THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

Neural Mechanisms of Optimal Multisensory Integration & Mechanism of Rapid Object Recognition in Human Ventral Temporal Cortex & Testing causal inference models of auditory, visual and vestibular behaviors

HSC-MS-05-0516

INFORMED CONSENT TO JOIN A RESEARCH STUDY

Principal Investigator: Michael S. Beauchamp, Ph.D.

INVITATION TO TAKE PART

You are being invited to take part in a research project called, **"Neural Mechanisms of Optimal Multisensory Integration & Mechanism of Rapid Object Recognition in Human Ventral Temporal Cortex & Testing causal inference models of auditory, visual and vestibular behaviors"** conducted by Dr. Michael Beauchamp.

Your decision to take part is voluntary and you may refuse to take part, or choose to stop taking part, at any time. A decision not to take part or to stop being a part of the research project will not change the services that are available to you from UT Physicians or affect your future care. It will also not affect your grades or employment.

You may refuse to answer any questions asked or written on any forms. This research project has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston as Protocol Number: HSC-MS-05-0516. Dr. Beauchamp will be glad to answer any questions regarding the study at any time (713-500-5978).

DESCRIPTION OF RESEARCH:

PURPOSE:
This study is being performed to help understand how the human brain processes auditory (sounds), visual (pictures), and somatosensory (touch) information. The study will enroll up to 350 subjects at this location. The National Institutes of Health (part of the United States government) are paying for this study to be completed.

PROCEDURE:

Taking part in these studies may require one to three visits. Some of these visits may include written or computerized behavioral tests, or tests of brain function, including functional magnetic resonance imaging (fMRI) and near-infrared spectroscopy (NIRS).

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. If your test involves fMRI, you will be asked to lie inside the MRI scanner for between half an hour and one and a half hours (you may get out of the scanner at any time).

NIRS is a brain imaging test that uses light to measure blood volume. In this method, you will sit in a comfortable chair while a dim red light (about a thousand times dimmer than a standard light bulb) will shine onto your head, and the reflected light will be measured while you see pictures, hear sound, or feel touches.

TIME COMMITMENT:

Taking part in these studies may require one to three visits. Each visit may take between 15 minutes and 2 hours.

BENEFITS:

You may receive no direct benefit from being in this study; however, your taking part may help us to understand how the brain works. This may help patients with brain disorders get better care in the future.

RISKS AND/OR DISCOMFORTS:

None of the experiments require needles or injections (they are non-invasive). Possible risks, discomforts, or inconveniences to you are as follows.

MRI: 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 wear a set of ear plugs 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.

NIRS: There are no risks, discomforts or inconveniences associated with NIRS, other than the requirement to sit still.

ALTERNATIVES and STUDY WITHDRAWAL:

Your decision to take part is strictly voluntary and you may refuse to take part, or to stop being in the study at any time.

IN CASE OF INJURY:

If you suffer any injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, all needed facilities, emergency treatment and professional services will be available to you, just as they are to the community in general. You should report any injury to Dr. Beauchamp at 713-500-5978 and to the Committee for the Protection of Human Subjects at (713) 500-7943. You will not give up any of your legal rights by signing this consent form.

COSTS, REIMBURSEMENT, AND COMPENSATION:

No costs are involved to you, and you will be paid for your inconvenience. Because these are ongoing experiments, you may be asked to return for additional scan sessions but you do not have to. For your inconvenience, you will be paid $10 for each behavioral experiment in which you take part, $40 for each MRI session in which you participate and $10 for each NIRS experiment in which you participate.

If you should receive a bill that you believe is related to your taking part in this research project, please contact, Dr. Beauchamp at (713) 500-5978.

If you are going to receive payment for taking part in this study, you will be asked to complete a W-9 form that will be sent to the UTHealth accounting department. If you receive more than $600 from UTHealth for being in research studies this year, you will be given a 1099-Misc form for tax reporting purposes.

CONFIDENTIALITY:

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 number will be used to identify you in the study and only the investigator will know your name. No protected health information will be gathered or used for this study.

QUESTIONS:

Dr. Beauchamp will be glad to answer any further questions at any time. Please contact Dr. Beauchamp at (713) 500-5978 to discuss problems, voice concerns, obtain information, and offer input in addition to asking questions about the research.

SIGNATURES:

Taking part in this study is your choice. If you sign this form it means that you wish to take part in this research study. Sign below only if you understand the information given to you about the research and choose to take part. Make sure that any questions have been answered and that you understand the study. If you have any questions or concerns about your rights as a research

subject, call the Committee for the Protection of Human Subjects at (713)500-7943. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date/Time

_____
Printed Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date/Time

CPHS STATEMENT:
This study (HSC-MS-05-0516) has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at (713) 500-7943.