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.

Defense Cascade: Physiology, Mobility, and Subjective Experience

PROTOCOL NUMBER:

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

19-585

PRINCIPAL INVESTIGATOR:

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FUNDING:

Sponsor(s): (not funded)
Funded already or in the proposal phase?: Click here to provide a response.
Is Virginia Tech the primary awardee or the coordinating center of this grant or contract? If not, list the primary institution: Click here to provide a response.

VERSION NUMBER/DATE:

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

1.0, 8/14/2019 - This version was authorized by the Virginia Tech IRB for BRANY transfer

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?
2.0	9/5/2019	Modified section 8.1 to clarify which questionnaires are given when, as well as the actual sequence of informed consent during the online and in-lab portions of the study.	No
3.0	10/31/19	Modified the following sections: 7.3 Updated equipment specification 8.1 Updated questionnaires, estimated time to complete surveys, and accompanying extra credit to be awarded. Clarified when informed consent will first be accessible to participants. 15.4 Reduced the amount of Sona extra credit awarded from 1.5 points to 1.0 points. 20.2 Updated the language to reflect the fact that our team now contains both male and female research assistants. Clarified the language to be used to solicit participant preference for the gender of the researcher who attaches their electrodes.	Yes

Table of Contents

1.0 Study Summary

Study Title	Defense Cascade: Physiology, Mobility, and Subjective Experience
Study Design	In-lab virtual reality (VR) stimuli will be presented for this psychophysiology study with online prescreen. Data will be analyzed using correlational analyses and OLS regression measuring mobility, SNS activation, PNS activation, and SUDS ratings. Moderation will be tested based on scores on anxiety, trauma, dissociation, and interoceptive awareness.
Primary Objective	Complete Master's thesis requirements for Brittany Nackley investigating whether patterns of mobility map to physiological patterns and subjective experience when engaged in the defense cascade.
Secondary Objective(s)	I plan to submit a paper for publication in psychology peer-reviewed research journal as well as to use the data for poster presentations at conferences such as the Society for Psychophysiological Research.
Study Population	Young adults
Sample Size	200 for online prescreen, 100 to be invited to lab
Research Intervention(s)/ Investigational Agent(s)	Research intervention/stimulus will be a series of videos and experiences all presented in a VR environment, with peripheral audio and tactile enhancement. Investigational agents will include surveys, collection of psychophysiological measures including ECG, ICG, EDA, and accelerometry, behavioral observations from participant video footage, and post-hoc interviews with participants.
Study Duration for Individual Participants	1.5 hours for online prescreen, 2 hours for in lab; total of 3.5 hours
Acronyms and Definitions	VT: Virginia Tech VR: Virtual Reality MBL: Mind-Body Lab ECG: ElectroCardioGram ICG: Impedance CardioGraphy EDA: ElectroDermal Activity PEP: Pre-Ejection Period HF-HRV: High-Frequency Heart Rate Variability PTSD: PostTraumatic Stress Disorder ANS: Autonomic Nervous System SNS: Sympathetic Nervous System PNS: Parasympathetic Nervous system SUDS: Subjective Units of Distress Scale

2.0 Objectives

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

The objectives of this study are to map patterns of mobility to patterns of physiology and self-reported subjective experience during a perceived threat experience.

2.2 State the hypotheses to be tested:

Mobility will be moderately positively correlated with SNS activation and moderately negatively correlated with PNS activation.

Transitions in mobility will be supported by ANS coactivation.

SNS activation will be moderately positively correlated with SUDS scores.

3.0 Background

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

Defensive and survival behavior describes responses to perceived threat. Research in this area flourished in the 1990s and early 2000s, developing an empirically-validated model called the defense cascade (Lang, Bradley, & Cuthbert, 1997). This model has enormous potential to explain and predict behavior under stress and to improve psychotherapy. However, research on defensive behavior has stagnated over the last decade. I am proposing this research in hopes of breathing new life into this important but recently neglected area of research.

