is adjusted across trials by using a decreasing-adjustment algorithm. This procedure determines the point at which participants are indifferent to the difference between the smaller, immediate reward and the larger, delayed reward. An area under the curve (AUC) procedure, as specified by Myerson, Green & Warusawitharana (2001) is used to characterize data from the discounting task. From the AUC, smaller values indicate greater monetary discounting by delay and greater impulsivity. K-values are also calculated.

Young Adult Alcohol Consequences Questionnaire (YAACQ; Read, Kahler, Strong, & Colder, 2006). The YAACQ contains 48-items that assess alcohol-related consequences.

Protective Behavioral Strategies (PBS-20; Treloar, Martens, & McCarthy, 2015) Protective Behavioral Strategies (PBS) are specific behaviors one can utilize to minimize the harmful consequences of alcohol consumption. There are three types of PBS: Serious Harm Reduction, Limiting/Stopping Drinking, and Manner of Drinking.

Personal Assessment of Responsible Drinker Identity Scale: A scale measure that assess how much being a responsible drinker is part of your identity

Perceptions of Protective Behavioral Strategies Questions: Questions about the percentage and frequency of use of protective behavioral strategies among college students.

Drinking Contemplation/Intention Measure: A measure assessing how much an individual is considering changing their drinking behavior

Negative Event Only (Condition 1). Participants will be asked to think of a specific example of the most (or one of the most) negative, unpleasant event with alcohol they have experienced; the event they choose must have occurred at least a year ago. Or they will be asked to think of the most significant event that has occurred in the past year. After thinking of a specific event, they will be given three minutes to write about their experience. The writing prompt will ask that they express the event information in a few sentences. This writing prompt will help participants place themselves back into that moment and access salient emotions and cognition about it. Similar negative event prompts have been used in counterfactual thinking studies (McFarland & Alvaro, 2000; White & Lehman, 2005).

Negative Event + Factual Thinking Task (Condition 2). Participants in this group, the event plus the factual thinking task condition, will be told the following after completing the negative event writing task, "After disappointing and/or negative experiences like the one you described on the previous page, people often think about the details of the situation. For example, when it happened, who was involved, and what happened right before or after the incident occurred. In the space below please provide examples of some of these details.." There will be 10 blank boxes below the instructions and participants will be asked to provide some examples of details from their traumatic event. They will be asked to only list as many as they can naturally recall without repeating any. This procedure is derived from Kray and colleague's (2010) study on counterfactual thinking and meaning in life.

Negative Event + Counterfactual Task (Condition 3). Participants in this group, the event plus the counterfactual task condition, will be told the following after completing the negative event writing task, "After disappointing and/or negative experiences like the one you described on the previous page, people sometimes cannot help thinking "what if..." or "if only..." and imagining how things might have gone differently. That is, if only I had done something differently, the negative drinking situation could have been avoided or turned out better than it did. In the box below please identify things that, had they been different, would have improved the outcome of the negative drinking situation you described earlier and briefly describe how the outcome would have been better." There will be 3 blank boxes below the instructions and participants will be asked to list three counterfactuals about the event they just described. They will be asked to only list as many as they can naturally recall without repeating any. After writing out their counterfactual thoughts, these participants will be asked to think of situations where these strategies could be used. Participants will also be asked to list out any obstacles that might prevent them from implementing these strategies. Lastly, participants in this condition will indicate their intention to use each strategy over the next week.

Personalized Normative Feedback (Condition 4). Participants in this group, the personalized normative feedback, will be asked to rate the frequency and quantity of TAMU students that use PBS when drinking.

Perceived Behavioral Control. (PBC; Cooke, Sniehotta, & Schuz, 2007; Ajzen & Sheikh, 2013) This measure is on a 7-point scale and is composed of six items: For me to avoid drinking alcohol is (difficult-easy); I am confident that, if I wanted to, I could avoid alcohol (definitely false-definitely true); How much control do you believe you have over avoiding alcohol (no control- complete control)? For me to drink less than 7(females)/10 (males) units in a single session in the next week would be (*very difficult-very easy*).If I wanted to I could drink less than 7(females)/10(males) units in a single session in the next week (*definitely false-definitely true*). How much control do you believe you have over drinking less than 7(females)/10(males) units in a single session in the next week? (*no control-complete control*).

Protective Behavioral Strategies Intentions (adapted from Treloar, Martens, & McCarthy, 2015).

Intentions to use protective behavioral strategies was adapted from the Protective Behavioral Strategies Scale -20. All participants will be asked how much they intend to use PBS in the next week when/if they drink, for each PBS subtype. Responses fall on a 6-point Likert-type scale of Never (1), Rarely (2), Occasionally (3), Sometimes (4), Usually (5), Always (6), and Do not wish to respond.

