H-36039- NEURAL MECHANISMS OF OPTIMAL MULTISENSORY INTEGRATION

Background

You are invited to take part in a research study. We are interested in understanding how the human brain works and we require volunteers to participate in our experiments to help us answer this question. We will use MRI to measure your brain activity. Please read this information and feel free to ask any questions before you agree to take part in the study. Your participation is voluntary and you may withdraw from the study at any time. Your participation or withdrawal from the study will not affect your grades or employment.

Purpose

This study is being performed to help scientists understand how the human brain processes auditory (sounds) and visual (pictures and videos) information, especially as it pertains to understanding speech.

Procedures

The research will be conducted at the following location(s): Baylor College of Medicine.

fMRI is very similar to magnetic resonance imaging procedures (MRI) that you may already be familiar with. In both MRI and fMRI, subjects lay inside an MR scanner and images of their brain are collected (no needles or injections are required). The only difference between the two is that in regular MRI, subjects may rest with their eyes closed. In fMRI, subjects must stay awake and look at pictures or listen to sounds. In this study, you will see videos of people saying words or syllables. The expected duration of your participation is the time that you will be asked to lie inside the MRI scanner and will be about one hour. You will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is gathered during this study will remain confidential to every extent of the law. A special code will be used to identify you in the study and only the investigator will know your name.

Potential Risks and Discomforts

None of the experiments require needles or injections (they are non-invasive). Patients with cardiac pacemakers, intracranial aneurysm clips, or other implanted metallic devices may not take part in MRI experiments. Welders and other metal workers may be at risk for eye injury because of small metal fragments in the eye, of which they might not be aware. Some patients may experience fear of enclosed spaces (claustrophobia) for a short time while in the MRI scanner. You will be provided with hearing protection to reduce the noise and increase your comfort during scanning. If it is difficult for you to tolerate the confinement within the scanner or the noise you will be taken out immediately. Current experience shows that there are no risks or adverse effects from the magnetic fields used in MRI; any risks that do exist are similar to those of talking on a cell-phone. There is a risk of loss of confidentiality. To minimize this risk, all of your information will be coded to protect your confidentiality. When we code your health information, we remove your name and identifying information and replace it with a code. Only we have the list that links the code to your name. We will keep that safe and private.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study.

Potential Benefits
You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand how the brain processes sounds and pictures; this may help patients with brain disorders get better care in the future..

Alternatives
You may choose to not participate in this study.

Subject Costs and Payments
You will not be asked to pay any costs related to this research.

You will be paid for your inconvenience, $40 in cash for each MRI session in which you participate.

Subject's Rights
Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

Your Health Information

We may be collecting health information that could be linked to you (protected health information). This protected health information might have your name, address, social security number or something else that identifies you attached to it. Federal law wants us to get your permission to use your protected health information for this study. Your signature on this form means that you give us permission to use your protected health information for this research study.

If you decide to take part in the study, your protected health information will not be given out except as allowed by law or as described in this form. Everyone working with your protected health information will work to keep this information private. The results of the data from the study may be published. However, you will not be identified by name.

People who give medical care and ensure quality from the institutions where the research is being done, the sponsor(s) listed in the sections above, representatives of the sponsor, and regulatory agencies such as the U.S. Department of Health and Human Services will be allowed to look at sections of your medical and research records related to this study. Because of the need for the investigator and study staff to release information to these parties, complete privacy cannot be

guaranteed. There may be a risk of loss of confidentiality by participating in this study.

The people listed above will be able to access your information for as long as they need to, even after the study is completed.

If you decide to stop taking part in the study or if you are removed from the study, you may decide that you no longer allow protected health information that identifies you to be used in this research study. Contact the study staff to tell them of this decision, and they will give you an address so that you can inform the investigator in writing. The investigator will honor your decision unless not being able to use your identifiable health information would affect the safety or quality of the research study.

The investigator, MICHAEL S BEAUCHAMP, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: Michael Beauchamp at 301-768-8758 at any time.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date