The defense cascade demonstrates six sequential survival strategies: freeze, flight, fight, fright, flag, and faint (Cannon, 1932, Blanchard & Blanchard, 1990, Bracha, 2004, Schauer & Elbert, 2010). Each stage is determined by a dynamic interaction with threat. Freeze, or attentive immobility, quiets the body to attend to a potential threat while minimizing predator detection of movement. As danger approaches, mobile defense is activated with flight, and continues into fight if escape options are eliminated. If the mobile defenses of flight or fight have failed, fright brings tonic immobility, preserving consciousness and muscle tone for vigilance and preparedness for the possibility of escape, while simultaneously quieting the movement and vocalization that would incite further predatory strike. In order to still the body during such seemingly terrifying moments, physiologically-driven changes include numbing physical pain (Ludäscher et al., 2007) and blunting emotions (Schmahl et al., 2006). If escape remains elusive, flag will reduce heart

rate to minimize blood loss from injury and transition to the final stage, faint (flaccid immobility), in which muscle tone and consciousness are lost. Faint conserves remaining resources for the potential of future escape, while maximizing dead-like appearance to become less interesting to a predatory threat.

The defense cascade illustrates dynamic switches between mobility and immobility. Yet in spite of its importance to defensive behavior, mobility has rarely been researched explicitly. Mobility therefore merits investigation as an explicit research variable.

Changes in mobility appear to be supported by the autonomic nervous system (ANS), which engages the sympathetic nervous system (SNS) to power mobile defenses (Cannon, 1932; Lang, Bradley, & Cuthbert, 1997) and the parasympathetic nervous system (PNS) for immobile defenses (Öst 1984; Kleinknecht, 1987; Bracha, 2004). A more exacting study of the literature suggests that changes in mobility are supported by coactivation of the SNS and PNS (Löw, Lang, Smith, & Bradley, 2008; Roelofs, Hagenaars & Stins, 2010), a finding that requires replication to validate.

ANS coactivation has been characterized as a "positive predictor of health" (Berntson, 2019). It appears to support oxytocin uptake, but only among socially-connected participants. Lonely participants given oxytocin showed an increase only in SNS activation (Norman et al., 2011). ANS patterns bear further research, revealing adaptive responding in times of danger and safety.

I propose to investigate the mobility and autonomic correlates of the defense cascade, and to examine a self-report measure of subjective experience that could be leveraged in both research and clinical settings.

3.2 Describe any relevant preliminary data:

N/A

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:

The defense cascade illustrates that defensive behavior is more than just "fight or flight" - these mobile defenses are but two of six stages. The remaining four stages are immobile defenses, each serving a unique purpose: avoiding detection, minimizing predatory aggression, reducing blood loss, and conserving resources. Yet defensive behavior is too often conceptualized as a set of mobile behaviors - "immobile defense" is viewed as an oxymoron. This view has pervaded American culture,

celebrating "action heroes" and stigmatizing victims of violence who did not fight back, mistakenly implying that an absence of mobility is an absence of defense.

Research into human defensive and survival behavior provides clues about both psychopathology and resilience. Freeze characterizes transition from calm to anxious states. The mobile defenses of flight and fight underlie stress and anxiety including most phobias (Hoehn-Saric & McLeod, 1988), as well as hyperarousal in PTSD (Morris & Rao, 2013). Dissociation can arise during fright and become a conditioned response after repeated experiences invoking the state (Adenauer, Catani, Keil, Aichinger, & Neuner, 2009). Non-suicidal self-injury involves willfully invoking the natural analgesia that comes with fright, providing temporary relief from physical and emotional pain (Schauer & Elbert, 2010). Faint is found in blood-injection-injury type-specific (BIITS) phobia in response to feared situations (Bracha, 2004). Trauma has the potential to engage all six stages of the defense cascade, and how far a person has moved through the stages can be a revealing descriptor of the traumatic experience (hyperarousal vs. dissociative-type). Finally, recovery from threat can help inform therapeutic practice with clients experiencing any of the aforementioned conditions.

In a setting without war, the applicability of survival behavior to modern psychology can sometimes be questioned. However, in responding to any challenge, human physiology has a limited repertoire that was shaped by an evolutionary history of avoiding life threats. Non-survival threats have the potency to activate the same physiological circuits used for survival threats, often deactivating cognitive circuits in the process (Van der Kolk, 1994; Lanius et al., 2002). Traditional cognitive-behavioral therapies that ignore physiologically-driven defensive behavior overlooks this driver of chronic stress, anxiety, and posttraumatic stress disorder (PTSD), with an estimated combined lifetime U.S. prevalence of 28.8% (Kessler et al., 2005).

Defensive and survival behavior not only allows humans to escape life-threatening situations but has also been proposed as the therapeutic link to resolving symptoms of PTSD and anxiety-related stress (Payne, Levine, & Crane-Godreau, 2015). Yet some of the most essential elements of survival behavior, its underlying physiology and accompanying subjective experience continue to be poorly understood and minimally incorporated into therapeutic settings.