Email

Please enter your TAMU email (example@tamu.edu) so we can contact you for future follow phases of the study if you qualify. Remember, everything you reported here is completely confidential. (free text)

Additional Resources

If you need additional assistance for any distress experienced due to the questions in the study you just participated in, please see the following links: <https://wfsc.tamu.edu/additional-info/student-support-resources/>

Counseling and Psychological Services: caps.tamu.edu (979)845-4427

Helpline (Crisis Hotline after hours or after 5 p.m.): caps.tamu.edu (979)845-2700

Parts 2-6

PBS-20: Participants will be asked to indicate for each day of the previous week how often they used the three types of PBS (Serious harm reduction, limiting/stopping, and manner of drinking). Participants will also be asked to indicate how effective they believe each type of strategy is.

Weekly Indication of Drinking and Strategy Use: During each follow up, participants will indicate, for each day the previous week (Sunday, Saturday, Friday, Thursday, Wednesday, Tuesday, Monday)), what they were doing, their general location, and if they consumed alcohol that day.

Counterfactual Behavior Use and Intentions: Participants in the counterfactual condition will reread their counterfactuals that they wrote in the baseline session. They will answer questions about whether they did those behaviors in the past week and their intentions to use those behaviors in the next week.

Perceived Behavioral Control. (PBC; Cooke, Sniehotta, & Schuz, 2007; Ajzen & Sheikh, 2013) This measure is on a 7-point scale and is composed of six items: For me to avoid drinking alcohol is (difficult-easy); I am confident that, if I wanted to, I could avoid alcohol (definitely false-definitely true); How much control do you believe you have over avoiding alcohol (no control- complete control)? For me to drink less than 7(females)/10(males) units in a single session in the next week would be (*very difficult-very easy*). If I wanted to I could drink less than 7 (females)/10(males) units in a single session in the next week (*definitely false-definitely true*). How much control do you believe you have over drinking less than 7(females)/10(males) units in a single session in the next week? (*no control-complete control*).

Intentions: (adapted from Treloar, Martens, & McCarthy, 2015). Intentions to use protective behavioral strategies was adapted from the Protective Behavioral Strategies Scale -20. All participants will be asked how much they intend to use PBS in the next week when/if they drink, for each PBS subtype. Responses fall on a 6-point Likert-type scale of Never (1), Rarely (2), Occasionally (3), Sometimes (4), Usually (5), Always (6), and Do not wish to respond.

Personal Assessment of Responsible Drinker Identity Scale [follow up 4 and 6 only]: A scale measure that assess how much being a responsible drinker is part of your identity

Perceptions of Protective Behavioral Strategies Questions: Questions about the percentage and frequency of use of protective behavioral strategies among college students.

Delay Discounting [follow up 4 and 6 only]. Delay discounting will be assessed utilizing an adjusting-delay task developed by Bickel & Colleagues (see Epstein et al., 2014 for description). Participants are presented with items prompting a choice between receiving a certain amount of money (\$1000) after a specified delay (i.e., 1 day, 1 week, 1 month, 3 months, 1 year, 5 years, or 25 years) or receiving a smaller amount of money immediately. The value of the immediate reward is adjusted across trials by using a decreasing-adjustment algorithm. This procedure determines the point at which participants are indifferent to the difference between the smaller, immediate reward and the larger, delayed reward. An area under the curve (AUC) procedure, as specified by Myerson, Green & Warusawitharana (2001) is used to characterize data from the discounting task. From the AUC, smaller values indicate greater monetary discounting by delay and greater impulsivity. K-values are also calculated.

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Procedure

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- ☐ Drugs
- ☐ Devices
- ☐ Supplements

Significance:

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The present research could have a variety of implications for clinical psychology research, treatment regimens for alcohol, and college alcohol campaigns. Since counterfactual thinking is a naturally occurring and automatic reaction to negative events, they are likely to influence individuals who have had a negative experience while drinking. However, counterfactuals can produce positive outcomes, such as meaning-making and increased intentions, as well as negative outcomes, such as rumination and regret. Investigating how these naturally occurring thoughts might be used to aid in behavioral strategies towards alcohol use, and decision-making more broadly, could help to inform plans to curb young adult binge drinking.

Subjects, enrollment, recruitment, inclusion and exclusion criteria, and informed consent:

Participants

Participants will be recruited via the Texas A&M University online research subject pool (SONA). To be included in the study procedures and subsequent data analyses, participants must be 18 or older and complete all parts. There are no exclusion criteria for participation in the baseline study (part 1). However, participants who do not follow the instructions for the specific writing task will be unable to sign-up for the remaining follow up sessions (Parts 2-6) and will be excluded from the final data analyses. For Part 1, they will be provided with a link to the qualtrics survey (if completing online) or will sign up via SONA for an in-person lab session. For Parts 2-5, participants will be able to sign up after successfully completing the prior session; however, if they do not successfully complete the writing prompt requirements outlined in Part 1, then they will be unable to continue on to the remaining study sessions (parts 2-6). If this is the case, then the researchers involved in this study will contact participants to let them know their remaining follow-up sessions will be canceled, but will still receive credit for what they have completed.

