CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

CROSS-SECTIONAL COHORT – Ages 0 – 17

STUDY TITLE: PEDIATRIC FUNCTIONAL NEUROIMAGING RESEARCH NETWORK

SPONSOR NAME: National Institute of Child Health and Human Development

SPONSOR STUDY NUMBER: HHSN275200900018C

INVESTIGATOR INFORMATION:

Jennifer Vannest, PhD	513-636-6959
Principal Investigator Name	Telephone Number 24 hr Emergency Contact

Subject Name: _____ Date of Birth: _____/_____/____

Throughout this document, references to "You" stand for the parents or legal guardians of the research study subject if the subject is under 18 years of age or otherwise unable to legally give informed consent to participate in the research study. The signature(s) at the end will clarify that the research study subject is signing this consent form via a legal guardian or legal personal representative.

INTRODUCTION:
You and your child have been asked to participate in a research study. Before agreeing to participate in this study, it is important that you read and understand the following explanation. It describes, in words that can be understood by a lay person, the purpose, procedures, benefits, risks and discomforts of the study and the precautions that will be taken. It also describes the alternatives available and the right to withdraw from the study at any time. No guarantee or assurance can be made as to the results of the study. Also, participation in the research study is completely voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw from the study at any time without penalty.

WHY IS THIS RESEARCH BEING DONE?
The purpose of this research study is to establish what areas of the brain are normally used during listening, speaking, or paying attention. The knowledge and experience gained from imaging language functions in your brain may be helpful in the future in better understanding how brain diseases and their treatment affect the brain and its function.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

Your child is being asked to take part in this research study because s/he is between the ages of 0 and 18 with no history of personal mental illness or head trauma and also no history of mental illness in your immediate family. Another reason s/he have been asked to participate is that s/he has average to above average grades (C- or above) in a general education classroom at school.

WHO SHOULD NOT BE IN THE RESEARCH STUDY?

Your child should not participate in this study if s/he has an electronic implant such as a pacemaker or neuro-stimulator since the magnet might affect them. It is also important that you inform the MRI technologist if your child has any metallic implants such as orthopedic pins or plates, including orthodontic braces. Finally, your child should not participate if s/he was born more than four weeks early and/or had a birth weight less than the 25th percentile.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for approximately one year, or the amount of time it takes for you to come in for all of the visits asked of you. We will ask you to come in for at least two visits, with most participants coming in for three or more. The research study will continue until September of 2014, and this consent, unless you choose to withdraw it, shall remain in effect until the end of the research study, in case we need any more information from you after you've participated. The researcher may decide to take you off this research study at any time.

Though your active participation will conclude by September of 2014, this consent form also authorizes us to enter your data into a future repository for an indefinite amount of time. All personal health information will be removed before your data is included in this repository/database.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is sponsored by The National Institute of Child Health and Human Development. The study is directed by Dr. Jennifer Vannest.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 200 people will take part in this study at Cincinnati Children's Hospital Medical Center.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

If you agree to participate in this study, the following will happen:

1. You will talk on the phone with the study staff and answer some questions. These questions help us decide who is going to be in the study.

2. If your child is chosen to be in the study, you may be asked to come in to our Imaging Research Center for a visit before your child's scan visits. This is dependent on your child's age, prior experience with MRI, etc. At this visit, the study staff will go over all the details of the study with you and your child and show you around the magnet.

3. Also, either at this desensitization visit or on the day of the first scan, your child will have a neurological examination, where a neurologist will check your child's reflexes, balance, vision and other functions. The neurologist will NOT stick your child with any needles.

4. When you go home after your first visit, the study staff will send with you a video giving you more information about the study and showing you a real person going through a similar scan so that you and your child can see what it will be like. Also, if your child is younger and might be frightened by the noises of the magnet, the study staff will send home a CD with those noises so that your child can get used to them. If you do not have a visit before the day of the first scan, these materials will be mailed to you.

5. When you come in on the day of the first scan, your child will get a hearing test. S/he will be asked to listen to some noises in a pair of headphones and communicate with the study staff about what s/he hears.

6. At each of the two scan visits, after all metal objects and jewelry are removed from your child's body and clothing, s/he will be taken into the magnet room and will lie down on a movable table that slides into the 3 Tesla MRI scanner.

7. During one or both of these MRI exams, we may put an EEG cap on your child's head. This cap looks like a swimmer's cap and will involve the application of conductive gel. This conductive paste can easily be washed out of your child's hair. EEG measures electrical activity from your child's brain ("brain waves") and lets the researchers know if your child is awake, asleep, or drowsy during the scan. When the scan is complete, the EEG cap will be removed.

