**Official Study Title:**

Flexible representation of speech in the supratemporal plane

**NCT Number:**

NCT05209386

**Document**:

Protocol

**Document Date:**

February 2, 2022

## Study Design

1. **Total number of subjects to be enrolled at this site (enter -1 for chart reviews, banking, registries):**
   25

2. **Describe and explain the study design:**
   This experimental study uses a within-subjects design.

   All enrolled participants will be implanted with sEEG electrodes in the auditory cortex based on clinical necessity. During the post-operative period, patients will complete self-paced blocks of trial stimuli by listening to sound via earphones and making behavioral, categorical decisions about speech sounds, duration of stimuli, and pitch of stimuli. Simultaneous sEEG and scalp EEG recordings will be obtained to record neural responses to stimuli.

   Participants will first complete a block of stimuli for clear speech to establish a baseline. They will then complete blocks of stimuli with experimental manipulations. All blocks will consist of intermixed exposure trials and test stimuli. Each participant will complete all tasks provided they are willing to do so and that their medical status permits.

   Auditory stimuli used in this part of the study are part of the dimension-based statistical learning (DBSL) paradigm developed and extensively tested by Dr. Lori Holt in previous research.

3. **Provide a description of the following study timelines:**

   **Duration of an individual subject's active participation:**
   Participants will continue to be enrolled in the study for the duration of their sEEG implantation in the EMU. This period of time may range from 3-10 days post-operatively until the participant completes all research tasks, indicates that they would like to disengage from research activities, or is taken back to the operating room for removal of electrodes.

   Each participant will have active participation in the study for only the amount of time per day that they voluntarily desire participating. Blocks are stimuli are self-paced and the research team will offer breaks between blocks as needed or requested by the participant.

   Based on previous research with similar protocols and stimulus paradigms, we anticipate that a subject may complete all research tasks over a cumulative period of 2-3 hours. This includes equipment setup and removal.

   **Duration anticipated to enroll all subjects:**
   This is a two year study. Based on historical volume of patients with similar inclusion criteria within PI Abel's clinical practice, it is anticipated that the desired number of participants (n=25) will be enrolled within the first year. Should enrollment be lower than anticipated after Year 1, the enrollment period will be extended into Year 2.

4. **List the inclusion criteria:**
   1. Individuals 15-25 years old and their parent/guardian where applicable
   2. Undergoing sEEG placement in the auditory cortex for clinically necessary localization of epileptic foci or language mapping
   3. Fluent English speakers
   4. Within the normal range on cognitive, speech-language, and hearing tests (as determined by a speech-language pathologist or neuropsychologist prior to surgery)
   5. Normal or corrected-to-normal visual acuity
   6. Normal hearing acuity in each ear (as determined during a full audiometric assessment)
   7. No history of autism or ADHD

5. **List the exclusion criteria:**
   1. Individuals with intellectual disability
   2. Abnormal epileptiform activity in the auditory cortex
   3. Lack of fluent English comprehension/production
   4. Severe language or auditory specific cognitive dysfunction
   5. History of autism or ADHD

## Research Activities

1. * **Provide a detailed description of all research activities (including screening and follow-up procedures) that will be performed for the purpose of this research study. This description of activities should be complete and of sufficient detail to permit an assessment of associated risks.**

The participants in this study will be 15-25 year-olds undergoing stereoelectroencephalography (sEEG) implantation in the STP for clinically necessary localization of epilepsy foci or language mapping. Enrolled participants will not meet any exclusion criteria. The study will only be conducted if the subject's medical condition permits and if the subject is willing to participate and continue.

Personnel performing the research procedures will be suitably trained research staff.

