

The following language should be inserted into any GMU HSRB (1) protocol or (2) consent form that will involve functional magnetic resonance imaging

I. Language for HSRB-approved Protocol:

Since MRI scanning is non-invasive, there are few risks associated with this activity. It uses magnetic fields to create pictures of the brain. This 3 Tesla MRI system meets FDA requirements for use in the proposed research.

There is a possible risk to volunteers for some emotional discomfort or frustration while performing computer games that increase in difficulty. The MRI scanner is shaped like a tube which makes some people feel claustrophobic. The machine is also noisy, which makes some people anxious. This noise is generated by the machine to make an image of the brain. Subjects will be in contact with the researcher during the entire scanning session. They will be able to see through a window and talk through a microphone system. They can be removed from the scanner quickly. There are no known long-term effects from MRI scanning. The subject's head will be held still in a foam cushioned head holder, which may be mildly uncomfortable. People with any metal clips or metallic implants, infusion pumps, cardiac pacers, defibrillators, or some braces may not undergo MRI scans. All metal or magnetic objects must be removed before entering the MRI scan room (for example, watches, coins, jewelry, credit cards). All possible measures will be taken to teach research staff about the dangers of metal objects becoming projectiles in the magnet room. Any individuals entering the magnet room will be completely screened for magnetic material. Subjects will not be sedated at any point during this study.

The researchers for this project are not trained to perform medical diagnosis, and the scans performed are not set up to find abnormalities. The researchers are not responsible for a failure to find an existing abnormality if one is shown on an MRI scan. However, every once in awhile, the investigator may notice something on an MRI scan that seems abnormal. When this happens, a specialist will be consulted as to whether this needs further investigation. Then, the researcher would contact the volunteer to inform them of the finding. The decision to contact their physician and proceed with further examination is their responsibility. The researchers, the consulting doctor, and George Mason University are not responsible for any examination or treatment that they undertake based on this information. The images in this study were not designed for clinical purposes and will not be made available for help with a diagnosis.

Avoidance of Pregnancy

The fMRI procedures used in this study may be unsafe for unborn babies and infants. If you are already pregnant or are breast feeding, you cannot participate in this study. If you, as a subject of study, are a woman with child bearing potential, you must agree to avoid pregnancy during the periods of this study that involve MRI procedures. If you do become pregnant during the study, you should immediately notify Dr. [INSERT NAME

OF PI] at [INSERT PHONE NUMBER OF PI]. All females with child bearing potential are required to consent to taking a pregnancy test before every MRI scan. GMU is required by law to inform the parent or guardian if it is discovered that a female under the age of 18 is pregnant.

Minimizing Potential Risks

All paper records will be maintained in locked files in an area that is kept locked when staff members are absent. Data obtained from interviews or screening that is stored on the computer will be password protected.

Precautions have been taken at the GMU Krasnow Imaging facility to map the peripheral fringe magnetic fields to comply with the accepted levels in unrestricted corridors and outside areas. All hallways and public areas surrounding the MRI facility are safe for general access. Warnings of the dangers of metal objects getting into strong magnetic fields are posted where necessary. All research staff are trained in MRI safety and attend a required refresher course once per year.

All females of child bearing potential will be required to take a pregnancy test as part of the screening process before entering the scanner. If the subject is under the age of eighteen and found to be pregnant, the researchers will inform the parent or legal guardian.

Justification for Risks and Anticipated Benefits

Subjects will not benefit directly from participation in this study. The results of these experiments might provide us with a better understanding of the neural mechanisms of [STUDY DESCRIPTOR]. Because the procedures used are non-invasive, the risk/benefit ratio is low.

II. Language for GMU HSRB-approved Consent Form:

RESEARCH PROCEDURES

This research is designed to look at [STUDY DESCRIPTOR]. Taking part in this will take [INSERT TIME VALUE] hours of your time. Some people work faster than others. [INSERT TIME VALUE] hours is the most time it will take you if you volunteer.

If you agree, you will play computer games that ask you to [DESCRIBE STUDY]. These games will take about an hour and a half to play. After that, you may be invited to take part in another session. In that session, you will play computer games while we

record how you play and take pictures of your brain using functional magnetic resonance imaging (fMRI). This session will take about [INSERT TIME VALUE] minutes.

If you are eligible, you will have a tour of the MRI rooms. We will use the MRI machine to take pictures of your brain while you play games. These games may involve [STUDY DESCRIPTOR]. The fMRI is able to see changes in oxygen concentration in the areas of the brain that help you play these games. We may have to repeat a scan if we have a technical problem.

If you are uncomfortable, we will stop, and you will be removed from the machine. The actual time in the MRI machine will take up to one hour. We will rehearse the games with you before you play in the MRI machine.

The researchers for this project do not perform medical diagnosis. The MRI scans are not set up to find problems. The researchers are not responsible for a failure to find an existing problem if one is shown on your MRI scans. But, every once in awhile, the researcher may notice something on an MRI scan that seems abnormal. When this happens, a specialist will be consulted as to whether this needs further investigation. Then, the researcher would contact you to inform you of the finding. The decision to contact your doctor for follow-up is your responsibility. The researchers, the consulting doctor, and George Mason University are not responsible for any exam or treatment that you may seek based on this information. The images in this study were not designed for clinical purposes and will not be made available for help with a diagnosis.

RISKS

There is a possible risk of some frustration while performing the computer games because they become more difficult to play.

The MRI scanner is shaped like a tube and makes some people feel claustrophobic. The machine also makes noise, which makes some people anxious. You will wear ear plugs and head phones to protect your ears from the noise. There are no known long-term effects from MRI scanning. Your head will be held still in a foam cushioned holder, which may feel a little stiff.

People with any metal clips or metallic implants, infusion pumps, cardiac pacemakers, defibrillators, or some braces cannot have MRI scans. All metal or magnetic objects must be removed before entering the MRI scan room (for example, watches, coins, jewelry, credit cards). You will not be sedated at any point during this study.