

Consent Form for Participation in a Research Study
University of Massachusetts Amherst

Principal Investigator: Seamus Decker
Study Title: Psychobiology of acute stress and behavior
Sponsor: UMass, Amherst, College of Social and Behavioral Sciences

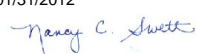
1. WHAT IS THIS FORM?

This form is called a Consent Form. It will give you information about the study so you can make an informed decision about participation in this research study. This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. We encourage you to take some time to think this over and ask questions now and at any other time. If you decide to participate, you will be asked to sign this form and you will be given a copy for your records.

2. WHO IS ELIGIBLE TO PARTICIPATE?

We are seeking to include a total of 90 healthy, non-smoker men between the ages of 18 and 30 years to participate in the study.

This study involves participating in an upsetting and stressful computer task involving viewing shocking, repulsive, disturbing, horrific, lewd, erotic, or gory images and words. Most people will find this 25-minute task difficult, unpleasant, upsetting, and stressful. You should not participate in this study if have any history of mental or psychiatric problems including: depression, anxiety, bipolar, autism, schizophrenia, phobias, ADHD, any personality or obsessive-compulsive disorder, PTSD, substance abuse, learning disorder, brain or head injury or *any other psychiatric disorders*. If you think you might be vulnerable to stress or mental health issues, you should NOT participate in this study.

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3. WHAT IS THE PURPOSE OF THIS STUDY?

The Psychological Anthropology and Human Adaptation Laboratory (PAHA Lab) in the Department of Anthropology at the University of Massachusetts, Amherst is conducting a study to better understand how physiological stress response influences decision-making behavior and health. We hope to publish our findings in either *Psychosomatic Medicine* or *Psychoneuroendocrinology*.

4. WHERE WILL THE STUDY TAKE PLACE AND HOW LONG WILL IT LAST?

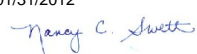
The research will be conducted, at the Psychological Anthropology and Human Adaptation Laboratory (PAHA Lab), E26 Machmer Hall, on the University of Massachusetts, Amherst campus. The research will be conducted during the spring through fall of 2010. Each participant will make one visit of approximately 110 minutes to the PAHA lab between the hours of noon and 4PM. You can stop participating in this study at any time you choose; anyone who wants to drop out of this study can tell the researchers at any time with no penalty.

Based on the results of this study, we may conduct future studies. Participants who are interested in participating in future studies can leave their name and contact information on the final page of this consent form. There is no obligation to participate in any future studies. Anyone who does not want to be contacted about any future studies can tell the researchers this at any time. If you decide you do not want to participate in any future studies even after you have stated you are interested, simply let a researcher know, and your name and contact information will be deleted from our records. There will be no negative consequences for not participating in any future studies

5. WHAT WILL I BE ASKED TO DO?

You should be aware that the *investigators have intentionally used deception or inaccuracy in describing the true purpose of this study*. This use of deception is necessary to conduct the study. However, an independent University ethics panel has determined that this consent form accurately describes the risks and benefits of the study and that the two points of deception in describing the purpose of the study are not intended, nor likely to manipulate individuals to volunteer when they would not have chosen to do so, had no deception been used. The ethics panel considers the information in this form to be sufficient basis for volunteers to make an informed decision whether or not to participate. At the end of your participation the investigators will explain the true purpose of the study and any inaccurately described or omitted aspects of the study to you.

At the conclusion of your involvement in this study, you will be given a ten-minute debriefing about the research. This debriefing will include complete and truthful disclosure and clarification of all points of deception or omission, and an opportunity for you to ask questions about the study, and/or to withdraw your data from the study. Past research has shown that, participants in studies using deception who received detailed and informative debriefing at the conclusion of their involvement had more positive experiences. Effective debriefing “may help to eliminate any negative effects perceived by participants” and help participants to experience their participation as being “more fun,” of higher “overall value,” and greater “educational benefit” than similar studies without such debriefing¹.

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If you participate in this study you will make a visit to the PAHA Lab (E-26 Machmer Hall) where you will participate in five research activities:

