Consent Document for Enrolling
Adult Participants in a Research Study
at the
Memory, Affect, and Planning Laboratory

School of Psychology, Georgia Institute of Technology,
654 Cherry St NW, Atlanta, GA 30332-0170

Project Title
Mechanisms of Stress on Memory and Cognition

Investigators
Dr. Thackery Brown, Principal Investigator
Dr. Scott Moffat
Jon Starnes
Sarah Freeman
Tal Ben-Yishai
Ling Liu
Paulina Maxim
Yiren Ren
Ursula Saelzler
Rhea Nichani
Avery Pope
Cara Doll

Address
Thackery Brown
School of Psychology, Georgia Institute of Technology, 654 Cherry St NW, Atlanta, GA 30332-0170

Telephone
404-894-1123

Purpose
The purpose of this study is to examine how memories for spatial and non-spatial events are formed and retrieved by the brain, and how this changes across the lifespan. We are interested in how the experience of stress affects those processes. Your results will be combined with those of other healthy volunteers. Your results will help us understand how the brain creates memories in young and older adults. We expect to enroll 300 people in this study.

Introduction
You are being asked to participate in a research study. Your participation is voluntary. Please feel free to ask questions at any time if there is anything that you do not understand. Stress will be induced in 50% of the participants (you will be randomly assigned to the stress or control group, and by signing this form you give consent to this).

Stress will be induced by a SAFE but unpredictable electrical stimulation on your ankle (more detail below).

If you are eligible to participate and you provide written informed consent, you will be asked to perform several tasks. These tasks involve viewing pictures on a computer screen or listening for words to be presented and responding quickly with judgments about them or simply to indicate that you have seen them. Your responses will be recorded by a researcher or automatically by a computer. These tasks will require between 30-180 minutes to complete. If you are participating in an aging study, sessions will require no more than 90 minutes to complete.

At the discretion of the protocol director subjects may be taken out of this study due to unanticipated circumstances. Some possible reasons for withdrawal are:

- failure to follow instructions
- the investigator decides that continuation would be harmful to you
- the study is canceled
- not meeting inclusion criteria
- other administrative reasons

Exclusion/Inclusion Criteria

It may not be appropriate for people with the following conditions to participate. The researchers will ask you to review a list of conditions and tell them if any apply to you. **If you have any of the following, you will be excluded from this study for your own comfort and the integrity of our findings:** history of neurological or psychiatric disorder; a history of stroke or seizure; history of head trauma; loss of consciousness; brain damage; pacemakers, vagus nerve stimulator, or other electrical implant; heart attack; epilepsy; bipolar disorder; untreated depression or anxiety; Attention Deficit Disorder; untreated or uncorrected vision; color blindness; people who regularly use illegal drugs; currently or regularly use psychoactive drugs. You must be fluent in English and have normal hearing. Individuals scoring < 3 on WAIS-R forward span, < 2 on WAIS-R backward span, and failing to name more than 2 vegetable names will be excluded from the study.

You must be between the ages of 18-40 or 60-80 to participate.

Procedures

- If you decide to participate, Dr. Brown or a designated representative will describe the procedure to you.
- As part of this study, you also may be asked to come into Dr. Brown's laboratory on one or more occasions. Whether this specific study involves one or two sessions depends on the experiment, and was communicated using the recruitment materials. During these sessions, you may be asked to fill out one or more questionnaires, and/or perform a computer-controlled cognitive task. In the

cognitive task, you will either passively attend to or actively respond in one or more of the following experimental conditions:

1. Passive watching or listening to stimulus information (e.g., visually or aurally presented words or numbers and/or visually presented images

2. Watching or listening to stimuli and making a response (e.g., a finger or verbal response) about the type of stimuli seen or heard. Typically, your study will be a blend of the two – e.g., you will passively view a video of a navigational route, and then you will be asked to actively respond to a memory probe such as "which way would you turn at this location" using a button box.

- No sessions may exceed 3 hours, no tasks may exceed 2.5. If you are participating in an aging study, sessions will require no more than 90 minutes to complete.
- First, you will review the screening questionnaires and complete the health screening forms. We will discuss activities of this specific study, and you may ask all the questions you have before proceeding.
  After a session is finished, you may be asked to perform some simple paper and pencil or computer tasks for a maximum of 30 minutes. These include standardized questionnaires, and we may ask you to briefly describe your experience with the task you completed - for example, were there virtual environments or pictures that you found harder to learn. They are very simple. They will be performed in the Memory, Affect, and Planning Laboratory
- **You are free to quit the study at any time, without penalty, and this will in no way affect any compensation you have earned.**

Electrical Stimulation

The electrical stimulation task will involve a calibration period in which your tolerance to pain stimulation will be assessed. During the electrical stimulation task, an electrode will be applied to your wrist or foot through which low and safe levels of electrical stimulation will be delivered for very brief durations during identified periods of the task. The level of stimulation you receive during the subsequent tasks will never exceed what you identify as your maximum during the calibration period.

In addition, we may obtain saliva samples from you for measuring hormone levels during the task. The method used to obtain a sample will involve a sterile cotton swab called a "Salivette" to collect saliva from your mouth. These sampling procedures will not cause you any discomfort. The saliva obtained will either be analyzed at a local laboratory at Georgia Tech or a research laboratory in another U.S. university that specializes in the analysis of hormone samples. There is nothing experimental in this cotton swab. The methods used to obtain and analyze hormones are based on standardized protocols. Research using saliva is an important way to try to understand the role hormones play in cognition and emotion. Your saliva will be stored under a unique identifier code. Only the Principal Investigator will have access to the single file in the laboratory that links you to the saliva sample. This file will be kept under lock and key. When the saliva is sent out for processing, it will be completely de-identified. There will be no personal information other than the unique identification number attached to each saliva sample.