Informed Consent

Participants will be presented with the informed consent form on Qualtrics that will provide an overview of what the study is about, who to contact if any questions arise, and other information deemed necessary to give complete informed consent (see attached form). Participants will be given an option on their computer screen to click "I agree" or "I disagree" to participate in the study. If they agree, then they will continue on and be reminded they are free to discontinue at any time. If they disagree, then they will taken to an exit screen and prompted to close the browser. Participants will be given as much time as they need to fully read the form as well as email the researchers any questions.

Will audio recordings be collected?

☐ Yes ☒ No

Will visual images be collected?

☐ Yes ☒ No

If visual images will be collected, are they full, facial identifiable images?

☐ Yes ☒ No

8.2 Locations

List locations or facilities where the research will be conducted (e.g. building name, physical address).

Research will be conducted online via a survey website (i.e. Qualtrics). Participants will either complete the online survey in the lab (Psychology Department) or, for those who are completing the study remotely, they will be given link after signing up, and can complete it wherever they feel comfortable completing the study.

Are any of the locations listed above non-Texas A&M facilities?

☒ Yes ☐ No

What is the role of each location?

Data collection site (lab computer or personal computer/other device participant has access to at their location).

Is the PI of this IRB study application the lead investigator of a multicenter study (i.e. the study is taking place at multiple institutions that are obtaining their own IRB approval and you are coordinating and overseeing the research)?

☐ Yes ☒ No

Has IRB approval been sought at another institution?

☐ Yes ☒ No

Please submit the Site Authorization letter(s) with this application as a study document or indicate when site authorization will be obtained. Guidance is available at <http://rcb.tamu.edu/humansubjects/resources/site-authorization-letter>

8.3 Other Committee Approvals

Select all that apply.

- ☒ None
☐ Animal Use
☐ Biohazards
☐ Chemical
☐ Radiation
☐ Other

If any committee approvals apply, please provide the permit number and approval date.

9.0

Study Population

9.1 Number of Participants

Approximately how many subjects do you plan to enroll?

1500

Provide the rationale for the number of subjects requested (for example, power analysis, sponsor requirements, etc.).

To have adequate statistical power to compare across the three conditions, assuming that not all participants will qualify after the baseline study and there will be some participant attrition across the follow up sessions.

Will human subjects be used from the Qatar population?

☐ Yes ☒ No

*** If Yes, then approval by an IRB in Qatar may also be required.**

Will human subjects be used from another international population?

☐ Yes ☒ No

***If Yes, then approval by an international review board or government may also be required.**

Will human subjects be used from a Native American population?

☐ Yes ☒ No

***If Yes, then approval by a tribal IRB(s) may also be required.**

If Yes for research in Qatar, in another country, or with Native Americans, provide justification for that research being conducted in that particular community.

9.2 Provide the age groups being enrolled into this study (Note the consent documents required for each age group listed in parentheses):

- ☐ 0-6 (parental consent only, Pediatric Assessment required for Clinical Trials)
- ☐ 7-11 (child's assent plus parental permission, Pediatric Assessment required for Clinical Trials)
- ☐ 12-17 (consent plus parental permission, Pediatric Assessment required for Clinical Trials)
- ☒ 18+ (consent only)

Enter the specific age range for study population (if overlap or specific within a category):

9.3 Indicate the gender of participants being enrolled into this study:

- ☐ Male
- ☐ Female
- ☒ Both male and female

9.4 Inclusion/Exclusion Criteria

What are the inclusion and exclusion criteria for study participation?

The only inclusion criterion for participation is the minimum age requirement (18 years old).

There are no exclusion criteria for participation in the baseline study (part 1). However, participants who do not follow the instructions for the specific writing task will be unable to sign-up for the remaining follow up sessions (Parts 2-6) and will be excluded the final data analyses. For Part 1, they will be provided with a link to the qualtrics survey. For Parts 2-5, participants will be able to sign up after successfully completing the prior session; however, if they do not successfully complete the writing prompt requirements outlined in Part 1, then they will be unable to continue on to the remaining study sessions (parts 2-6). If this is the case, then the researchers involved in this study will contact participants to let them know their remaining follow-up sessions will be canceled, but will still receive credit for what they have completed.

Do the exclusion criteria exclude specific populations or individuals based on gender, culture, language, economics, race, or ethnicity?

☐ Yes ☒ No

If Yes, then justify each exclusion:

9.5 Describe the setting where the informed consent process will take place (e.g. classroom, clinic, laboratory, office, park, personal computer, etc.).

If a waiver of documentation of informed consent is requested, then describe how participants will review the information sheet.

Before beginning Part 1 of the study, Qualtrics will present participants with the online informed consent.

