Official Study Title:

Flexible representation of speech in the supratemporal plane

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Informed consent form

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UPMC | CHILDREN'S HOSPITAL OF PITTSBURGH

Department of Pediatric Neurosurgery
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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Title: Contextual & Statistical Stimulus Weighting in Human Auditory System

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National Institutes of Health
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Key Information about the Study:

1. Your child is being asked to participate in a research study and your child's participation is voluntary. Research studies include only children whose parents choose to take part in them. The study team will explain the study to you and your child and will answer any questions you might have. You should take your time to make your decision.

2. The purpose of this study is to help your child's physicians better understand how the brain responds to and understands speech.
    a. Your child's participation is expected to last between 1 day to 2 weeks depending on how long your child will undergo monitoring in the hospital as part of their medical plan decided by their medical team.
    b. While your child is recovering from surgery, they will have up to 64 scalp/skin electrodes placed to monitor the activity that is happening while they recover from surgery. During your child's participation in the study, they will be asked to listen listen to sounds through headphones and make decisions about speech sounds in words, and the length and timing of sounds you heard.
3. Risks and side effects to your child during this study are:
    a. Likely: Boredom or frustration during the performance of the requested tasks,
    b. Less Likely to Occur: Breach of confidentiality, skin irritation from scalp electrodes
    c. Rare but Serious: Unexpected seizure activity.

4. Your child will not receive direct benefit from participation in this study however the results of this study may benefit the general population with neurological disorders in the future.

5. If you decide that you do not want your child to participate in this research your other choices include: Getting treatment or care for epilepsy without being in a study.

6. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this website at any time.

General Information about the Study:

***Why is this research being done*?**

Your child is being asked to participate in a research study to help us gain a better understanding of how the human brain responds to and understands speech and other sounds.

***Who is being asked to take part in this research study*?**

We are asking patients who are between the ages of 15-25 years old, who are undergoing chronic intracranial monitoring with electrode implantation in the epilepsy monitoring unit (EMU) of the hospital as part of the standard of care.

***How many people will be in the study*?**

The target enrollment for this study is about 25 participants at our site.

What procedures will be performed for research purposes?

Before your child's surgery, they will complete a short hearing screening by listening to words and sounds through headphones and using a computer to choose which words and sounds they heard. Your child will complete this hearing test at home using your own computer and headphones. The study team will provide you and your child with instructions on how to log in and complete the test, which should not take more than 10 minutes.

During this study, your child will have scalp/skin electrodes placed on their head to monitor their brain activity while they recover from surgery. Your child will be asked to perform behavioral tasks, which will take between 60 and 90 minutes per session; the number of sessions in a day will be based on your child's schedule and their interest in participating. No more than 6 total hours of testing will be done in a single day. Some children might be studied for one day, while others may be studied for several days, depending on how long it is clinically necessary for the child to stay in the EMU. Therefore, the total number of sessions can vary from 1 to 10 depending on your child's interest, how they are feeling after surgery, and their length of stay.

Activities can start once your child has recovered from surgery and is in the EMU. This is typically 1-3 days after surgery and will be determined by a clinical team member. During each session, your child will be seated in front of the testing computer and detailed instructions will be given to them, both written and verbally. Your child will first complete a short language assessment that looks at their ability to add, subtract, and blend sounds within a word. Your child will then participate in one or more tasks, and other sounds. The number of sessions your child completes will depend on their length of stay in the epilepsy monitoring unit (EMU) and their desire to participate. If your child becomes tired or uncomfortable while completing the experiment, they may take a break by letting the tester know.

The number and location of sEEG electrodes placed during your child's surgery will not be impacted by their participation in this study. No additional sEEG electrodes will be placed for research purposes. Your child's length of stay in the EMU will not be impacted by their participation in this study.

Your child's brain activity will be monitored by sEEG in the EMU for the entirety of their stay in the hospital as this is part of their clinical care. Your child's brain activity will be monitored by scalp EEG electrodes only while they are participating in research activities.

If you have already given consent for your child to complete research activities under a separate study (Intracranial Recording of EEG to Understand Human Brain Function and Development) and received this consent form at a visit with your child's physician following their stay in the EMU, no further activities will be completed for research purposes. By signing this consent form, you are giving permission for researchers to access and share data that was already collected for analysis and reporting of results for this sub-study. We will receive identifiable data and all related study data from your child's participation in the other research study.

What are the possible risks, side effects, and discomforts of this research study?