8. Your child's head will be surrounded by a special antenna (RF coil), which picks up the radio signals used to make the images of his/her brain. While s/he is in the magnet, s/he will be in constant contact with the technologist performing the examination outside the magnet room through a closed circuit television camera and an intercom system.

9. If your child is over the age of seven, s/he will be asked to perform several simple tasks at specific times while pictures of the brain are made by the magnet. These tasks will include tapping the fingers, looking at pictures, and hearing words and sounds. S/he will be given instructions over the intercom telling him/her when to perform each task and when to rest.

10. Brain activity in response to these sounds will be recorded in the pictures of your child's brain. The total time spent in the scanner will not exceed 75 minutes.

11. The doctors will look at the scans of your child's brain immediately. If the scans are of poor quality due to motion of your head or technical problems, s/he may be asked to repeat one or more scans, thus prolonging the examination past the 75 minute limit. If s/he is not comfortable in the scanner at any time s/he can contact the technologist

using the intercom or alarm button and ask to be removed from the scanner.

12. The pictures of your child's brain activity, as well as the pictures of his/her brain's structure will be used for the study.

13. If the first scan visit is successful, we will ask you and your child to come back for a second scan very soon after the first scan visit. We want your child to come in two times so that we can get as much information about his/her brain as possible without making him/her stay in the scanner too long during any individual MRI session.

14. In addition to the MRI scan, we may also administer tests of intelligence, language and other skills as part of this research study. For these tests, we will bring your child into the Imaging Research Center one more time on a different day than the scan. This will be done by a psychologist or another study staff member outside of the MRI scanner in a testing room. The results of these tests will be reviewed by a clinical psychologist and will be made available to you and your child.

15. If your child is over the age of 6, s/he may also be asked to complete a questionnaire describing the development of her/his body on a scale of 1-5, compared to photographs of normal development through puberty.

16. On your first visit, we will ask you for information about who your primary care doctor is. A radiologist will look at the images we take to make sure that there are no concerns that would need follow up with a medical doctor. If anything is found, we will get in touch with your doctor from the information you gave us and let she or he know.

Data acquired from this study may be deidentified and used for future research that may not be directly related to this research study.

This research includes children and is subject to Title 45, code of Federal Regulations, Part 46, Subpart D (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd)

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

There are no known biological risks to MRI imaging. The main discomforts involved in MRI include anxiety and potential claustrophobia. The children enrolled in this study are carefully instructed as to what to expect. The EEG cap may also cause some mild discomfort from the placement of the electrodes against the scalp.

If you become uncomfortable and do not wish to proceed, the examination will be immediately terminated. Your child will be screened for any metal objects that might become dislodged by the magnet and produce harm as a projectile. These will all be removed prior to entering the scanner room. Your child will not be given any sedation in order to perform this study.

If your child is a female of childbearing potential, she will not participate in this research study if there is a possibility that she could be pregnant. You agree to inform the investigators if you or

your child have any reason to suspect a pregnancy at the time of the MRI scan. If your child is over the age of nine, she will be verbally screened for pregnancy by a member of our study staff.

There may be unknown or unforeseen risks associated with study participation.

ARE THERE DIRECT BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

This research is part of a study that will help us to see how and where the brain normally functions when language and attention are used. The results of this study may improve our understanding of language development and representation in the brain, and thus affect the treatment of neurological diseases, which affect language such as epilepsy or brain tumors. However, this research will not have any direct benefit to your child as a participant, but will help our understanding of language development and language and attention disorders in the future.

WHAT OTHER CHOICES ARE THERE?

You may refuse to enroll in the study. Entry into the study will in no way affect your child's care at Children's Hospital.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Every effort will be made to maintain the confidentiality of your medical and research information ("Protected Health Information" or "PHI"), consisting of your child's name, your name, your child's primary care doctor's name, address and phone number, your address(es), telephone number(s), date of birth, dates of study related hospital visits, your child's medical record number, and portions of your child's medical record including neurological test results, laboratory results, and radiology reports and pictures.

Protected Health Information is defined as health information, whether verbal or recorded in any form (such as on a piece of paper or entered in a computer), that identifies you (or in this case, your child) as an individual or offers a reasonable basis to believe that the information could be used to identify you.

By signing this consent form you are giving permission for representatives of the Cincinnati Children's Hospital Medical Center ("CCHMC"), the Investigator and CCHMC employees involved with the research study including the Institutional Review Board and the Office for Research Compliance, and any sponsoring company or their appointed agent as well as the NIH's to be allowed to inspect sections of your child's medical and research records related to this study.

The information from the research study may be published; however, your child will not be identified in such publication. The publication will not contain information about your child that would enable someone to determine your child's identity as a research participant without your authorization.