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 endpoint will be the Pearson's correlations between the following variables:

- Mobility in X, Y, and Z planes each with pre-ejection period (PEP)

- Mobility in X, Y, and Z planes each with phasic electrodermal activity (EDA)

Secondary endpoint will be the Pearson's correlations between the following variables:

- Mobility in X, Y, and Z planes each with HF-HRV

- PEP and Subjective Unites of Distress Scale (SUDS)

- EDA and SUDS

- HF-HRV and PEP during one minute intervals where mobility is transitioning

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.)*:

In order to minimize dangers associated with disoriented movement in the VR environment, one research assistant will be assigned the role of participant spotter, attending to any unsafe movements that participants may attempt while navigating their virtual environment.

Experiencing VR can increase the risk of dizziness or nausea because of the discrepancy between the actual and the virtual environment. The consent form includes a description of this possibility and how the participant can address it if they do not have tolerance of such symptoms.

The probability of psychological discomfort is assessed to be the same or less than that of watching a horror movie or playing a horror video game.

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):

This will be a quantitative study examining variables indexing physiology, mobility, and subjective experience of participants as they are exposed to stimuli designed to move them through stages of the defense cascade.

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):

Data will be analyzed using Pearson's correlations to examine degree of correspondence between primary variables of interest that index mobility, SNS, and PNS activation, as well as SUDS. Additionally, as time allows, moderation analysis will be conducted to determine if higher scores on trauma, PTSD, dissociation, anxiety, and BIITS phobia affect the overall patterns observed in the primary variables of interest.

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.*

Undergraduates over 18 years old will be recruited as study participants via flyers posted in Williams Hall and via the Virginia Tech Psychology Department's participant management system, Sona.

Those signing up for the study will be directed to fill in an online prescreen. Those passing the prescreen will be invited to the in-lab portion of the study. This in-lab portion will be conducted in a room in Williams Hall. The room will contain physiological measuring equipment, a desktop computer, two small webcams, and a VR headset connected to the desktop computer.

There is no community advisory board for this study (only my department-specific Master's Thesis Committee). All research will be conducted at Williams Hall on the Virginia Tech Blacksburg campus.

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.*

This study's intervention will be a series of video clips projected in a VR environment, combined with a threat scenario designed uniquely for the VR environment. Additional interventions will include an audio white noise stimulus, a tactile vibrational stimulus, and a post-stimulus debrief. Video clips will be viewed as if on a projector within the VR environment and will include: (1) an approximately 3-minute instructional video on the use of the SUDS rating system, (2) an approximately 4-minute non-narrated video depicting marine life in a sunny, non-threatening situation accompanied by a soothing musical score, and (3) a portion of the threat scenario begins with images projected on the virtual projector. Both (1) and (2) are vanilla baseline clips, designed to measure physiological and mobility responses in a non-threatening situation as a baseline. The unique VR scenario begins again by a presentation of stimuli as if projected on a movie screen within the VR environment. The culmination of this threat scenario depicts a creature emerging from the projected movie screen and appearing to approach the participant in the VR environment.

Following presentation of the VR stimuli, participants will be assisted in removing the VR headset, will be asked to complete the MAIA questionnaire, and then will be asked to review a split-screen video showing the video they just watched in part of the screen and the video footage of themselves watching the stimulus videos in the other part of the screen. During this period, participants will be asked to comment on or explain any of the physiological, mobility, or subjective experiences they remembered during the stimulus video. This period will actually continue to track their physiology and mobility in hopes of better understanding the mechanisms by which physiology and mobility recover following the experience of a threat.

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:

N/A

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:

Biopac physiological equipment will be used in accordance with its specified uses, as follows:

The BioNomadix Non-Invasive Cardiac Output system will be used to gather ICG data, which provides one of two inputs to the calculation of PEP, an estimate of SNS control of the heart. The Biopac ECG100C and Biopac RSP100C and/or the BioNomadix RSP & ECG System will be used to gather respiration and ECG data, which provides the second of two inputs to the calculation of PEP. It is also used to calculate HF-HRV, an estimate of PNS control of the heart. The Biopac Tri-axial Accelerometer and/or the BioHarness Physiology Monitoring System and/or the BioNomadix Accelerometer System will be used to calculate participant mobility in X, Y, and Z planes. Finally, the Biopac EDA100C and/or the BioNomadix PPG & EDA System will be used as a second estimate of SNS activation using galvanic skin response, an SNS index not influenced by the cardiac system. Uncertainty about which units will be used (the "and/or" language above) are due to uncertainty at the time of this application about whether the BioNomadix units will be funded by pending applications for scholarship and lab funds. Nevertheless, all aforementioned units will be used in accordance with their approved and attended purposes.