Your name or other public identifiers will not be included with any data shared with other investigators, and no analysis on the sample will be done outside of the hormone level measure. There is no risk associated with the method for obtaining the sample.

Risks or Discomforts
There are no known risks associated with the behavioral procedures. Some of the questionnaires will ask you for personal information (e.g. medical history). You do not have to answer any questions that make you uncomfortable.

Some participants may experience motion sickness specific to completing virtual navigation tasks. This is rare, and should you experience motion sickness, you must notify the experimenter(s) and are free to quit the experiment at any time.

Due to the highly focal and carefully restricted nature of the stimulation, there are no known risks of the stimulation to fetuses in women who may be pregnant.

Though the levels of electrical stimulation used in the calibration and tasks are safe and have been used in previous experiments, there are several things you should know before participating in this component of the study.

1. You will experience physical discomfort due to electrical stimulation. The level of stimulation is designed to be uncomfortable and require some effort to tolerate. This level of stimulation is completely safe and has been used in experimental research at a number of institutions.
2. Some participants experience mild skin irritation from the application of the stimulation electrodes. This irritation is not expected to last long.
3. We will, to the extent possible, attempt to minimize such risks through careful adherence to safety precautions and study procedures, and through continuous attention to your well-being. If you experience discomfort at any time, notify the experimenter. You may discontinue participation at any time.
4. Voltage is potentially dangerous if applied improperly to the body. Electrodes will be placed next to each other on the same ankle, far from the heart, so that the safe level of stimulation that you set cannot cross your body or heart.

Benefits
Although there is no direct benefit to you, your participation will help us to better understand the relationship between the brain and memory and how memory and the brain change as people get older.

Compensation to You

- You may choose to either receive course credit or to be compensated with money for your participation. Monetary compensation is $15 per hour. If you drove to the Joint Center for Advanced Brain Imaging or took public transportation, you will also be compensated $5 for your travel costs (e.g., MARTA, gas).
- For course credit, you will receive 1.0 credit for Psychology courses for each hour of your participation. Your professor can give you another option to receive course credit.

- If you are physically unable to complete the study, you will receive full compensation.
- U.S. Tax Law requires that a 1099-misc be issued if U.S. tax residents receive $600 or more per calendar year. If non-U.S. tax residents receive more than $75, mandatory 30% withholding is required. Your address and Tax I.D. may be collected for compensation purposes only. This information will be shared only with the Georgia Tech department that issues compensation, if any, for your participation.

Storing and Sharing and Future Use of Your Information
Your participation in this study is gratefully acknowledged. It is possible that your information/data will be enormously valuable for other research purposes. By signing below, you consent for your **de-identified** information/data to be stored by the researcher and to be shared with other researchers in future studies. Your data may also be included in the National Institutes of Health (NIH) data archive. If you agree to allow such future sharing and use, your identity will be completely separated from your information/data. Future researchers will not have a way to identify you. Any future research must be approved by an ethics committee before being undertaken.

Confidentiality
The following procedures will be followed to keep your personal information confidential in this study: The data collected about you will be kept private to the extent required by law.

- To protect your privacy, your records will be kept under a code number rather than by name.
- Your records will be kept in locked files and only study staff will be allowed to look at them.
- Your name and any other fact that might point to you will not appear when results of this study are presented or published.
- Your privacy will be protected to the extent required by law.
- To make sure that this research is being carried out in the proper way, the Joint Center for Advanced Brain Imaging IRB may review study records. The Office of Human Research Protections may also look over study records during required reviews.

Requirements of Certificate of Confidentiality policy that applies to research conducted or supported by NIH involving a participant's identifiable or sensitive information
We have obtained a Certificate of Confidentiality from the National Institutes of Health to help us keep your information confidential. This Certificate provides a way that researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). A Certificate of

Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Cost to you
There are no costs to you, other than your time, for being in this study

In Case of Injury/Harm
If you are injured as a result of being in this study, please contact Principal Investigator, Dr. Thackery Brown, Ph.D., at 404-894-1123. Neither the Principal Investigator, nor Georgia Institute of Technology, nor Georgia State University has made provision for payment of costs associated with any injury resulting from participation in this study.

Participant Rights

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will be given a copy of this consent form to keep.
- You do not waive any of your legal rights by signing this consent form.

Questions about the Study
If you have questions about the study, contact the principal investigator, Dr. Thackery Brown at the School of Psychology, Georgia Institute of Technology, 654 Cherry St NW, Atlanta, GA 30332-0170. Voice: 404-894-1123, thackery.brown@psych.gatech.edu.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Questions about Your Rights as a Research Participant
If you have any questions about your rights as a research participant, you may contact Ms. Kelly Winn, Office of Research Integrity Assurance, Georgia Institute of Technology, Atlanta, GA 30332-0420. Voice 404-385-2175, Fax 404-385-2081

Signatures
If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

_____
Participant Name (printed)

_____ _____
Participant Signature Date

_____
Person Obtaining Consent (printed)

_____ _____
Signature of Person Obtaining Consent Date

<u>Consent to Store and Share your Information:</u>
I agree that my de-identified information/data/scans may be stored and shared for future, unspecified research.

SIGNATURE _____

I do not allow my de-identified information/data/scans to be stored and shared for future, unspecified research. These may only be used for this specific study.

SIGNATURE _____