1. Cincinnati Children's Hospital Medical Center and/or the Investigator will take the following precautionary measures to protect your privacy and confidentiality of your child's research and/or medical records: All pictures obtained from the MRI scan and used for research purposes will be coded, and will not contain your child's name, medical record number, or any other protected health information belonging to you.
2. Electronic and hard-copy records containing your child's PHI will be password protected or locked at all times, with only authorized, study-related personnel having access to them.
3. Reports or publications generated as a result of this research will not contain any of your child's personal identifiers.

A copy of this consent form will be included in your child's medical research record. Your child will be registered in the Cincinnati Children's Hospital Medical Center's computer system as a research subject which may be beneficial for future clinical care.

The Privacy Act is applicable to the information that will be collected through participation in this study (see Privacy Act System of Records Notice (SORN) #09-25-0200, http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm)

The authority to collect this information is under 42 USC Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) – 42 USC 285g.

WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

To further protect your child's privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the investigators may not disclose information (for example by court order or subpoena) that may identify you or your child in any federal, state or local, civil, criminal, administrative, legislative or other proceedings. Disclosure will be necessary, however, upon request of the DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself, your child or his/her involvement in this research.

Even with the Certificate of Confidentiality, the investigators continue to have ethical and legal obligations to report child abuse or neglect and to prevent you or your child from carrying out any threats to do serious harm to yourself, his/herself or others. If keeping information private would immediately put you, your child, or someone else in danger, the investigators would release information to protect you, your child, or another person.

USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

The Protected Health Information described in the section above will be used /disclosed for the purpose of research by CCHMC to the other persons or entities identified above.

"Use" of an individual's health information is defined as the sharing, examination or analysis (break down) of the information that is collected and maintained for the length of the research study. "Disclosure" of an individual's health information is defined as the release, transfer, providing access to, or to reveal in any other manner, the information outside the persons or entity holding the information as described in the section "How Will Information About You Be Kept Private And Confidential" in this consent form.

Once your or your child's Protected Health Information is disclosed, the information may be subject to re-disclosure and may no longer be protected by the federal privacy regulations.

AVAILABILITY OF INFORMATION?

All data gathered will be made available to you, as the parents/legal guardian, upon request. Any question or concerns may be directed to Dr. Jennifer Vannest or Dr. Scott Holland. With respect to information concerning your child's rights as a research subject, direct all questions to the IRB Chairman.

Jennifer Vannest, PhD
Imaging Research Center
Children's Hospital Medical Center
3333 Burnet Avenue, MLC 5033
Phone (513) 636-6959

IRB Chairman
IRB Committee
Children's Hospital Medical Center
Cincinnati, Ohio 45229-3034
(513) 636-8039

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

The cost of the functional MRI scanning will be paid from a Grant. There will be no charges to you or your child as a result of participation in this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

For each visit, you will be compensated $50 for your time and travel; as long as a reasonable attempt is made to cooperate with the MRI scanning and intelligence testing procedures. This means, you will receive $150 ($50 x 2 scan visits and $50 for intelligence testing visit).

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Your child's participation in this study is completely **voluntary**. You and your child may choose either to take part or not to take part in this research study. Your decision whether or not to participate will not result in any penalty or loss of benefits to you or your child and the standard medical care for your child's condition will remain available to him/her.

If you and your child decide to take part in the research study, you are **free to withdraw** your consent and discontinue participation in this research study at any time. Leaving the study will not result in any penalty or loss of benefits to you or your child.

You may revoke (choose to withdraw) this Authorization as provided under the Health Insurance Portability and Accountability Act of 1996 (HIPAA") at any time after you have signed it by providing Dr. Jennifer Vannest, Dr. Scott Holland, or their representatives with a written

statement that you wish to withdraw this Authorization. Your withdrawal of this Authorization will be effective immediately and your Protected Health Information can no longer be used/disclosed for research purposes by CCHMC and the other persons or entities that are identified in the "Use or Disclosure of Your Protected Health Information" section of this consent, except to the extent that CCHMC and/or the other persons or entities identified above have already taken action in reliance upon your consent. In addition, your child's Protected Health Information may continue to be used/disclosed to preserve the integrity of this research study.

The investigators will tell you about significant new findings developed during the course of the research and new information that may affect your child's health, welfare, or willingness to stay in this study.

If you are a CCHMC employee, your opportunities, rights, and benefits will NOT be jeopardized by your withdrawal of your child from or by your or your child's refusal to take part in this study.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

Nothing in this consent form waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

For further information about your rights, please see CCHMC Notice of Privacy Practices. A copy of the CCHMC Notice of Privacy Practices may be obtained from any patient registration area or online at www.cincinnatichildrens.org (From the internet page select in the following order: About Us, Corporate Information, HIPAA). You may also contact our Privacy Officer at 513-636-4707 to obtain a copy.