- 1) Complete a written questionnaire about your eating, alcohol consumption, smoking, physical activity, mood, personality, childhood recollections of parents, and demographic information (income, grade level, GPA, school, work & volunteer activities). This will take about 45-minutes to complete broken into two sessions at the beginning and end of your visit to the lab. To complete the survey, you will read statements or questions and mark your answers on the answer form.
- 2) Three types of “anthropometric measures” will be collected: (1) height (stature); (2) weight (body mass); (3) body composition measurements will be collected by an Omron body composition monitor. This machine will use “bioelectrical impedance” to calculate your body mass index (BMI), body fat percentage, skeletal muscle percentage, body age, amount of visceral fat, and your resting metabolism. This involves sending an extremely weak electrical current through your body, similar to the heart rate monitors on exercise machines at the gymnasium. For these measurements you will need to remove your shoes and socks, but otherwise can remain clothed. If you are fitted with a cardiac pacemaker, or other implanted medical device you should not have measurements taken by the Omron body composition monitor.
- 3) Participate in a computer-based reaction-time task sitting at a computer screen and viewing images and words, solving problems by hitting the space-bar, and imagining yourself involved in the events and scenes shown on the screen. Participants will be randomly assigned to participate in different versions of this task, some of which are unpleasant and some pleasant. Depending on the version of the task to which you are randomly assigned, you may be asked to experience an upsetting and stressful computer task involving rapidly distinguishing neutral from unpleasant words and images which may be shocking, repulsive, disturbing, horrific, lewd, erotic or aversive. Most people will find this 25-minute task difficult, unpleasant, upsetting and stressful. For example, you may view images such as emergency room, crime scene or morgue photos, victims of mutilation or gruesome diseases or injuries, erotic images of nude men or women, exhumation photos, images of depravity or desperation, starvation, genocide, natural disaster victims, acts of violence or scenes of terrifying acts like beheadings, execution by electric chair, plane or car crashes. While watching these scenes you may be asked to imagine yourself experiencing the events or effects depicted. You may experience stress or anxiety as a result of viewing these disturbing images. You may be asked to solve problems involving memory, word and image recognition, attention-shifting, or categorization by pressing the spacebar on the keyboard at a rapid pace that will be difficult to maintain. Solving these tasks may be difficult, frustrating and discouraging and may not perform well at these tasks. You may feel that the task is too difficult to perform well and feel discouraged at how poorly you perform at the task.

You should not participate in this study if you have any history of mental or psychiatric problems including: depression, anxiety, bipolar, autism, schizophrenia, phobias, ADHD,

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any personality or obsessive-compulsive disorder, PTSD, substance abuse, learning disorder, brain, head, neck or face injury or surgery or *any other psychiatric disorders*. If you think you might be vulnerable to stress or mental health issues, you should NOT participate in this study.

Even if you have no history of mental health problems there is still some risk from participating in these tasks. The most gruesome and unpleasant scenes and images are as bad as the worst you have ever seen in some contemporary action and horror films (e.g., *Saw, Hostel, Seven. No Country For Old Men, Saving Private Ryan*). Many are as bad as gruesome and repulsive images on certain popular internet sites that host disturbing or gory pictures and videos.

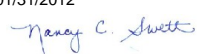
- 4) During the computer-based tasks four physiological measurements will be taken with an “AD Instruments” machine. These measurements will be collected using small sensors secured to the fingers with a band of Velcro. The sensors will measure heart rate; nervous system activity; and temperature. Respiration will also be measured during the task by wearing an elastic belt. There is no risk of harm from these measures, although you may experience some mild discomfort resulting from holding the one hand with sensors on it motionless for approximately 25 minutes during the course of the task. You will be provided with a pillow to keep the motionless hand comfortable, and the research assistant will work with you when hooking up the device to try to insure you are comfortable.
- 5) Before, during and after the computer-based tasks a research assistant will also be collecting 4 samples of saliva. These samples will be used to analyze participants’ salivary cortisol and alpha-amylase levels, hormones related to physiological reactions and health. There is no risk of harm from these measures, and the collection of saliva should not cause any discomfort.

6. WHAT ARE MY BENEFITS OF BEING IN THIS STUDY?

There are no direct benefits associated with participating in this study. You may benefit from this study by having your body mass measurements assessed. This information will be available to you immediately at the time of the measures. Although such information will not constitute a medical diagnosis or medical advice, the information may alert you if there is a need for you to seek professional medical advice from your doctor. The benefit you may gain by participating is intended for informational use only. Do not rely on it to make decisions about your health. Always consult your doctor for personal medical advice. We expect this study to benefit young adult males and society in general by providing information about how personality and lifetime experiences influence behavior and health.

7. WHAT ARE MY RISKS OF BEING IN THIS STUDY?

There are four distinct types of potential psychological harm that participants in this study could suffer, as well as two potential sources of mild physical discomfort, and one potential form of inconvenience. Each of these potential sources of harm is described below, along with provisions to prevent and/or ameliorate harm, and to insure that the research experience is as positive and rewarding for participants as possible.

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Participants who are under 21 years of age should know that questions 6 through 11 (questionnaire part 2) in this study are about alcoholic drinking, which is illegal. Every effort will be made to maintain the confidentiality of your responses, but there is a low risk of breach of this information. You should skip these questions if you do not feel comfortable answering, or do not want to answer

Potential Psychological Harm

1) Deception: You should be aware that the *investigators have intentionally used deception or inaccuracy in describing some aspects of this study and/or left out information about certain aspects of this study.* This use of deception is necessary to conduct the study. However, an independent University ethics panel has determined that this consent form accurately describes the major risks and benefits of the study. At the end of your participation the investigators will explain the inaccurately described or omitted aspects of the study to you.

