

Please do not sign this form. We will review it with you at your first visit.

Protocol Title: ACE: Brain Mechanisms for Language Processing in Adolescents with Autism Spectrum Disorders (ASD)

Principal Investigator: Helen Tager-Flusberg

Description of Subject Population: Adolescents - age 14 to 17 years

Version Date: Jan. 2013

Research Consent Form

Parent/Guardian Consent

Introduction

The purpose of this form is to provide you with information about taking part in a research study. Your child is invited to take part in a research study investigating brain differences related to processing sounds and initiating speech in adolescents with autism spectrum disorders (ASD) compared to adolescents who do not have ASD. If you have any questions about the research or any portion of this form, please ask us. If you decide to take part in this research study with your child we will ask you to sign this form. We will give you a copy of the signed form.

The person in charge of this study is Dr. Helen Tager-Flusberg. Dr. Helen Tager-Flusberg can be reached at 617-358-5919 or via email at htagerf@bu.edu. We will refer to this person as the “researcher” throughout this form.

Why is this study being done?

The purpose of this study is to learn why some people with ASD do not acquire spoken language. In this research study we compare adolescents with ASD to typical adolescents without ASD in their performance on our research activities and we investigate brain differences related to processing sounds and initiating speech. We hope that this study will contribute to improving language-related interventions for people with ASD, and to enhancing our understanding of the brain mechanisms involved in processing sounds and in acquiring speech.

Your family is being asked to take part in this study because your child is between the ages of 14 to 17 years, or is over 18 years but cannot provide written consent for themselves

About **160** subjects will take part in this research study at Boston University and Massachusetts General Hospital.

This research is funded by the National Institutes of Health.

How long will I take part in this research study?

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We expect that your child will be enrolled in this research study for approximately one year. During this time, we will ask you to make between 3 and 8 study visits, some of which will take place at Boston University (BU), and others at Massachusetts General Hospital (MGH).

What will happen if I take part in this research study?

If you agree to take part in this study with your child, we will ask you to sign the consent form before we do any study procedures.

Prior to the study you will have been asked to complete a telephone interview.

The first research session will take place at Boston University and will take approximately 3-4 hours to complete. Depending on the adolescent, these activities may require one or more visits. At the first visit to our BU lab we plan to conduct an inclusive assessment following procedures and guidelines developed by the National Institute of Health Working Group on Assessing Minimally Verbal School-aged Children with ASD.

Assessment measures will be divided into behavioral and experimental, and assessment time will alternate with breaks, snacks, visits with parents, etc. Adolescents will be tested in a room in close proximity to their parents and often with the parent present or observing through a one-way mirror.

Behavioral Assessments

During the first lab visit your child will be given several behavioral tests by trained staff, which will primarily involve looking at books, talking and playing some games with the researchers. This should take a total of 3-4 hours and may need to be split over multiple visits.

Experimental Assessments

Following the completion of standardized assessments, the next 2-3 study visits will include experimental assessments, and each visit will last about 2 hours. The following experimental assessments will be conducted:

Eye-tracking measures. Your child will be seated in front of a computer monitor and images or videos will be displayed on the screen while a small camera embedded in the monitor records where your child is looking on the computer screen, as he/she is listening to auditory messages (e.g., words, sounds). We will examine your child's visual attention monitoring during listening activities as a measure of comprehension. These measures will be collected at BU and should take about 20 minutes.

Electrophysiology methods. We will record your child's electrical brain activity (electroencephalogram or EEG) while they watch a video and listen to sounds. An EEG is a test that measures and records the electrical activity of your brain. To record your child's brain

[Type text]

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activity we use recording electrodes. The electrodes are inside of small sponges, which are held together in a cap made of stretchable material. The sponges are placed in salt water with a small amount of baby shampoo to get them wet, and the cap is then placed on your child's head. There is a wire attached to each sensor. The wires connect to a computer and the computer records the brain's electrical activity on the screen. We will measure event-related potentials (ERPs) as children are presented with auditory stimuli played through speakers and videos. We will also look at their ability to understand speech and non-speech sounds by recording the brain's electrical activity while listening to sounds. These measures will be collected at BU and should take about 45 minutes.

Magnetic Resonance Imaging (MRI) methods. A MRI is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. During the MRI, we will ask your child to lie still on a table that slides into a tunnel-shaped machine. To help your child get accustomed to lying in an MRI machine, he/she will practice in a "mock scanner", that looks and feels just like the real MRI scanner. The MRI machine is slightly wider than the person's body. The MRI machine makes loud noises as it take pictures and your child will be given earplugs to reduce the noise. Your child will be able to hear and speak to the research staff at all times during the MRI procedures. We can stop the procedure at any time, if necessary. Overall the MRI will take about 20 minutes including the preparation time and will take place at MGH.

For the MRI part of the study additional screening will take place at MGH. You will be given a separate consent form to read and to sign at MGH.