ABILITY TO CONDITION TREATMENT ON PARTICIPATION IN THIS STUDY

You have a right to refuse to sign this consent to use/disclose your Protected Health Information for research purposes. If you refuse to sign this consent, your rights concerning treatment, payment for services, enrollment in a health plan or eligibility for benefits will not be affected.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions about this research study or to report a research-related injury, you can contact the researcher **Dr. Jennifer Vannest** at 513-636-6959. Researchers are available to answer any questions you may have about the research at any time.

If you have general questions about your rights as a research participant in this research study, you can call the Cincinnati Children's Hospital Medical Center Institutional Review Board at 513-636-8039.

HIPAA AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH

INFORMATION FOR A RESEARCH STUDY

We understand that information about you and your health, as well as that of your child, is personal and we are committed to protecting the privacy of that information. Because of our commitment to protect your privacy, we must obtain your written authorization (permission) before we may use or disclose (release) your "protected health information" (sometimes referred to as "PHI") related to the study described to you. This form provides that authorization and helps us make sure that you are properly informed of how this information will be used or disclosed. Please read the information below carefully before signing this form either for you, as the participant, or as the personal representative (parent, legal guardian, etc.) for the participant. Note that when we refer to "you" or "your" throughout this document, we are referring to the participant, even when this form is signed by the participant's personal representative.

USE AND DISCLOSURE COVERED BY THIS AUTHORIZATION

If you sign this document, you give permission to Cincinnati Children's Hospital Medical Center ("Cincinnati Children's") to use or disclose your child's medical and research information for the purpose of this study. Your PHI that will be used and disclosed in connection with this study consists of:

- Your child's Cincinnati Children's medical records
- Your child's research record for this study
- Results of your child's laboratory tests
- Clinical and research observations made during your child's participation in the study
- In the event that your child's medical record contains such information, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

WHO WILL DISCLOSE, RECEIVE AND/OR USE THE INFORMATION?

This form authorizes the following to disclose, use and receive your child's PHI:

- Every research site of the study (including Cincinnati Children's and each site's research staff and medical staff)
- Every health care provider who provides services to your child in connection with the study
- Any laboratories and other individuals and organizations that analyze your child's PHI in connection with the study
- The Sponsor and the people and companies they use to oversee, administer and/or conduct the study
- Federal regulatory agencies, other foreign regulatory agencies, and others as required by law

- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs
- The Principal Investigator and members of the study's research team
- Data Safety Monitoring Board (if applicable)

By signing this document, you are authorizing Cincinnati Children's to use and/or disclose your child's PHI for this study. The purpose for the uses and disclosures is to conduct the study explained to you and your child during the informed consent process and to ensure that information relating to the study is available to all parties who may need it for research purposes.
Those persons who receive your child's information may not be required by Federal privacy laws (such as the Health Insurance Portability and Accountability Act, also known as "HIPAA") to protect it and may share the information with others without your permission, if permitted by laws governing them.

You may revoke (choose to withdraw) this authorization at any time after you have signed it by providing the Principal Investigator (listed on the first page of the informed consent document) with a written statement that you wish to revoke it. Your revocation will be effective immediately and your PHI can no longer be used or disclosed for this study by Cincinnati Children's and the other persons or organizations that are identified above, except to the extent that Cincinnati Children's and/or the other persons or organizations identified above have already acted in reliance on the Authorization. In addition, the information may continue to be used and/or disclosed to preserve the integrity of the study.

Unless you notify us in writing of your decision to withdraw this authorization to use and disclose your PHI, it will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.
If you refuse to sign this authorization, you may not be able to receive research-related procedures and may not be able to continue in this study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

For further information about your rights, please see the Cincinnati Children's Notice of Privacy Practices on our website at http://www.cincinnatichildrens.org/about/corporate/hipaa.

SIGNATURES:

I have read the information given above. The investigator or his/her designee have personally discussed with me the research study and have answered my questions. I am aware that, like in any research, the investigators cannot always predict what may happen or possibly go wrong. I have been given sufficient time to consider if my child should participate in this study. I hereby consent for my child to take part in this study as a research study subject.

_____ Date:_____
Signature of subject's parent
or legally authorized representative*

_____
*Legally authorized representative's printed name

_____
*Description of legally authorized representative's authority to sign

_____ Date:_____
Investigator or specific individual who has
been designated to obtain consent (Signature)

This research study and consent form have been reviewed and approved by the Cincinnati Children's Hospital Medical Center Institutional Review Board (telephone number 513-636-8039).