PARENT PERMISSION FORM

Temple IRB Approved

03/26/2019

Title:	**ASSIST: Treatment for Childhood Apraxia of Speech**
Protocol No.:	25807
Sponsor:	National Institutes of Health – National Institute of Deafness and Other Communication Disorders (NIH NIDCD)
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RESEARCH CONSENT SUMMARY

Your child is being invited to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to have their child take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you and your child.
- Whether or not your child takes part is up to you and your child.
- You and your child can choose not to take part.
- You and your child can agree to take part and later change your mind.
- Your decision will not be held against you or your child.
- You and your child can ask all the questions you want before you decide.

How long will my child be in this research?

We expect that your child will be in this research for up to 5 months, including a 7-week study period that includes 4 weeks of a summer camp (4 days per week) and several evaluation sessions before the summer. Below is an overview of the study time line.

Weeks	**pre-camp**	**1**	**2 & 3**	**4**	**5 & 6**	**7**
Dates	April-June	6/17-6/21	6/24-7/5	7/8-7/12	7/15-7/26	7/29-8/2
Visits	2 – 7 total	1-2 visits	4 days/week	1-2 visits	4 days/week	1-2 visits
Purpose	Screening/Evaluation; Goal selection	Testing	ASSIST / group camp	Testing	ASSIST / group camp	Testing

Why is this research being done?

The purpose of this study is to learn more about treatment for children with childhood apraxia of speech (CAS). The treatment is called ASSIST (Apraxia of Speech Systematic Integral Stimulation Treatment).

What happens to my child if my child takes part in this research?

If you agree to have your child participate in this research, we will first perform an evaluation of your child's speech, language, hearing, and cognitive skills (pre-camp). We will also ask you to complete several questionnaires to obtain relevant background information and help select appropriate goals for treatment. If your child is eligible, your child will then be randomly assigned to receive 16 hours of individual ASSIST speech therapy either in weeks 2-3 or in weeks 5-6. Treatment will be individualized for your child and provided by Masters students in a clinical graduate program in Speech-Language Pathology. These students will be supervised by experienced and licensed speech-language pathologists. The treatment involves many repetitions of words or phrases that are difficult for your child to say, with feedback and support provided by the therapist. These words or phrases may be relatively simple or more complex. Your child will be

randomly assigned to one of these conditions. During times when your child is not receiving individual treatment, your child will participate in camp activities (such as arts and crafts) led by trained research assistants. During weeks 1, 4, and 7, your child will produce words and phrases, and you will be asked to complete questionnaires. These tests and questionnaires will be used to determine the effects of treatment. All testing and treatment sessions will be audio and/or video recorded for data analysis.

Could being in this research hurt my child?

The things that your child will be doing have no more risk than in daily life. The most important risks or discomforts that your child may expect from taking part in this research include becoming tired or frustrated with some of the tasks during testing or treatment that may be difficult. Your child may also become bored with some of the tasks.

Will being in this research benefit my child?

The most important benefit that your child may expect from taking part in this research is that your child's speech may improve. However, we cannot guarantee any improvements. Your child may also benefit from participating in group activities with other children with childhood apraxia of speech (CAS).

You may also gain a better understanding of your child's speech abilities. If you like, we will provide you with a report that summarizes the evaluation results. This evaluation is performed for research purposes and not intended for clinical purposes beyond the study.

Findings from this study will also provide important information about CAS, and will help in developing better treatments for children with CAS.

What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is that we will make audio and video recordings of your child during testing and treatment. These recordings will only be used for research purposes and will not be shared with others, except with your explicit written permission.

This research involves a summer camp for children with childhood apraxia of speech, and will take place on Temple University's main campus in North Philadelphia. You are responsible for arranging transportation to and from the study site for your child. Testing visits will be scheduled at your convenience. During treatment weeks (see shaded areas in figure above), camp starts at 8:00 am and ends at 3:00 pm. You will also be required to provide a lunch for your child on camp days, and any other items your child might need.

DETAILED RESEARCH CONSENT

Your child is being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you and your child.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether or not your child takes part is up to you and your child.
- You and your child can choose not to take part. There will be no penalty or loss of benefits to which you or your child are otherwise entitled.
- You and your child can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you or your child are otherwise entitled.
- If you don't understand, ask questions.
- You and your child can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to learn more about treatment for children with childhood apraxia of speech (CAS). The treatment is called ASSIST (Apraxia of Speech Systematic Integral Stimulation Treatment).

About 60 children with CAS will take part in this research.

How long will my child be in this research?

We expect that your child will be in this research for up to 5 months, including a 7-week study period that includes 4 weeks of a summer camp (4 days per week) and several evaluation sessions before the summer (see figure below for overview). Before camp (pre-camp), there will be up to 7 hours of testing, divided over 2 to 7 visits. In weeks 1, 4, and 7, your child will visit once or twice to complete up to 2 hours of testing. During weeks 2-3 and 5-6 (shaded areas in figure below), your child will attend camp four days per week (Mondays, Tuesdays, Thursdays, and Fridays) from 8:00 am to 3:00 pm.

Study timeline.