Two Microsoft webcams will be used to collect video footage of the participants from two angles: one will record facial expressions, while the other will record from the participant's side for behavioral coding to assess degree to which the participant is exhibiting approach versus avoidance behavior.

A noise-cancelling wireless headset will be used to deliver the audio portion of the video clips and to deliver a 98 decibel burst of white noise with 0 ms rise time and 750 ms duration.

A vibrational unit will be used to deliver a 5 volt vibration to the neck of the participant. This voltage is roughly three times the intensity of the vibration delivered by a standard smart phone in "vibrate" mode.

An Oculus Quest or Oculus Go headset will be used to present the Virtual Reality portion of the experiment to participants.

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***	

N/A

8.0 Procedures Involved

8.1 Describe and explain the study design:

People interested in participating will find the study through VT Psychology Department's participant recruitment system, called Sona. Those selecting the study will be presented with the online informed consent document. Those consenting to participate will complete a series of online questionnaires as well as a prescreen and eligibility assessment. This will include collecting demographic information including age, race/ethnicity, biological sex, gender identity, use of substances and prescription medication. Prescreen questions will be used to ensure they meet key inclusion criteria for the in-lab study such as being over 18 years old, no history of heart conditions, no medications affecting the cardiovascular system and non-smoking status.

Once the prescreen questions are complete, the following questionnaires will be presented: the Penn State Worry Questionnaire, the Anxiety Control Questionnaire, the Anxiety Sensitivity Index-3, the Trauma History Screen, the PHQ-Panic Assessment, the UCLA Loneliness scale, Version 3, and the Big Five Aspects Scale, the Five Facet Mindfulness Questionnaire, and the Mind-Body Lab Health History Questionnaire. It is estimated that this process will take 15 to 50 minutes to complete, and participants will be awarded 1 Sona credit for their participation.

Participants passing the Sona pre-screen will be invited to participate in the study. Those accepting this invitation will be given instructions to abstain from the following: alcohol for 12 hours prior to the study, caffeine and other non-prescription drugs for 6 hours, and eating and exercise for 2 hours. Immediately following this invitation, these planned participants will be emailed a copy of the informed consent form and encouraged to review it before they arrive the day of their lab appointment.

Upon arrival the day of the study, the researcher will begin by providing a verbal description of the project following the script uploaded to Protocol Management, which will include a description of the purpose for the study, the procedure, risks and benefits, and the compensation they will receive (extra credit in their chosen Sona-participating psychology class). The participant's right to end the study at any time will be emphasized.

Following the verbal summary of the procedure, the researcher will then invite the participant to ask any clarifying questions, and once questions have been asked, the researcher will ask the participant to tell them in their own words their understanding of the study. Any misunderstandings of the study will be clarified by the researcher. The participant will be invited to ask any further clarifying questions they might have. Once no further participant questions remain, the researcher will present the written consent form, invite the participant to take whatever time is needed to review the form and to decide whether to sign it. The researcher will leave the room and await indication from participant that they are ready for the researcher to return. When written consent is provided, the researcher will nevertheless verbally ask the participant if they are ready to begin before proceeding. Researchers will be trained to take as much time as needed for the in-lab consent process in order to minimize any sense of urgency that might be construed as coercion.

Participants consenting to the in-lab portion will complete the Mind-Body Lab Recent Health Behaviors Questionnaire, which asks about their compliance with the abstention requirements. Non-compliant participants will be withdrawn from the study. Those consenting will have equipment placed as follows:

Participants will be connected to physiological equipment including electrocardiography (ECG), impedance cardiography (ICG), electrodermal activity (EDA), and an accelerometer in order to measure ANS responses and mobility.

Participants will then complete the following additional questionnaires: the Multidimensional Assessment of Interoceptive Awareness, the PTSD checklist, the Fear Survey Schedule, and the State-Trait Anxiety Inventory.

As each participant prepares for the next phase, two cameras will begin video recording. The first camera will view participants directly from the side. This video recording will be used for later behavioral coding to indicate times when participants moved their body away from the stimulus and toward the stimulus. The second camera will record partial facial expressions and frontal body language of the participant during the experiment and will be used for the post-stimulus debrief with each participant.