Participants who check "I agree" to indicate that they consent to their participation in the study will be allowed to participate in the study and be asked to provide their TAMU email. Before beginning each follow up part (Parts 2-6), participants will see the same informed consent form on Qualtrics once again and check "I agree" once again before starting the follow up sessions and be asked to provide their TAMU email once again.

9.6 Experience of Subjects

Describe the experience of subjects while participating in this research. (Please describe what the participant will experience from the time of learning of the study through completion.)

Participants (undergraduate students at TAMU who need to participate in research for class credit) will sign up to participate in the study by using the SONA subject participation pool. After signing up for Part 1, online participants will receive a link to a Qualtrics survey. Those who are completing the study in lab will participate on the day they signed up for. After reading information about the study and consenting electronically by clicking "I agree", participants will report their TAMU email and then continue on to complete the Part 1 questionnaires. This should take 30 minutes of their time and they will receive 1 credit toward their class research requirement for completing Part 1.

After completing Part 1, participants will be allowed to participate in the follow up sessions (parts 2-6) if they correctly and completely fulfilled the writing task requirements. Each follow up session will be completed through Qualtrics and should not exceed 30 minutes for each follow up session. Each follow up session will take place one week after the previous session. A summary of this is below:

Part 1: Baseline

Part 2: First follow up (One week after baseline)

Part 3: Second follow up (One week after Part 2)

Part 4: Third follow up (One week after Part 3)

Part 5: Fourth follow up (One week after Part 4)

Part 6: Fifth follow up (One week after Part 5)

Note: If there is not enough time in the semester, some participants may not complete all follow-ups; they will complete the number of sessions and follow ups described in their consent forms

How long will the participants be engaged in the research (length of time, e.g., 15 minutes, 45 minutes on Day 1, 60 minutes on Day 2, etc.)?

30 minutes for Part 1 (week 1)
30 minutes for Part 2 (week 2)
30 minutes for Part 3 (week 3)
30 minutes for Part 4 (week 4)
30 minutes for Part 5 (week 5)
30 minutes for Part 6 (week 6)

10.0

Privacy and Confidentiality

10.1 How will the identities of subjects be protected in all research records? The information collected/analyzed is:

Note: Data that are coded, where the key to the code is accessible to researchers, are considered confidential information and subject to privacy regulations.

- ☐ Anonymous: The identity of the participant cannot readily be determined by the investigator AND the identity of the participant is not connected to information gathered.
- ☒ Confidential: Research participants can be identified; however, information gathered will be protected.
- ☐ Neither: Research participants can be identified, and information gathered may be connected to the participant.

Summarize procedures to protect the confidentiality and anonymity of participants (e.g., replies coded, etc.).

Pre-screen data will be collected as part of the larger Psychology Subject Pool pre-screen survey conducted by the department and managed by the Psychology Subject Pool Coordinator. The pre-screen survey is distributed via the SONA system and participants complete the pre-screen survey on their own time and on their own device, wherever they are comfortable. All data is maintained in the SONA system (which can only be accessed by the Psychology Subject Pool Coordinator). At the completion of the pre-

screen period, the Subject Pool Coordinator will give PI access to the pre-screen results for the AUDIT questions. The PI will store the pre-screen data on the Liberal Arts IT computer servers (see description below).

Participants data will initially be saved using their TAMU email as identification codes, which will allow us to connect data from Part 1 of the study to data from Parts 2-6 of the study. However, for extra safety precautions, once the data set has been collected and assembled, we will delete participant emails and replace them with randomized participant ID numbers.

All data (pre-screen and study data) is housed on Liberal Arts IT computer servers at Texas A&M University. These servers are physically protected by a 24/7 armed security guard and multiple physical barriers that require card/fingerprint/keys to pass through. Physical access is limited to the Liberal Arts Server team members and is reviewed every year. To access the share requires a campus IP address or VPN access, and also membership in the active directory group that is allowed access to that particular folder. Only researchers involved with this study will have access to the particular IT server folder where data will be stored.

What are the plans for retention and/or destruction of linkages between study data and personal identifying information? (Specify when and how personal identifying information will be destroyed.)

TAMU emails will be deleted and changed to randomized participant ID numbers once the study data has been collected and compiled. No identifying information, including names, will be collected as the online information sheet system only requires participants check "I agree" to consent to their participation.

If these linkages will not be destroyed, explain how you will maintain confidentiality of the personally identifying information.

If personally identifying information will not be kept confidential, then justify and explain the informed consent process for sharing this information.

Will a Certificate of Confidentiality (through DHHS or another Federal agency) be utilized?

<https://humansubjects.nih.gov/coc/index>

☐ Yes ☒ No

11.0 Potentially Sensitive Subject Matter and Procedures

11.1 Will this type of information be collected?

☒ Yes ☐ No

11.2 Select all that describe the information.

- ☐ No sensitive matters
- ☐ Abortion
- ☒ Alcohol
- ☐ Body composition
- ☐ Criminal activity
- ☐ Depression
- ☐ HIV/AIDS
- ☐ Learning disability
- ☐ List of current medications
- ☐ Medical/dental problems
- ☐ Medical history
- ☐ Potential child abuse/neglect
- ☐ Psychology/psychiatry
- ☐ Sexual activity

- ☐ Suicide
- ☐ Unethical behavior
- ☐ Other

If other, please specify:

If Medical History or Mental Health History information will be collected, please describe:

11.3 Deception

Will deception be used as part of the study?

