Informed Consent for Participants
in Research Projects Involving Human Subjects

Study Title: Episodic Memory in the Medial Temporal Lobe

Principle Investigator: Rachel A. Diana, PhD, Assistant Professor, Department of Psychology

I. Purpose of this Research/Project

You are being asked to participate in a research study. We hope to learn more about the functioning of the human brain. In particular, we will study your memory abilities, brain waves (electroencephalograms or EEGs) and/or brain scans (magnetic resonance images or MRIs) in order to learn about mental functions such as memory processes.

II. Procedures

If you decide to volunteer, we will ask you to participate in some or all of the following tasks over the next 1 to 3 hours. The exact procedure and duration of your participation depends on the particular portion of the study in which you participate. You will be informed in advance about the specific subset of the following procedures in which you are being asked to participate. This will be indicated in the following text in written form by the investigator crossing out, in advance, those sections that are not relevant.

**Behavioral studies:** (Approximately 1 hour)
For these studies you will sit in a comfortable chair in a small room (located in the Diana Research Lab in Williams Hall) and see/hear pictures, sounds, and/or words shown to you by the experimenter using a computer. You will be asked to make decisions about what you see or hear and to make responses to the stimuli by either pressing a button or by making a verbal response. The timing and accuracy of these button-press responses or verbal responses will be analyzed to make inferences about mental processes. In these studies, your actual brain activity will not be directly recorded.

**Brainwave Studies:** (Approximately 3 hours)
1. Several locations on your face will be cleansed and disks made of silver and plastic (electrodes) will be stuck to those locations with a sticker. Additional electrodes will be placed in an elastic cap that you will be asked to wear over your head.
2. A small amount of electrode jelly (a hypoallergenic, water soluble, and non-toxic conductive gel) will be applied to your skin where the electrodes make contact using a blunt-tipped gel applicator.
3. You will sit in a comfortable chair in a small room (located in the Diana Research Lab in Williams Hall) and pay attention to lights, sounds, words, or pictures shown to you by the experimenter using a computer.
4. You will be asked to make decisions about what you see or hear and to make responses to the stimuli by pressing a button. Some of these responses will involve judgments about your memory for particular items.
5. At the conclusion of the experiment the electrodes will be removed from your scalp and face and you will be given the opportunity to clean off the gel residue.
Brain Scans: (Approximately 2-3 hours)

For studies involving magnetic resonance imaging (MRI) of your brain:

1. You will be placed in a standard, FDA-approved, 3 Tesla strength, MRI machine at the Virginia Tech Carilion Research Institute Imaging Center (in either Blacksburg or Roanoke), and a three-dimensional picture of your brain and blood flowing in your brain will be taken using this device while you view visual stimuli or listen to sounds or words.
2. You will lie on your back on a table and be moved into the MRI machine and images will be taken of your brain.
3. Padding will be placed around your head to help you hold it still during the scans, and ear plugs will be placed in your ears to protect them from the loud sounds produced by the machine during scanning.
4. Once in the scanner, you will be asked to remain very still throughout the experiment so that a clear picture of your brain can be obtained.

III. Risks

Behavioral Studies: The risks of participating in this study are minimal. The stimuli presented will not be emotionally provocative or threatening in any way. You may become bored during the procedure. If this becomes a problem please notify the experimenter. You are free to take a break at any time if necessary.

Brainwave Studies: The risks of participating in this study are minimal. Brain waves are measured using standard machines designed to make the procedure harmless. No stimulation will be applied to your scalp, only your own brain’s electrical signals will be measured. Some electrode gel (a hypoallergenic, water soluble, and non-toxic conductive gel) may remain in your hair until it is washed. You will be allowed to clean up the gel as best as possible before leaving the experiment. In some cases, unexpected allergic skin reactions to the electrode gel may occur. These reactions are extremely rare but please notify the experimenter if you experience any discomfort.

Brain Scan (MRI) studies: An MRI scan is a painless radiology technique, which does not expose you to x-ray radiation. There are no known risks involved with MRI scanning. The MRI scanner will be operated by trained individuals. Because the scanner produces loud noises during the procedure you will be required to wear earplugs as protection against hearing damage.

If you are claustrophobic, you may not want to participate in the study as the scanner is relatively narrow and you may feel enclosed. If you choose to participate and become unexpectedly uncomfortable with being inside the machine, please notify the experimenter immediately and we will discontinue the study if necessary.

If you have a tattoo or permanent makeup on your face or neck, you may experience temporary skin irritation or swelling in the tattooed areas but this is very rare. If you have tattoos on your neck or face you will be asked not to participate. If you have tattoos on other parts of your body they will not be affected.