Participants will be assisted in placing the VR headset on and ensuring that they are adjusted for comfort and focus. Physiological recording will then begin while participants are shown the 3-minute instructional video in the use of the SUDS rating system. Participants will then be asked to report their first SUDS rating shown as if on a projector screen within the VR environment. Participants will be instructed that as they watch the subsequent videos, they will be periodically prompted for their SUDS ratings. They will further be instructed to complete this as quickly as possible. This timeliness instruction is designed to minimize distraction from the stimulus. SUDS requests will be given at one-minute intervals throughout the remainder of the experiment.

Following the SUDS instructional video, participants will see a 10 second black screen on the virtual projector within the VR environment, followed by the marine video as described in section 7.0. Following the marine video, participants will again see a 10 second black screen on the virtual projector within the VR environment. While the projected screen continues to be blank, a 98 decibel burst of white noise will be delivered with 0 ms rise time and 750 ms duration (Vila et al., 2007). This stimulus will be used to measure cardiac defensive response to acoustic stimuli in isolation of new visual stimuli. There will continue to be no new visual stimuli for the subsequent 80 seconds to allow a complete cardiac defensive response to be captured without other sensory confounds.

Finally, the VR experience will begin with the imagery described in section 7.0. As the creature described in section 7.0 appears to approach the participant and reach for them, the tactile module will be engaged to deliver a mild, but sudden vibration to the neck of the participant. This

will serve as the equivalent of a jump scare (a sudden cinematic stimulus meant to surprise), but with a switch in sensory modality.

When this final VR stimulus has concluded, participants will be assisted with removing the headset and then asked to complete the MAIA questionnaire again. Participants will receive a debriefing regarding the experience. Participants will also be asked questions about their experience as a manipulation check on the procedure itself. They will review a split screen video that depicts 3 time-synchronized videos of: (1) what they saw through the VR lens, (2) the side-angle video of their own reactions, and (3) the front-angle video of their reactions. Moments of apparent high or low mobility will yield a question from the researcher asking what the participant was experiencing at that moment. The researcher will then ask the participant a series of general questions as follows: "How fearful did the VR experience make you?", "How difficult was it to stay engaged with this experience?", "If you had difficulty, can you explain why?", and "Do you have any other comments or suggestions about the experience you'd like to add?".

Following this debriefing period, physiological and tactile equipment will be removed. The participant will be asked to give a final SUDS report and asked if they have any further questions, concerns, or comments about the study. When no further questions, concerns, or comments are expressed, the researcher will inform the participant that the study is complete and they will be awarded their 2.0 credit points in the Sona system. It is estimated that this in-lab portion of the study will take 90 minutes.

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.*

All participants will follow the same procedure as noted in 8.2.

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*

Screening and demographic questionnaires, online surveys, and interview guide have all been uploaded to Protocol Management. Subjects will be instructed to remain seated throughout the procedure.

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:

Self-report data will be collected prior to the intervention and will include the questionnaires, surveys, and interviews itemized in section 8.1 and uploaded to Protocol Management. This will be collected by asking participants to complete the questionnaires on a computer. VT's Qualtrics will be employed for this purpose and all answers will be maintained in the Qualtrics system.

Physiological data will be collected using the aforementioned physiological equipment and will include ECG, ICG, EDA, and mobility in X, Y, and Z planes. Acquiring physiological signals requires placement of the electrodes as follows:

ICG requires placement of 8 electrodes: 2 on each side of the neck and 2 on each side of the torso, under the arms. ECG requires placement of 3 electrodes: 1 on each side of the collarbone and one on the bottom left rib bone. EDA requires placement of 2 electrodes: one on the index finger and one on the middle finger, both on the non-dominant hand.

To prepare each site for electrode placement, cotton swabs with alcohol will be rubbed on the participant's skin to remove oils and ensure optimal conductivity of physiological signals. After placement of electrodes, a lead will be clipped to each electrode that connects to the appropriate Biopac module (i.e. ICG leads will be attached to the ICG device) to relay

the signal to the Biopac Amplifier, which in turn allows the AcqKnowledge software to display the physiological signal on the computer screen.

Self-report SUDS ratings will be entered on screen by participants at one-minute intervals during the stimulus presentation.

Video recordings will be made of participants: one from a side angle and one from a front angle during the stimuli and will be used for behavioral coding to document approach vs. avoidance behavior in participants and for participant debrief and as a statistical manipulation check.

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

Co-Investigator Brittany Nackley and the Other Study Personnel (undergraduate research assistants) will behaviorally code the video recordings.