☐ Yes ☒ No

If Yes, please describe the deception.

Please describe the debriefing procedures to be used.

Debriefing procedures will occur after Part 6 of the study. After the final survey, Qualtrics will show participants a debriefing sheet that will include additional information pertaining to the aims and implications of the study. We will also provide a list of resources (which will appear on Qualtrics), both on and off TAMU's College Station campus, that are available to students should they need extra support.

Provide justification for the deception.

12.0

Risks and Benefits

12.1 Regulatory definition of minimal risk is that the probability and magnitude of harm or discomfort anticipated in the research 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 (45 CFR 46.102(h)(i)).

Identify the types of risk associated with participation in the study:

- ☐ Physical
- ☐ Privacy
- ☐ Confidentiality
- ☒ Psychological/emotional
- ☐ Social
- ☒ Legal
- ☒ Other

If Other, please describe the risks:

If participants are under the legal drinking age or disclose illegal activities while under the influence of alcohol, there might be additional risk.

Describe the potential risks or discomforts to participants. Include justification of the known risks, which were selected above.

A mild stress reaction may be experienced by the part of the study that involves writing about a negative alcohol event but this should be comparable to disclosing any negative event during the course of a day. Furthermore, in the consent form, participants will be told that they will be asked to write about a negative alcohol event and be reminded that they are free to discontinue their participation at any time. In some individuals, this stress reaction may be greater and we will provide resources for all participants, in case they need extra support after discussing their negative alcohol event. Questionnaires may also cause minimal amounts of distress, since some encourage participants to think about, and thus be in-tune with their levels of distress.

Describe the approaches you will take to minimize these risks and/or to minimize their impact.

All participants will be provided with resources that they can utilize should they feel distressed by the study. Instructions will be given to participants before beginning the writing task to leave out specific locations, names, and other personally identifiable information. Finally, the writing about a negative event involving alcohol will be emphasized in the consent forms and participants who do not feel comfortable writing about this will be asked not to participate. They will also be asked to take the study in a place they feel is private and comfortable for them to discuss sensitive topics, such as alcohol use and consumption. In addition, the consent form will remind participants that they are free to discontinue their participation in the study at any time, should they feel uncomfortable or distressed.

What alternatives are available to subjects outside the research (i.e., what is the standard of care, is the research intervention available without participating)?

Students are provided with alternative assignments that can be completed in lieu of research participation by their professors. Furthermore, participants may choose any of the other studies available on the TAMU SONA system as alternatives to participating in our study.

12.2 What are the potential benefits of this study to individual participants? (This does not include payments, compensation, or incentives.)

Primary benefits to participating in this study include exposure to Protective Behavioral Strategies and, for those in the counterfactual condition, a mental tool to help implement these strategies throughout one's everyday life. Some secondary benefits may be experienced: Participation in the study gives participants a first-hand look at research. This "laboratory" experience may help participants obtain a better understanding of psychology research that they may be interested in pursuing in the future, as these are all students currently taking a psychology course at TAMU.

12.3 What are the potential benefits of this study to the population or society?

The present study aims to increase psychology's understanding of the social-cognitive mechanisms (specifically, counterfactual thinking) that foster intention formation and promotion. By understanding the most salubrious way to think about negative alcohol events, the present study could influence alcohol-use strategies for treating binge-drinking in college students or other health-related issues. Furthermore, we hope to increase psychology's understanding of the effect of counterfactual thinking on other research areas (such as, perceived behavioral control) correlated with behavioral change.

13.0 Personally Identifiable Information

13.1 Indicate which of the following personally identifiable information (PII) will be accessed or recorded in association with this study:

- ☐ None
- ☒ Name
- ☐ Web addresses (URLs)
- ☐ Full Face Photographic Image
- ☐ Internet IP Address
- ☐ Health Plan Beneficiary Number
- ☐ Certificate/ License Number
- ☐ Any Other Unique Identifier or Combination
- ☐ Geographic Information (including city and ZIP)
- ☐ Vehicle Identification Number and Serial Numbers Including License Plate Number
- ☐ Telephone Number
- ☒ Email address
- ☐ Fax number
- ☐ Social Security Number
- ☐ Medical Record Number
- ☐ Account Number
- ☐ Medical Device Identifiers
- ☐ Biometric Identifiers
- ☐ Dates directly related to an individual (including birth, death, admission, discharge, date of procedure)
- ☐ Educational Records

Will any PII in your possession be coded?