Overall, completion of all the study activities will take between 3 and 8 visits, or between 10 and about 15 hours of research activities for each subject over the course of the study.

Videotaping

We would like to videotape your child during this study. If your child is videotaped it may be possible to identify them in the video. We will store these tapes in a locked cabinet and only approved study staff will be able to see the tapes. We will label these tapes with a code instead of your child's name. The key to the code connects your child's name to their videotape. The researchers will keep the key to the code in a password-protected computer/locked file and they will be stored for five years following the end of the study.

Do you agree to let us audio/videotape you during this study?

_____ YES _____ NO _____ INITIALS

Storing Study Information for Future Use

[Type text]

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We would like to store your child’s study information for future research related to children with ASD. We will label all of the study information with a code instead of your child’s name. The key to the code connects your child’s name to their study information. The researchers will keep the code in a password-protected computer/locked file.

Do you agree to let us store your child’s study information for future research?

_____YES _____NO _____INITIALS

Sending Study Information to Research Collaborators Outside Boston University

Due to the size of the funding received for this study we are collaborating with institutions outside of Boston University. We will send your child’s study information to research collaborators at outside sites. We will label all study information with a code instead of your child’s name. The key to the code connects your name to the study information. The researchers will keep the key to the code here at Boston University and will not share it with our research collaborators. Nobody outside of Boston University will know which study information is yours. Data without identifiers (de-identified) from this research study will also be sent to the National Database for Autism Research (NDAR), as required by our funding and research agreements.

How Will You Keep My Study Records Confidential?

We will keep the records of this study confidential as all study documents will be identified by a unique study ID. The unique study ID will be linked to the subject via a mastercode. Access to the mastercode will be limited to the PI and senior research staff and the key to the mastercode will be stored separately from the study data in a secure password protected computer at Boston University. We will make every effort to keep your records confidential. However, there are times when federal or state law requires the disclosure of your records.

We will store your/your child’s study records for five years following the end of the study.

The results of this research study may be published or used for teaching. We will not put identifiable information on data that are used for these purposes.

Reporting child abuse, if applicable: If, during your participation in this study, we have reasonable cause to believe that child abuse is occurring, we must report this to authorities as required by law. The researchers will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court might demand the release of identifiable research information.

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Reporting Suicidal Risk: If, during your participation in this study, we have reason to believe that your child is at risk for being suicidal or otherwise harming themselves, we are required to take the necessary actions. This may include notifying your doctor, your therapist, or other individuals. If this were to occur, we would not be able to assure confidentiality.

As part of this study, you will be asked to provide information for your child's medical record.

The following people or groups may be able to see this information: The Researcher and any member of his/her research team

- The Institutional Review Board at Boston University. The Institutional Review Board is a group of people who review human research studies for safety and protection of people who take part in the studies.
- The sponsor or funding agency for this study
- Federal and state agencies that oversee or review research

If some law or court requires us to share the information, we would have to follow that law or final ruling

Study Participation and Early Withdrawal

It is your choice as to whether your child takes part in this study. You are free to decide you do not want your child to take part and you are free to withdraw at any time for any reason. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. If you decide to withdraw from this study, the information that you have already provided will be kept confidential.

The researcher may take you out of this study without your permission. This may happen because:

- Your child does not meet all the inclusion criteria to move onto the next project
- The researcher thinks it is in your child's best interest
- You can't make the required study visits
- Other administrative reasons

Future Contact

We may like to contact you in the future either to follow-up to this study or to see if you are interested in other studies taking place at Boston University.

Do you agree to let us contact you in the future?

_____ YES _____ NO _____ INITIALS

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What are the risks of taking part in this research study?

MRI Risks

There are no known harmful effects from the strong magnetic field used for MRI. But the magnet is very powerful. The magnet may affect pacemakers, artificial limbs, and other medical devices that contain iron. The magnet will stop a watch that is close to the magnet. Any loose metal object has the risk of causing damage or injury if it gets pulled toward the strong magnet.

An MRI should not take place if your child has claustrophobia (fear of small spaces). The top and sides of the machine will be very close to the body. Because of this, your son/daughter may feel anxious while inside the MRI machine. If you feel your son/daughter is in distress during the procedure you can request to stop the MRI at any time. If your son/daughter feels anxious during the procedure, they can request to stop the MRI at any time.

If your daughter is pregnant or suspects she is pregnant, the study staff should be informed before the MRI examination. Although there is no known risk of using MRI in pregnant women, the safety of MRI during pregnancy has not been established, so women who are pregnant or think that they may be pregnant cannot take an MRI for this study.

We are doing the MRI in this study to answer research questions, not to give medical care. This MRI is not the same as one that your own doctor would order. It may or may not show problems that would be found on a regular MRI.

If we do see something that looks like a medical problem, we will ask a radiologist (a doctor who specializes in looking at MRI scans results) to review the results. If the radiologist thinks there might be a problem, we will tell you and help you get follow-up care.