During the research sessions your child will be performing behavioral testing in which there is minimal risk of boredom or frustration. Previous experience with these types of testing sessions suggests that children can perform these tasks reasonably well with minimal impact on them. It is also possible that

individuals may suddenly have a seizure in the middle of a behavioral task. The seizure could be spontaneous. However, there is a very slight chance that being tired or putting a lot of effort and concentration into a task may trigger a seizure, though this remains a very minimal risk. If your child becomes tired while completing the experiments, they may take a break.

During the study, your child will have up to 64 scalp/skin electrodes placed as part of their routine clinical care to monitor their brain activity while they are recovering from surgery. Your child may experience mild skin irritation from the scalp electrodes, but this is uncommon. If this should occur and your child becomes uncomfortable, the electrodes can be removed by a member of the clinical care team.

As with all research, there is a chance that the confidentiality of your child's personal information could be compromised; however, we are taking precautions to minimize this risk.

You or your child may decide at any point to stop participating in the research study. If you believe that the research procedures have resulted in an injury to your child, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your child's participation in this research study will be provided to you and your child by the hospitals of UPMC. Your child's insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your child's research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. Currently there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form.

What are the possible benefits from taking part in this study?
There is no direct benefit from participating in this research study for your child. However, the information learned from this study may benefit with people with neurological disorders in the future.

If I agree to enroll my child in this research study, will we be told of any new risks that may be found during the study? You and your child will be promptly notified if, during the course of this research study, any new information develops which may cause you or your child to change your mind about continued participation.

Are there any alternative treatments for this study?
Currently there are no alternative treatments available for this study.

Will my child's insurance provider or I be charged for the costs of any procedures performed as part of this research study? Neither you, nor your child's insurance provider, will be charged for the costs of any of the procedures performed for this research study (i.e., the Screening Procedures or Testing Procedures described above). All behavioral and medical assessments will be paid for by research funding.

Will my child be paid if they take part in this research study?
Your child will be paid $15/hour for participating in research activities during their stay in the EMU. This includes listening tasks from this sub-study as well as other tasks covered under the study "Intracranial Recording of EEG to Understand Human Brain Function and Development."

If your child has already completed research activities and you are providing consent only for data sharing, your child will not receive any additional payment for this consent.

Payment to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a "Form 1099 – Miscellaneous" with the IRS and provide a copy to the taxpayer. We are required to give your name and social security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that a portion of the payment be withheld for tax purposes.

Who will know about my child's participation in this research study?
Any information about your child obtained from this research will be kept as confidential (private) as possible. All records related to your child's involvement in this research study will be stored in a locked file cabinet. Your child's identity on these records will be indicated by a unique study number rather than by their name, and the information linking their study number with their identity will be kept separate from the research records, in a secure manner. Research records will be kept a minimum of 5 years past the age of majority (age 23 per PA State law) after study participation ends. Your child will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

Will this research study involve the use or disclosure of my child's identifiable medical information?
This research study will involve the recording of current and/or future identifiable medical information from your child's hospital and/or other (i.e., physician office) records for a period of up to 2 weeks. This is needed so that the investigator can review medical information related to the study, such as the area of your child's brain being monitored by implanted electrodes and their medical history related to any conditions that impact the brain. Information that may be obtained from your child's medical record includes their: date of birth, diagnoses, medications, previous imaging studies, previous test or assessment results, and previous physical examinations. Authorization to access your child's medical record information related to their participation in this study is valid for an indefinite period of time.

Will any research information be placed into my child's permanent medical records about their participation in this study? Your child's brain activity will be continuously recorded by the sEEG electrodes throughout their stay in the EMU as part of their clinical care. Therefore, your child's brain activity during research activities will become part of their medical record. If your child has a seizure while they are completing the research activities, this information will also become part of their medical record as they will be hospitalized at the time. Otherwise, we will not place any information about your child's participation in this study into their permanent medical record at any time.

Who will have access to identifiable information related to my child's participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include identifiable medical information) related to your child's participation in this research study:

- Authorized representatives of the University of Pittsburgh's Office of Research Protections may review your child's identifiable research information (which may include their identifiable medical information) for monitoring the appropriate conduct of this research study.

- Information that may be obtained from your medical record includes your: date of birth, diagnoses, medications, previous imaging studies, previous test or assessment results, and previous physical examinations. If the investigators learn that your child or someone with whom they are involved is in potential danger or harm, they will need to inform the appropriate agencies as required by Pennsylvania law. We will protect your child's privacy and the confidentiality of their records, as described in this document, but cannot guarantee the confidentiality of your child's research records, including information obtained from medical records, once your child's personal information is disclosed to others outside UPMC or the University.