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)*

N/A

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:

N/A

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:

No specimens will be obtained. Participant data will all be stored digitally on the Mind-Body Lab server. The Other Study Personnel will have access to this server via prior login access authorization by the PI. Non-Mind-Body Lab investigators do not have access to this server and therefore will not be able to access the data. All Mind-Body Lab computers are set to time out after 10 minutes of inactivity and cannot be re-accessed without logging back in with approved credentials.

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

N/A

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:

Requests to release the data must be made in writing and will require approval by both the PI and Co-I. Approved requests will be granted with only de-identified data. If no requests are made, only the named investigators will have access to this data.

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:

Participant name, phone number, email address, and ID number will be needed strictly for purposes of contacting participants following the prescreen to invite them to the in-lab portion of the study, as well as for granting credits within the Sona system for their participation in the study.

This personal information will be stored in a stand-alone data file with a unique code assigned to each participant. Remaining participant data will

be stored in a separate file in de-identified format except for the unique participant code. To determine the actual identity associated with any given participant's study data, one must look up the unique code in the personal information database.

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:

Subjects will review the video recording of themselves as part of the post-hoc interview. Other than this reviewing session, actual results will not be shared with research subjects.

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.*

Each subject's participation is estimated to last 3.5 hours, including 1.5 hours for the online prescreen and 2 hours for the in-lab portion. A target of 85 subjects will be sought. It is estimated that it will take a maximum of 1 year to enroll all study subjects with a goal of completing enrollment within 6 months. Primary data analysis will be conducted as data is acquired and is expected to be completed within the same 1 year period.

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:

Eligibility will be determined during the online prescreen which will include the Mind-Body Lab Health History Questionnaire (HHQ; uploaded to Protocol Management), which screens for the conditions that will serve as exclusion criteria.

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):

The following will be the exclusion criteria for the study:

No use of drugs with cardiovascular effects

No history of physical diseases or disorders in the following categories:
- cardiovascular
-metabolic
-neurological

No history or current psychological diagnosis of:
-psychotic
-developmental

No chronic alcoholism

No smoking

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*

The study will not include minors, prisoners, or adults not capable to consent on their own behalf. Pregnant women will not be knowingly used, although no explicit pregnancy test will be given to confirm the status of the women.

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.*

13.1 This study will include Virginia Tech undergraduates which might include students in the class of either the PI and/or the Co-I. However, these students will not be coerced into participating. Compensation will be extra credit research incentive for the student's psychology class, but will not include the PI or the Co-I's classes. Neither the PI nor the Co-I offer extra credit for their class on Sona for this particular study. The study will take place outside of class time.

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):

This study will seek to enroll 85 participants. A power analysis was calculated using the G*Power applet (Faul et al., 2007) to determine required sample size for a target correlation of 0.3. With $\alpha = 0.05$ and $\beta = 0.20$, the target effect size requires a sample size of at least 85 participants. It is estimated that 85 out of the 100 participants completing online screening will be in compliance with abstention requirements

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:

N/A

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:

It is estimated that 200 subjects will be screened for enrollment in order to obtain 100 subjects to invite to the lab. Of these, we need 85 participants to follow abstention requirements and complete the research procedure.

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

N/A

15.0 Recruitment Methods

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

Paper flyers advertising the study will be posted throughout Williams Hall. In addition, this study will be advertised on the Psychology Department's participant recruitment system, called Sona. This recruitment method will begin immediately following IRB approval for the study, which is hoped to be obtained as soon as possible at the beginning of the Fall 2019 semester.

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):

The Sona system, which recruits undergraduate students currently taking a psychology class at VT.

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

Students clicking through the links on the Sona system and completing the prescreen survey will self-identify as a potential subject.

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.*

Flyer attachment, Sona final wording, and email are attached in Protocol Management. Compensation will be extra credit points awarded via the Sona system to the applicable psychology course as follows:

- 1.0 points for completion of the online prescreen
- (0.5 points for partial completion of the online prescreen)
- 0.5 points for arriving to the lab for the in-lab portion
- 0.5 points for completing the in-lab questionnaire portion of the study
- 0.5 points for completing the stimulus portion of the study
- 0.5 points for completing the remainder of the study including video review and post-hoc interview

16.0 Withdrawal of Subjects

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

Subjects who have not complied with abstention requirements prior to arrival in the lab will be withdrawn without their consent upon determination of such non-compliance. Subjects who cannot remain still enough for a clean physiological signal to be obtained might be withdrawn without their consent. Before such withdrawal, subjects will be reminded to remain still in order to obtain a clean physiological signal.