If the radiologist thinks that there may be a medical problem, but it turns out that there is not, we may have caused you to worry unnecessarily.

Risks of Completing Tasks

Your child may get tired during the study activities and they can rest at any time.

Questionnaire/Survey Risks

If you or your child feels distressed during a questionnaire/survey you can ask the interviewer to take a break or stop the interview at any time. You and your child do not have to answer any questions that make you feel uncomfortable.

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Loss of Confidentiality

The main risk of allowing us to use and store your information for research is a potential loss of privacy. We will protect your privacy by labeling your information with a code and keeping the key to the code in a password-protected computer.

Are there any benefits from being in this research study?

There are no direct benefits to you or your child. In the long term, the information gathered by the Project will help us to understand why some children with ASD fail to acquire spoken language. Ultimately, we expect this information to contribute to changes in clinical practice and advances in treatment for children and adolescents with ASD, especially those who are minimally verbal.

What alternatives are available?

You may choose not to take part in this research study.

Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your medical care will not be affected. If you would like to stop taking part in this research you should let us know.

Will I get paid for taking part in this research study?

We will pay for your parking and transportation while you are taking part in this study.

A gift certificate averaging \$15 will be given to participants at each visit. The participant will receive \$50 for completing the MRI activities. If your child completes all the study assessments we will pay an additional \$50 at the end of the study .. If your child does not complete the entire study, we will pay you \$15 for each visit that your child completes.

What will it cost me to take part in this research study?

There are no costs to you for taking part in this research study.

What happens if I am injured as a result of participating in this research study?

If you are injured as a result of taking part in this research study, we will assist you in getting medical treatment. However, your insurance company will be responsible for the cost. Boston University does not provide any other form of compensation for injury.

If I have any questions or concerns about this research study, who can I talk to?

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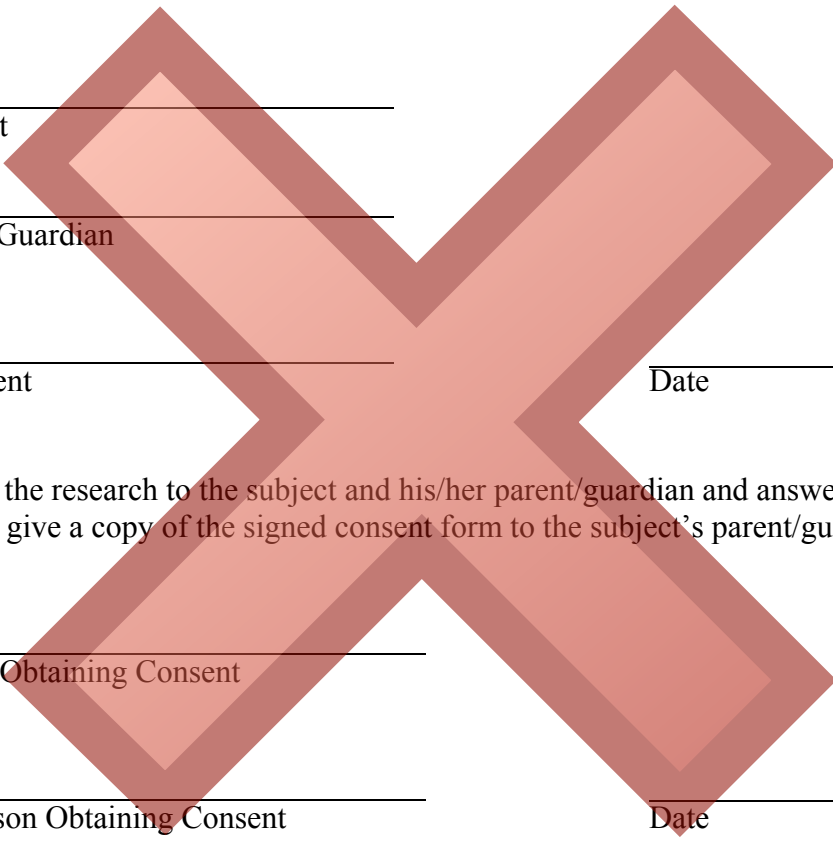
You can call us with any concerns or questions. You may contact the Project Principal Investigator, Dr. Helen Tager-Flusberg, at 617-358-5919 or htagerf@bu.edu. If you have questions about your rights as a research subject or want to speak with someone independent of the research team, you may contact the Boston University IRB directly at 617-358-6115.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. I have been given the chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in the study. I have been given a copy of this form.

Please do not sign this form. We will review it with you at your first visit

SIGNATURE



Name of Subject _____

Name of Parent/Guardian _____

Signature of Parent _____ Date _____

I have explained the research to the subject and his/her parent/guardian and answered all their questions. I will give a copy of the signed consent form to the subject's parent/guardian.

Name of Person Obtaining Consent _____

Signature of Person Obtaining Consent _____ Date _____

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