THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER - HOUSTON

Language Development in Children Studied Using fMRI and NIRS

HSC-MS-10-0582
PARENTAL CONSENT FOR CHILD TO JOIN A RESEARCH STUDY (ages 5 – 12)
Principal Investigator: Michael S. Beauchamp, Ph.D.

INVITATION TO TAKE PART

Your child is being invited to take part in a research project called, **"**Language Development in Children Studied Using fMRI and NIRS **"** conducted by Dr. Michael Beauchamp, of the University of Texas Health Science Center. For this research project he will be called the Principal Investigator or PI.

Your child is being invited to join this research study because they are a healthy child between the ages of 5 and 12. Your child's 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 to take part being a part of the research project will not change the services that are available to your child from UT Physicians or affect your child's future care.

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 HSC-MS-10-0582.

DESCRIPTION OF RESEARCH:
PURPOSE:
This study is being performed to help find out how the human brain processes language. This study is taking place at one location and will be enrolling a total of 50 people. The university is paying for this study to be completed.

PROCEDURE:
Your child will have their brain activity measured with one of two techniques, fMRI or NIRS. Before your child undergoes imaging he/she will be required to remove any metal objects from his/her body. 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 child's test involves fMRI, your child will be asked to lie inside the MRI scanner for between twenty minutes and one hour (your child 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, your child 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 child's head for between 5 minutes and 30 minutes, and the reflected light will be measured.
Your child will see videos of people talking (with or without sound) or hear recordings of people talking. By comparing brain activity in different conditions, we will be able to learn how children's brains process language stimuli.

TIME COMMITMENT:
Taking part in these studies will require one visit. Each visit may take between 15 minutes and 1 hour.

BENEFITS:
Your child may receive no direct benefit from being in this study; however, your taking part may help us to find out how the brain works. This may help patients with brain disorders get better care in the future. Your child may receive an MRI of the brain while taking part of this study. While this study is not designed to find brain abnormalities, if we discover one (known as an incidental finding) we will refer you to a neuroradiologist or appropriate clinical practitioner.

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. 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 MRI or NIRS, other than the requirement to sit still.

ALTERNATIVES
The only alternative is for your child not to take part in the study.

STUDY WITHDRAWAL:
Your child's decision to take part is strictly voluntary and you may refuse to take part, or to stop being in the study at any time. If your child is unable to complete the test, for instance because they are uncomfortable inside the MRI scanner, then the PI may decide that your child should be withdrawn from the study.

IN CASE OF INJURY:
If your child suffers 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 your child, 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 take part, and $40 for each NIRS experiment in which you take part. Your child will receive a small token gift of their choosing valued at $10.

If you receive a bill that you believe is related to your taking part in this research study, please contact Dr. Beauchamp at 713-500-5978 with questions.

CONFIDENTIALITY:
Your child will not be personally identified in any reports or publications that may result from this study. Any personal information about your child that is gathered during this study will remain confidential to every extent of the law. A special number (code) will be used to identify your child in the study and only the investigator will know your child's name. No protected health information will be gathered or used for this study. All data will be stored in a secure computer facility that is only accessible with a password.

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. You may also call the Committee if you wish to discuss problems, concerns, and questions; obtain information about the research; and offer input about current or past participation in a research study. 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 Child

_____
Printed Name of Parent or Legal Guardian

_____ _____
Signature of Subject Date/Time

_____
Printed Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date/Time

CPHS STATEMENT:
This study (HSC-MS-10-0582) 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.