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

Should participants ask to withdraw at any time during the in-lab portion, their request will be granted immediately. Any physiological equipment that had been attached will be carefully removed. Participants will be debriefed about the study goals and offered coaching on managing distress from the threat stimuli if they had reached this stage of the in-lab research. Participants will be invited but not required to express any concerns they had that led to their request.

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):

Same as 16.2. There is no way to partially withdraw from this study, so any withdrawal will be a full withdrawal.

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)*

The online portion of the study is determined to have no more risks than are found in everyday life. The in-lab portion of the study is assessed to have the following risks:

Physical:

The single-use electrodes are affixed to participants' skin much as a Band-Aid would be affixed. The adhesive contained in the electrodes is about as strong as medical grade tape, so removing them may cause redness or irritation to the skin. The chances of such irritation are estimated to be 25% and the estimated duration of the discomfort is estimated to be 24 hours.

Virtual reality can cause dizziness or nausea because of the mismatch between the virtual and actual environment. Odds of such a reaction are estimated to be 25% and the estimated duration of such a response is 10 to 30 minutes.

Psychological: The main stimulus video portrays a threat that is approaching at an escalating rate. It is designed to activate the human defense cascade. Some individuals who are particularly sensitive to their own physiological responses might become distressed about their own physiological activation. The probability of such a reaction is estimated to be 5% For participants who do have such a reaction, the duration of the reaction could be anywhere from 1 minute to 1 week. However, the threat stimulus is judged to be no more physiologically arousing than the average horror movie or horror video game.

The investigators are not aware of any risks from this study that fall into the categories of social, legal, privacy, or economic.

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.)

An explicit aspect of the study design is the frequent request for the participant's SUDS rating (1 to 10 scale expressing how distressed they are feeling). These SUDS requests will occur every minute throughout the stimulus portion of the study. Therefore, researchers will have a regular update to indicate degree of participant distress.

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:

N/A

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

N/A

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):

N/A

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:

It is hypothesized that SUDS requests do more than just help researchers or therapists to gauge their participant or client's well-being. The very nature of taking an emotionally-charged experience of distress and making it objective by giving it a number, can be a powerful neutralizer to fear and distress. There is an estimated 10% chance that participants will recognize this process as potentially useful for future distressing situations. For this reason, the study explicitly adds a second MAIA questionnaire at the end of the study to determine if the SUDS process changed participant's interoceptive awareness during the course of the study.

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

N/A

19.0 Data Management and Confidentiality

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

Participant survey data will be saved to the database directly from their computer survey responses with no steps in between to potentially invalidate the data. This applies to both the Sona prescreen and the in-lab questionnaires.

Researchers will be trained on proper electrode placement to minimize signal artifact reflecting electrical signals from non-cardiac muscles. Physiological data is displayed in real time on a computer screen accessible to the researchers, all of whom will be trained to recognize typical signals for ECG, ICG, EDA, and mobility. These signals will also be monitored throughout the in-lab session and any unexpected signals will be cross-checked with electrode placement.

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*

All data gathered for this study will be new and not pre-existing.

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.:

All researchers will be trained on the importance of data security and participant confidentiality.

Surveys will be gathered and stored using Virginia Tech's Qualtrics system. This system allows access to be restricted to only the named researchers on this IRB application. Qualtrics access is further restricted using Virginia Tech's dual factor authentication system. Researchers must be logged in to their own instance of Qualtrics to access data.

Physiological data will be gathered using Biopac AcqKnowledge software and stored on the MBL server. This server access is restricted to those previously authorized by both the PI and Co-I to establish a unique username and password combination. Further, data on the MBL server can only be accessed from MBL computers which are secured in the MBL lab rooms in Williams Hall. These rooms follow a strict locked door policy, where all doors remained locked unless an authorized lab member is actively present in such room.

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):

N/A

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?*

De-identified data will be stored for the long term. Data on Qualtrics and the Mind-Body Lab server will be destroyed 3 years following the study.

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):

Personally-identifying data will be only stored for the purposes of contacting qualifying participants to invite them to the in-lab portion of the study and to schedule them for this portion. The in-lab portion of the study will require the study researchers to interact with the participants to run the study. Non-research personnel should not be present for the in-lab portion. Personally-identifying data will not be shared with any non-named researchers on this study.

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):

Participants will be asked their preference for a male or a female researcher to be attaching electrodes to their torso.

Research assistants will be trained and will rehearse how they work with participants throughout the study. They will be coached on the importance of a non-intrusive approach, and how to clearly convey the pertinent details in a non-threatening manner. They will further be coached on the supremacy of the participant's word with respect to withdrawal of consent.