It is NOT SAFE to go in the MRI machine if you have metal implants or metal objects in your body. This includes a pacemaker, aneurism clip, or other metal device. This also includes bullets or metal fragments that may be lodged in your body if you work with grinding metals. You will be given a safety questionnaire prior to entering the scanner. Please fill out the questionnaire honestly so that we can assure your safety. Due to the investigative nature of this study, there may be other risks that are currently unknown. Although there is no evidence of harmful effects of magnetic fields on a developing fetus, we feel that women who are pregnant should not participate in this study.

Note that the MRI pictures of your brain are for research and are not meant to evaluate your health as they would be if they were part of a clinical (non-research) visit to the doctor or hospital. The pictures will not receive routine clinical review by specially trained physicians (radiologists) who interpret MRI scans. This means that all abnormalities may not necessarily be noticed. However, if in the routine administration of the
MRI pictures, the MRI research technicians do notice any possible problem, they will notify Dr. Rachel Diana, who will obtain consultation by a radiologist on the possible problems. When the radiologist looks at the pictures, your name will be absent to protect your identity. Dr. Diana will discuss the findings with you and will help you obtain a more complete review of your MRI scan by a trained physician who can determine if any clinical health condition is present. If the radiologist thinks a clinical problem is present, we will provide you with a copy of the MRI picture to take to the physician of your choosing. If you prefer, we can send the pictures electronically; there is a small risk that someone else could view electronically sent files. If as a result of this research project, the investigator recommends that the participant seek medical treatment, a list of local services will be provided. Any expenses accrued will be the responsibility of the participant and not of the research project, research team, or Virginia Tech.

IV. Benefits

It is not likely that you will benefit directly by participating in this study, except for the educational experience of participating in a research study. Please feel free to ask the experimenter about the methods, purpose, and expected outcome at the end of the study if you are interested. We hope that this research will improve our understanding of human brain functions, which would yield many benefits for society. By signing this consent form, you confirm that no promise or guarantee of benefits have been made to encourage you to participate.

V. Extent of Anonymity and Confidentiality

We will maintain confidentiality of your data. This means that you may be identifiable but the researchers promise not to divulge any identifying information. The data that we obtain from you in this study may be published as scientific abstracts or journal articles, but your name will not appear in any publication. To maintain the confidentiality of your records, we will assign you an arbitrary identification number that will be used when we process your data. All paperwork with your identifying information (such as this consent form) will be stored separately from the study data and will be kept in a locked, private location. Only investigators directly involved in this study will have access to identifying information about you. It is possible that the Institutional Review Board (IRB) may view this study’s collected data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research. Identifying data from this study will be destroyed 3 years after publication of the results.

VI. Compensation

You will either receive payment for your time (at least $10 per hour) at the end of the study (a prorated amount will be paid if you withdraw before completion of the study) or extra credit through the Psychology Department SONA system. The amount of extra credit is determined by your instructor in the course affiliated with the SONA system. An alternative method of earning extra credit is available in lieu of experiment participation, please refer to your course syllabus. We will also provide a copy of your brain images if you participate in an MRI study. If as a result of this research project, the investigator recommends that the participant seek medical treatment, a list of local services will be provided. Any expenses accrued will be the responsibility of the participant and not of the research project, research team, or Virginia Tech.

VII. Freedom to Withdraw

You are free to withdraw from the study at any time without penalty. If you choose to withdraw, you will be compensated for the portion of time of the study you completed. If you are a student and you choose to withdraw, you will not be penalized by a reduction in points or grade in a course. You are free not to answer
any questions or respond to experimental situations that you choose without penalty. The investigator may withdraw subjects from the study at his/her discretion and such a decision does not imply that you or the investigator has done anything improper. In such cases you will be compensated for the portion of time of the study you completed.

VIII. Subject’s Responsibilities

I voluntarily agree to participate in this study. I have the following responsibilities:

1. To report the presence of any metal within or upon your body prior to entering the MRI suite.
2. To notify the investigator if I experience any discomfort or would like to discontinue participation from this study.
3. To notify the investigator I have any questions or concerns regarding participation in this study.

IX. Subject’s Permission

I have read the Consent Form and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent:

______________________________________________ Date_____________
Subject signature

Rachel A. Diana, PhD, Faculty Advisor, rdiana@vt.edu, 540-231-6582
Robert S. Stephens, PhD, Psychology Department Chair, stephens@vt.edu, 540-231-6304

If I should have any questions about the protection of human research participants regarding this study, I may contact:
Dr. David Moore
Chair, Virginia Tech Institutional Review Board for the Protection of Human Subjects
Telephone: (540) 231-4991
Email: moored@vt.edu
Address: Office of Research Compliance
2000 Kraft Drive, Suite 2000 (0497)
Blacksburg, VA 24060

Virginia Tech Institutional Review Board: Project No. 11-505
Approved June 27, 2012 to June 26, 2013