13.4 Will the PHI used in this study be stored with encryption?

☐ Yes ☐ No

How is PHI transmitted electronically being protected?

How is PHI data protected?

Who has access to PHI?

14.0 Retrospective Details (Please note: This refers to the analysis of data, documents, records, or specimens that were existing as of the date of the IRB application.)

14.1 Will existing data or documents be used (e.g., patient records/charts, samples/specimens, public records, surveys, evaluation tools, etc.)? NOTE: If you answer NO to this question, please skip the remaining questions in this section.

☐ Yes ☒ No

If Yes, then:
Describe the data or documents that will be used.

What is the date range of the original data collection?

How will the existing data be obtained? Additional information may be required to establish authority to use the data previously collected.

14.2 Will your research be limited to only existing data or specimens? NOTE: If data/specimens will be collected after submission of this application, then the answer here is "No". If you answered NO to this question and the main question above, please skip the remaining questions in this section.

☐ Yes ☒ No

14.3 Will existing specimens be used (e.g., human blood, tissue, saliva, etc.)?

☐ Yes ☒ No

If Yes, then describe the specimens that will be used and how they will be obtained.

Indicate the number of specimens.

How will the specimens be obtained?

Provide the documentation from the holder of the samples that gives you permission to use the samples for research purposes. If the samples were collected for research purposes, provide a copy of the approved informed consent document used to obtain the samples.

14.4 Retrospective Details – Publicly Available

Is the source of the data for your research accessible by the general public?

☐ Yes ☒ No

Provide the link if applicable.

14.5 Retrospective Details – Identity

Will it be possible to determine a subject's identity directly or indirectly through a link (e.g., Medical Record Number (MRN), participant code, IP address, email)?

☐ Yes ☒ No

14.6 Retrospective Details – Waiver of Informed Consent

Is it impractical to obtain informed consent from the subjects?

☐ Yes ☒ No

If Yes, then please complete the Waiver of Informed Consent information in the next section.

14.7 Retrospective Details - Waiver of Document of Informed Consent

Is it possible to obtain informed consent, AND the only link between the data and the human subject would be the signed informed consent document?

☐ Yes ☒ No

15.0 Costs and Compensation

15.1 What are the costs to participants (monetary, time, expense, etc.)? Identify the costs and specify the amount.

The only cost to participants is the amount of time required to complete the study. All parts of the study will be completed online (using Qualtrics survey). Each part can be completed in about 30 minutes time.

15.2 Will participants receive any compensation for participation in the study? Note: For payments to participants, please see University SAP Payment of Survey and Research Participants 21.01.99.M0.03. (<http://rules-saps.tamu.edu/PDFs/21.01.99.M0.03.pdf>)

☒ Yes ☐ No

If Yes, then identify the amount of compensation, method of payment, payment schedule, and justification. If more than a single session with the participant, then the schedule should include incremental payments.

Participants will receive compensation in the form of research credits for their psychology course. Participants will receive 1 credit of research participation after Part 1 (regardless of whether they continue on to Part 2, 3, 4, 5, and 6). Participants will receive additional credits of research participation credit after each additional follow-up they complete (1 credit for each part). This means that participants who complete Parts 1-6 will receive a total of 6 credits. They will receive 1 credit after they complete Part 1 and those who complete Part 2, 3, 4, 5 and 6 will receive the additional 6 credits. For those waves conducted later in the semester, they will receive the number of credits based on the number of sessions they complete (4 weeks = 4 credits; 5 weeks = 5 credits). These credits will be applied using the TAMU SONA online participation system.

15.3 In case of injury, explain who will pay for the treatment. (If not applicable, then note "N/A.") Is there a contract in place - is subject injury covered by an outside entity?

N/A

15.4

What extra costs will be incurred by third-party payers because of subjects' participation?

No costs will be incurred by third-party payers because of subjects' participation.

16.0

Recruitment

16.1 How will potential subjects be identified? (How do you know who to contact to participate in the study?)

Potential subjects will be recruited by the TAMU online participation pool system, SONA. Participants will sign up for Part 1 and either complete part 1 in the lab or receive a link to the qualtrics survey online. Once they complete Part 1, they will be allowed to participate in Part 2 a week later, which will take place either in the lab or online as well. After completing Part 3, participants will then be allowed to complete Part 4 one week later. After completing Part 4 participants will be allowed to complete part 5 one week later. Finally, after completing part 5, participants will then be allowed to continue on to part 6. Each study part will be one week apart.

16.2 Bulkmail

Will Texas A&M University bulkmail be used for recruitment?

☐ Yes ☒ No

Please note that bulkmail recruitment applies to main campus, Health Science Center (HSC), Law School, and Galveston only. Recruitment to the Qatar campus may be require approval by an IRB in Qatar.