- Authorized representatives of the sponsors of this research study, the National Institutes of Health and the National Science Foundation, may review and/or obtain identifiable information (which may include identifiable medical information) related to your child's participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analysis of the research data. While the study sponsor understands the importance of maintaining, the confidentiality of your child's identifiable research and medical information, UPMC and the University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor. The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable research and medical information related to your child's participation in the study.

- We may share data with co-investigators are collaborating institutions outside of the University of Pittsburgh. In this case, any data shared will be de-identified.

- Identifiers might be removed from the identifiable private information so that, after this removal, the information could be used for future research studies or shared with another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

- Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify your child in any action or suit unless you say it is okay. They also cannot provide them as evidence

unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your child's information from being used for other research if allowed by federal regulations.

Researchers may release information about your child when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your child's involvement in this research. It also does not prevent you from having access to your child's information.

For how long will the investigators be permitted to use and disclose identifiable information related to my child's participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include identifiable medical information) related to your child's participation in this research study for an indefinite period.

Is my child's participation in this research study voluntary?

Your child's participation in this research study, including the use and disclosure of their identifiable information for the purposes described above, is completely voluntary. If you do not provide your consent for the use and disclosure of your child's identifiable information for the purposes described above, your child will not be allowed to participate in the research study. Whether or not you provide consent for your child's participation in this research study will have no effect on their current of future relationship with the University of Pittsburgh. Whether or not you provide consent for your child's participation in this research study will not affect your child's current or future medical care at a UPMC hospital or affiliated health care provider of their current or future relationship with a heath care insurance provider.

Your child's doctor is involved as an investigator in this research study. As both your child's doctor and a researcher investigator, he is interested both in your child's medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your child's care with another doctor who is not involved with this research study. Your child is not under any obligation to participate in any research study offered by your doctor.

May I withdraw, at a future date, my consent for my child's participation in this research study?

You may withdraw your consent for your child to participate in this research study at any time. This includes the use and disclosure of your child's identifiable information for the purposes described above. If you withdraw consent for the use and disclosure of your child's identifiable medical record information for the purposes described above, your child will also be withdrawn, in general, from

further participation in this research study. Any identifiable research or medical information recorded for, or resulting from, your child's participation in this research study before the date that you formally withdrew consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw consent for your child's participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for your child's participation in this research study will have no effect on your child's current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for your child's participation in this research study will have no effect on your child's current or future medical care at a UPMC hospital or affiliated health care provider or their current or future relationship with a health care insurance provider.

Should you choose to withdraw your child from the study during their stay in the EMU, scalp electrodes can be removed. Recording and placement of sEEG electrodes will continue for as long as medically necessary as this is part of your child's clinical care.

If I agree to my child taking part in this research study, can my child be removed from the study without my consent?

The investigator can withdraw your child without your approval. Possible reasons for withdrawal include 1) your child is no longer able to cooperate in research for any reason or 2) your child's medical course includes a neurological deficit incompatible with the study inclusion criteria.

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VOLUNTARY CONSENT

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions about any part of this research during this study, and that any future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone numbers(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; receive information; offer input; or discuss situations that have occurred during my child's participation.

By signing this form, I agree to have my child to participate in this research study and provide my authorization to share my child's medical records with the research team.

_____ _____

Participant's Name (Print) Date

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study.

_____ _____

Parent's or Guardian's Name (Print) Relationship to Participant (Child)

_____ _____

Parent's or Guardian's Signature Date

ASSENT

This research has been explained to me, and I agree to participate (for children 15-17 years of age or who are developmentally able to provide assent).

_____

Participant's (Child's) Name (Print)

_____ _____

Participant's (Child's) Signature Date

VERIFICATION OF EXPLANATION:

I certify that I have carefully explained the purpose and nature of this research study to the child subject in age-appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e. assent) to participate in this study

_____ _____

Investigator's Signature Date

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CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individuals(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed name of person obtaining consent	Role in research study
_____	_____
Signature of person obtaining consent	Date

CONSENT FOR CONTINUED RESEARCH PARTICIPATION

I understand that I am currently participating in a research study. I further understand that consent for my participation in this research study was initially obtained from my authorized representative since I was unable to provide direct consent at the time that this initial consent was requested. I have now turned age 18 and I am able to provide direct consent for continued participation in this research study.

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during the course of this study. Future questions, concerns or complaints will be answered by a qualified person or by an investigator listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. I agree to participate in this research study and provide my authorization for the use of my medical records.

By signing below, I agree to continue my participation in this research study. A copy of this consent form will be given to me.

_____	_____
Participant's Signature	Date