2) Extremely Disturbing, Shocking, and/or Repugnant Images/Words: One potential risk is increased anxiety as a result of viewing negative images during the computer-based tasks. This anxiety may be a problem for participants with a history of depression, anxiety, or other psychological issues. ***You should not participate in this study if have a history of PTSD, depression or anxiety disorder or other psychiatric or behavioral health disorders.***

3) Extremely Difficult, Frustrating, Annoying & Exhausting Computer-Based Task: the computer task is exceptionally difficult. You may not be able to perform well, and you may feel discouraged or frustrated by your inability to perform well at the task.

4) The survey items may cause some immediate minor embarrassment due to questions about topics such as eating, and life events. All responses are completely anonymous; the identity of the participant will remain anonymous to the researchers via the use of a randomly assigned ID number.

Potential Mild Physical Discomfort

5) The computer-based tasks may cause some immediate minor discomfort from holding one hand motionless while physiological measures are collected with sensors on the hand. There is no risk of electrocution or injury from either the body measures or the physiological measures. The risk of minor discomfort from holding the hand motionless will be minimized by providing participants with a cushion on which to rest the hand, and by assisting participants to adjust their chair and posture to achieve the most comfortable position prior to starting the task.

6) The body measures may cause immediate minor embarrassment/discomfort from being measured by another person. To minimize the risk of embarrassment, all body measures will be taken by a trained researcher.

Potential Inconvenience

(7) A possible inconvenience may be the time it takes to complete the study, which we estimate will be approximately 110 minutes for each session.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

The following procedures will be used to protect the confidentiality of your records:

Apart from the informed consent form, participants' names will not be recorded on any paper questionnaire response forms, or in any digital computer files. Instead, each participant's

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name will be recorded on a single page (hereinafter referred to as NAME PAGE) in association with a random participant ID number. All paper and digital copies of research data will be associated ONLY with this six-digit participant ID number. None of the paper survey forms or electronic data files (e.g., database, spreadsheet, etc.) will contain any information that would allow individual participants' identities to be identifiable except the random participant ID number.

All documents related to this study (including the NAME PAGES) will be kept in a locked filing cabinet, inside a locked office. All documents related to this study will be destroyed three (3) years after the close of the study. All computer files will be password protected and all computers hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords.

At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. Study data will not be released.

9. WILL I RECEIVE ANY PAYMENT FOR TAKING PART IN THE STUDY?

Upon completion of the study, you will receive a total of \$20.00 as a token of thanks for your participation in the study. After receiving your signed informed consent forms, your completed survey forms, your anthropometric measures, and completion of the computer and physiological assessment task the research assistant will give you your compensation. Compensation provided will be prorated in the event that a participant does not complete the entire study.

10. WHAT IF I HAVE QUESTIONS?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the principal investigator, Seamus Decker (413-545-3592). If you have any questions concerning your rights as a research subject, you may contact the University of Massachusetts Amherst Human Research Protection Office (HRPO) at (413) 545-3428 or humansubjects@ora.umass.edu.

11. CAN I STOP BEING IN THE STUDY?

You do not have to participate in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or negative consequences of any kind if you decide that you do not want to participate. If you decide you do not want to participate in the study even after you have started to participate, simply let one of the researchers know; you will be dropped out of the study, all information you provided will be deleted, and you will suffer no negative consequences.

In the event that you decide you are interested in being contacted about future studies, you will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

12. WHAT IF I AM INJURED?

None of the procedures in this study are likely to cause any injury or physical harm. However, University regulations require the following statement to be included as a legal disclaimer: The University of Massachusetts does not have a program for compensating subjects

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for injury or complications related to human subjects research, but the study personnel will assist you in getting treatment.

13. SUBJECT STATEMENT OF VOLUNTARY CONSENT

I HAVE READ THIS FORM AND DECIDED THAT I WILL PARTICIPATE IN THE PROJECT DESCRIBED ABOVE. THE GENERAL PURPOSES AND PARTICULARS OF THE STUDY AS WELL AS POSSIBLE HAZARDS AND INCONVENIENCES HAVE BEEN EXPLAINED TO MY SATISFACTION. I UNDERSTAND THAT I CAN WITHDRAW AT ANY TIME.

Participant Signature:

Print Name:

Date:

By signing below I indicate that the participant has read and, to the best of my knowledge, understands the details contained in this document and has been given a copy.

Signature of Person
Obtaining Consent

Print Name:

Date:

Based on the results of this study, we may conduct future studies. There is no obligation to participate in the future study if you participate in the present study.

Please indicate however, if you agree for us to contact you in the future about possible participation in any future studies.

May we contact you in the future about additional research? ____ Yes ____ No

If you checked yes, please provide your contact information (address, email, telephone):

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