16.3 How will potential subjects be recruited? Select all that apply:

- ☐ Direct contact in a medical setting
- ☐ Direct contact in a non-medical setting
- ☐ Newspaper ad
- ☐ Television
- ☐ Radio
- ☐ Website
- ☐ Social/professional networking site
- ☐ Posted notice(s)
- ☐ Letter
- ☐ Telephone solicitation
- ☐ Email
- ☒ Recruiting Pool (See next question)
- ☐ Other (specify):

If you selected Recruitment Pools option above, please identify the groups below.

- ☐ Economics
- ☐ Marketing
- ☐ Motor Behavior
- ☐ Motor Neuroscience
- ☒ Psychology
- ☐ Sociology
- ☐ TTI

*** Skip to the next section if using a Recruitment Pool.**

16.4 How will initial contact be made with potential participants?

All contact regarding study participation will take place via the SONA recruitment pool. Participants will choose to sign up for the study after viewing the options for all studies available for research participation credit on SONA. For Part 1, they will be provided with a link to the qualtrics survey. For Parts 2-6, participants will be able to sign up after successfully completing the prior session; however, if they do not successfully complete the writing prompt requirements outlined in Part 1, then they will be unable to continue on to the remaining study sessions (parts 2-6). If this is the case, then the researchers involved in this study will contact participants to let them know their remaining follow-up sessions will be canceled, but will still receive credit for what they have completed.

16.5 How will the researchers protect subject privacy during the recruitment process?

Researchers will protect subject identity during recruitment by adhering to the password protected university SONA system. SONA will grant automatic credit after completion of each part of the study, and any incompletes will be manually granted by the associated researchers after the timeframe for the study is up. This information is protected by SONA and only PIs and research assistants will be able to access information about participation in this study.

16.6 Who will do the recruiting?

SONA systems

16.7 Will recruiting be conducted off Texas A&M University property?

☐ Yes ☒ No

If Yes, describe (Site Authorization(s) may be required.)

16.8 Will screening or recruiting be from or through the patient base of a healthcare provider?

☐ Yes ☒ No

16.9 Do you have any relationship other than as an investigator with participants (e.g. doctor-patient, teacher-student, counselor-student, family member, etc.)?

☐ Yes ☒ No

If Yes, then specify the relationship.

Describe how you will avoid any type of coercion.

By using the SONA system we allow participants to choose from a wide variety of studies and therefore avoid coercion.

16.10 If the subject is a student who is participating in the research for course credit, then how will you ensure that the subject was not coerced into participating?

Psychology professors are required to provide additional options for meeting research participation credit. Furthermore our consent/information forms, which are presented to the subjects before each study session, remind subjects that their participation is entirely voluntary and they are free to withdraw at any time.

16.11 If this study meets a requirement for course research credit, then how is this study suited to the course for which research credit is required?

Since this is a psychological study, students in a psychology course who are receiving course credit for the study will also get the experience of participating in an experiment that hopes to discover more about health psychology, cognitive psychology, and social psychology (all topics that appear in an introduction to psychology course and relate to more advanced psychology courses, such as abnormal or clinical psychology).

16.12 What alternatives to the participation in the research without negative consequences will you allow (e.g., not to participate, alternative assignment)?

Participants are welcome to receive research credit by choosing other studies besides ours. They are also given the option of participating in another assignment in which they can write about psychological research instead of participate themselves.

16.13 Will there be any penalties or other disadvantages for those declining to participate?

☐ Yes ☒ No

16.14 Will any pre-screening surveys or questions be used?

☒ Yes ☐ No

If Yes, then please describe and include in Other Study Documents.

The AUDIT will be used as part of a pre-screening procedure, to increase the rates of alcohol users who complete the study. This measure is already included in the baseline session (and study measures). It is separately included now as a prescreen materials document.

17.0

Data Management

17.1 General Information

STANDARD ADMINISTRATIVE PROCEDURE

15.99.03.M1.03 The Responsible Stewardship of Research Data

<http://rules-saps.tamu.edu/PDFs/15.99.03.M1.03.pdf>

Do you agree to adhere to the SAP with your data?

☒ Yes ☐ No

Where will the data be stored? Indicate building and room number on TAMU property.

The data will be collected using the password-secured survey program, Qualtrics. Once data has been collected, it will be saved on TAMU Liberal Arts IT computer server folders associated with the Social-Cognition lab, which are located in the Psychology Building, room 347A. These folders are password protected. The room is also locked and requires a key to enter the office space.

How long will the data be stored? (Note: This time period should be a minimum of 3 years post completion of the research and perhaps longer, depending on sponsor requirements.)

4 years

If you are storing or transmitting collected data, is the storage and transmission of the data encrypted?

☒ Yes ☐ No

Please note that PHI must be stored and transmitted with encryption.

Who will have access to the data?

PI and researchers

17.2 Data Safety Monitoring Plan

☐ Yes ☒ No

If so, then:

How is it managed?

With what frequency is data reviewed for this project?

How often does the DSMB meet?

What is the frequency of reports from the DSMB?

Describe any planned interim analysis.

Provide names, affiliations, and qualifications of members.