All research activities will take place at UPMC Children's Hospital of Pittsburgh (CHP). After the clinically necessary sEEG electrodes are placed, patients will be monitored in the acute inpatient setting of the epilepsy monitoring unit (EMU). The EMU offers a fully staffed team of clinicians who will ensure the health of the patient. When patients feel well enough, they will be approached with the opportunity to participate in the proposed research by engaging in behavioral tasks and screening assessments. Participants will have up to 64 scalp electrodes placed at the completion of the surgical procedure to obtain scalp EEG recordings for research purposes. Scalp electrodes will come from the study team's own equipment inventory and will be covered by the head dressing applied to all sEEG patients post-operatively. These electrodes will remain on the scalp until the completion of sEEG recording or upon a participant's withdrawal from the study. sEEG and EEG recordings will occur simultaneously during behavioral tasks.

All clinical decisions, including placement of sEEG electrodes, will be made by the patient's clinical team based solely on medical necessity and benefit. Dr. Abel will obtain consent for the surgical procedure to implant sEEG electrodes in a separate process after an extensive clinical evaluation to determine medical utility of the surgery and discussion of risks and benefits involved.

All potential subjects will be patients of Dr. Abel and the CHP neurological surgery service, who will decide when and if the patient is medically able to participate in research activities. All research-specific activities will be stopped at the request of the patient, patient's parents, or medical team. It will be made clear to patients and parents that participation is entirely voluntary and that patients or parents may make the decision to discontinue involvement in the study at any time.

Prior to completing research activities described below, participants will complete a 5-minute hearing screening via headphones by providing click responses on a computer. The hearing screening will be completed remotely within the participant's home and will be hosted and accessed on the Gorilla experiment platform (gorilla.sc). The research team will meet briefly with participants via Zoom on a non-recorded video call to provide instructions and guidance on accessing and completing the screening. Participant responses will be recorded directly and saved in a database on the Gorilla platform. This screening will occur prior to sEEG implantation.

Participants will also participate in a brief (~12-15 minute) language screening that evaluates phonological awareness. Participants will listen to single-word or single-letter speech stimuli played from a laptop, and provide verbal responses that require them to add, subtract, or blend sounds within a word. This screening procedure will occur in-patient following sEEG implantation but prior to the activities described below which involve neural recordings.

Neither screening procedure will be used for the purposes of determining eligibility.

Each participant will complete self-paced blocks of stimuli that will first establish a baseline for neural activity and behavioral responses with clear speech, and will then record responses for experimentally manipulated blocks to introduce 1) speech-in-noise and 2) a Canonical-Reverse block to model an "accent." Each block involves listening to sound via earphones and making a categorical decision between initial consonants (/b/ or /p/) by tapping a button to indicate the word heard by the participant.

All auditory stimuli will be adjusted to a comfortable level for each participant as determined by a calibration process completed by the participant. The blocks can be completed with breaks in between as needed or desired and can occur over the course of the participant's clinical stay in the EMU. All blocks involves listening to sound via earphones and making a categorical decision. Because participation is self-paced, the number of sessions in a day over the total course of an individual's participation will depend on their schedule, health, and motivation to complete research tasks. This period may be up to 10 days, however the patient participant's inpatient stay will not be extended for research purposes.

sEEG electrodes and scalp EEG electrodes will be connected to the study team's recording system before beginning research tasks in order to collect neural recordings specifically for research. The recording system will be disconnected at the completion of each research session. sEEG electrodes will be connected to the EMU's recording system for the duration of each participant's inpatient stay per standard of care.

The study team's recording equipment consists of the software required to present stimuli on MATLAB and record electrical signals from electrodes as well as behavioral responses from subjects. Therefore, no audio or visual recordings will be taken.

The risks and benefits of clinical procedures that are part of the patient's standard of care will be explained in a consent process separate from research activities. Electrode placement and recording are conducted strictly based on a patient's clinical needs and will not be dictated or manipulated by research. Participants will incur minimal additional risk by participating in the behavioral research task. Any risks involved will be explained and documented in the informed consent process and may include fatigue, boredom, or frustration. Research staff will ensure that participants and parents/guardians are aware that participation is entirely voluntary and may stop at any time. Every effort will be made to ensure patient comfort throughout study procedures.