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:

We do not plan to access any existing sources of information about the participants.

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)*

Research assistants will be instructed to report directly to the PI (a mandatory reporter) the following: any suspicions or indicators of abuse, neglect, or exploitation of children or vulnerable adults, sexual discrimination or violence, intent to harm self or others.

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).*

The current study is not assessed to involve more than minimal risk. Participants will be instructed to sit throughout the procedure, minimizing any safety concerns.

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:

N/A

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:

N/A

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:

Participants will be allowed to schedule their participation to fit with the rest of their class and campus schedule. Because participants will be VT undergraduate students on the Blacksburg campus, it is expected that their transportation to and from campus for participation will rely on the same transportation they regularly use to get to campus and can even occur within the same visit to campus as other required classes or student activities.

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 form has been uploaded to Protocol Management. Consent to the online prescreen will be made by the participant via computer, from whatever location they are accessing the online forms.

The online consent process is estimated to take between 5 and 15 minutes, depending on factors unique to each potential participant and their setting such as attention span and the presence of distractors in their environment while reviewing consent.

The in-lab consent process is estimated to take 15 minutes, but will last as long as needed for participants to gain comfort with their understanding of the study and to make a comfortable decision about whether to sign the consent document. All named researchers will be trained in the consent process. During this time, the researcher will begin by providing a verbal description of the project following the script uploaded to Protocol

Management, which will include a description of the purpose for the study, the procedure, risks and benefits, and the compensation they will receive (extra credit in their chosen Sona-participating psychology class). The participant's right to end the study at any time will be emphasized. Following the verbal summary, the researcher will then invite the participant to ask any clarifying questions, and once questions have been asked, the researcher will ask the participant to tell them in their own words their understanding of the study. Any misunderstandings of the study will be clarified by the researcher. Participant will be invited to ask any further clarifying questions they might have. Once no further participant questions remain, the researcher will present the participant with the written consent form, invite them to take whatever time is needed to review the form and to decide whether to sign it. The researcher will leave the room and await indication from participant that they are ready for the researcher to return. When written consent is provided, the researcher will nevertheless verbally ask the participant if they are ready to begin before proceeding. Researchers will be trained to take as much time as needed for the in-lab consent process in order to minimize any sense of urgency that might be construed as coercion.

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.*

This study will be conducted in English, so participants will be expected to understand English well enough to proceed successfully through the previously-described consent process.

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).

N/A

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.*

N/A

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.*

Because participants will all be VT undergraduates, they are expected to be capable of consent. No minors will be allowed to participate in this study.

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:

After the process described in section 24.1 ensuring participant understanding of the study and their consent rights, each participant will be presented with the consent form (attached to Protocol Management) and asked to provide their signature if they agree to consent.

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):

I request the waiver of written consent documentation for the consent to the online survey portion of the study.

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:

Written Consent document attached to Protocol Management.

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).*

26.1 The PI of this study has regularly-scheduled weekly meetings with the Co-I throughout the anticipated study duration. Further, the PI is additionally available to meet during regularly-scheduled office hours and outside of office hours by appointment.

Graduate psychology researchers including the Co-I have access to a large pool of undergraduates for research studies via the Sona participant management system. The target of 85 in-lab participants should easily be obtainable given the large pool from which to draw and given the minimal exclusion criteria for this study.

The Co-I expects to devote at least 20 hours per week to this project once data collection begins, including managing laboratory sessions with research assistants. Each research assistant will be signed up for a minimum of 6 and usually 9 hours per week for this project via their enrollment in field study credits. Altogether, up to 10 sessions per week could be run by the research team. With a target of 85 participants, this study could be done as quickly as 8½ weeks. Given that the fall semester has 15 weeks, it is realistically hoped that the entire in-lab portion of the study can be concluded by the end of the fall semester.

The research for this study will be conducted in Williams 255, and will be specially dedicated for this research. Fellow Mind-Body Lab researchers running concurrent research studies each have separate dedicated rooms in Williams for their research.

Being on the Virginia Tech Blacksburg campus, both medical and psychological resources are readily available should unanticipated medical or psychological needs arise as a result of the study.

Research assistants will each be required to be trained on the research protocol until they can demonstrate a facility with all aspects of the procedure. Research assistants will be trained to perform all aspects of the research protocol from informed consent, to electrode placement, to reading the physiological signals and troubleshooting signals that do not look correct by adjust physiological equipment, as well as removal of electrodes and conclusion of the procedure.

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.

N/A