18.0

Informed Consent

18.1 Select all that apply and attach to the application:

For templates and guidance regarding informed consent, see <https://rcb.tamu.edu/humans/toolkit/templates/templates>

- ☐ Informed Consent Document (signed consent, typically needed in Texas for research involving adults)
- ☐ Parent Informed Consent Document
- ☐ Parent Permission Form
- ☐ Assent Form (typically needed in Texas for research involving children under 18)
- ☐ Recruitment Script (verbal)
- ☐ Recruitment Email
- ☒ Information Sheet (also select Waiver of Documentation of Informed Consent)
- ☐ Waiver of Informed Consent
- ☒ Waiver of Documentation of Informed Consent
- ☐ Other

If other, please specify:

18.2 Please provide the readability statistics for each informed consent document in terms of the Flesch-Kincaid Grade Level. In general, informed consent document for adults should be on an 8th grade level.

<https://rcb.tamu.edu/humans/resources/tips-for-writing-consent-forms>

The Information sheet was deemed to be about a 9.0 grade reading level using the Flesch-Kincaid system.

18.3 Please describe the informed consent process. Include how participants will be adequately informed of what they will be asked to do in the study as well as how they will be protected. Include how the forms selected above will be used in the process including that the participants will have sufficient time to review any information provided to them.

If a waiver of documentation of informed consent is requested, then the information sheet use must be described here.

After clicking on the Qualtrics link from SONA, participants will be presented with the informed consent form that will provide an overview of what the study is about, who to contact if any questions arise, and other information deemed necessary to give complete informed consent (see attached form). Participants

will be given an option on their computer screen to click "I agree" or "I disagree" to participate in the study. If they agree, then they will continue on and be reminded they are free to discontinue at any time. If they disagree, then they will be taken to an exit screen and prompted to close the browser. Participants will be given as much time as they need to fully read the form as well as email the researchers any questions.

18.4 Where will the informed consent process take place (e.g. building name, physical address)?

The informed consent form that participants will either agree to or decline will be housed on the Qualtrics survey program along with other study materials and measures. For all study sessions (Parts 1-6), which are online and can be completed wherever participants see fit, participants will read the consent form wherever they decide to begin the study.

Where will the informed consent documents be physically stored?

See attached consent document (Stored electronically using Qualtrics online survey system that only researchers have the password to).

Who will have access to the Informed Consent documents?

Only the researchers and principal/co-principal investigators.

18.5 For studies involving research on children, will participants who reach age of majority be consented?

☐ Yes ☐ No

18.6 Have the PI, Co-I(s), and any persons interacting with study subjects completed CITI training?

☒ Yes ☐ No

If No is selected, have the PI, Co-I(s), and any persons interacting with study subjects completed alternative human subjects training? If so, please provide a description and copy of the alternative training.

18.7 Please indicate the research personnel who will be obtaining informed consent from participants. (Use N/A to indicate that informed consent will not be collected.)

N/A

18.8 What project-specific training/experience have individuals obtaining informed consent received (e.g. verbal instruction by the PI, practice with the PI)?

N/A

18.9 Will the subject have the opportunity to review the informed consent document or Information Sheet, ask questions, and understand the details of the study prior to participation?

☒ Yes ☐ No

If Yes, then how much time will be provided?

However much time participants choose to take. Participants first have the opportunity to review the information sheet during Part 1 of the study which is completely online and completed wherever and whenever the participant chooses.

18.10 How will cultural issues, including language, be addressed?

Since the study population currently includes only students from an American university, we do not expect any completely non-English speakers to sign up for our study. The information sheet, which is english asks that participants only click "yes" if they understand what they have read and agree to participation. Our demographics questionnaire does inquire about native language and english fluency. Participants who do not consider themselves fluent in English may be excluded from final analyses since the writing tasks may be influenced by this linguistic issue.

18.11 Will non-English speaking people be approached to participate in this study?

☐ Yes ☒ No

Will a translation be available for non-English speaking subjects?

- ☐ Verbally (provide script)
☐ In writing (provide documents)
☐ Both
☐ Neither

18.12 If the study involves minors, then describe the informed consent process of parental permission and how the assent of the minor will be sought. Attach the documents to the application.

19.0 Waiver of Documentation of Informed Consent

19.1 Provide protocol-specific reasons and justification on how *at least one* of the following criteria are met:

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.

Protocol-specific explanation:

Participants will be given contact information with which they can contact the researchers for a copy of the documentation

That the research presents no more than minimal risk of harm to participants and involves no procedures for which written informed consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

Protocol-specific explanation:

Participants will read an information sheet which contains all the elements of informed consent according to 45 CFR§46.116(a). After reading the information sheet, participants will select a box (yes or no) indicating whether they agree to participate in the research. Those who agree to participate will be completing the same measures and procedures as participants recruited via SONA. Participants retain the right to refuse to answer questions which they do not wish to answer.