Weeks	**pre-camp**	**1**	**2 & 3**	**4**	**5 & 6**	**7**
Dates	April-June	6/17-6/21	6/24-7/5	7/8-7/12	7/15-7/26	7/29-8/2
Visits	2 – 7 total	1-2 visits	4 days/week	1-2 visits	4 days/week	1-2 visits
Purpose	Screening/Evaluation; Goal selection	Testing	ASSIST / group camp	Testing	ASSIST / group camp	Testing

What happens to my child if my child takes part in this research?

If you agree to have your child participate in this research, we will first perform an evaluation of your child's speech, language, hearing, and cognitive skills (pre-camp). The evaluation will involve standardized or routine clinical procedures, such as language

tests, an articulation test, and a hearing screen. In these tests, your child may be asked to answer questions, describe or point to pictures, repeat words, and perform simple movements with their mouth and tongue. We will also ask you to complete several questionnaires to obtain relevant background information and help select appropriate goals for treatment. If your child does not meet the study selection criteria based on this evaluation or information, we will explain to you why your child does not qualify.

If your child is eligible, your child will then be randomly assigned to receive 16 hours of individual ASSIST speech therapy either in weeks 2-3 or in weeks 5-6 (shaded parts in figure above), with group activities during the other period. In other words, all children will receive the same amount of individual ASSIST and group activities, but in different periods. Your child will have a 50-50% chance of receiving ASSIST in weeks 2-3 or weeks 5-6. It is important that your child attend all weeks, including when your child is not assigned to receive individual treatment but instead participates in group activities. During times when your child is not receiving individual treatment, your child will participate in camp activities (such as arts and crafts) with other children with childhood apraxia of speech. These camp activities are led by trained research assistants.

Treatment will be individualized for your child and provided by Masters students in a clinical graduate program in Speech-Language Pathology. These students will be supervised by experienced and licensed speech-language pathologists. The treatment involves many repetitions of words or phrases that are difficult for your child to say, with feedback and support provided by the therapist. The goal of the treatment is to help your child practice these words and phrases to make it easier to say them. The specific words or phrases will depend on your child's speech abilities and the condition to which your child is assigned. Words or phrases may be relatively simple or more complex. Your child will be randomly assigned to one of these conditions, with a 50-50% chance.

Treatment sessions will be 30 minutes, and your child will receive up to four treatment sessions (2 hours) per day, with at least one hour in between sessions to minimize fatigue, frustration, and boredom. The treating clinician and supervisor will also monitor your child's frustration levels in each treatment session so that we can discuss any concerns with you. Treatment sessions are conducted in individual rooms, following a so-called "pull-out" model (children are retrieved from the group for their individual treatment sessions and then return to the group).

In each of weeks 1, 4, and 7, your child will visit only once or twice to complete up to 2 hours of testing. During these visits, your child will be asked to produce words and phrases, and you will be asked to complete questionnaires. These questionnaires include the Intelligibility in Context Scale (ICS; a rating scale with 7 items to determine how easy it is for others to understand your child) and the Focus on Communication Outcomes Under Six (FOCUS-34; a rating scale with 34 items to determine your child's participation in daily communication activities). These tests and questionnaires will be used to determine the effects of treatment.

All evaluation, testing, treatment, and camp activities take place at Temple University's main campus on the first floor of Weiss Hall (1701 N. 13th Street).

All evaluation, testing and treatment sessions will be audio and/or video recorded for data analysis. Recordings of the evaluation will be shared via a secure file-sharing system with

members of our research team outside Temple University. These team members are expert speech-language pathologist who will help determine a speech diagnosis. Recordings of speech samples from weeks 1, 4, and 7 will be played to unfamiliar adult listeners who will write down the words they hear, to determine how easy it is for unfamiliar listeners to understand your child's speech. These recordings will not contain information that can identify your child, such as their names or addresses.

If you do not give permission for these recordings, your child cannot participate in this study. Please indicate below whether you give permission for us to record your child by checking the appropriate box:

☐ I give permission for audio and video recordings to be made of my child during this study.

☐ I do NOT give permission for audio and video recordings to be made of my child during this study. I understand that my child cannot participate if I choose this option.

In addition to data analysis, there are other, optional uses for these recordings, detailed below. No identifying information (other than your child's face or voice) will be included in these recordings when used for these purposes. You are not obligated to allow any of these uses. You can decline such uses without negative consequences to your or your child's relationship with our research team or Temple University. Your decision does not affect whether your child can participate in this research. Please indicate whether or how we may use the recordings by checking the appropriate box(es) below:

☐ Recordings may be used for <u>scientific publications and presentations</u>.

To enable other researchers to verify our findings and compare them to other findings, it is sometimes helpful to illustrate certain speech or language characteristics in publications or at conferences by playing a recording. If you check this box, we may include recordings in conference presentations and with scientific publications.

☐ Recordings may be used for <u>nonscientific publications and presentations</u>.

Sometimes we do outreach and education to raise awareness and understanding of communication disorders among the general public. If you check this box, we may include recordings in nonscientific presentations and nonscientific publications to help people understand different speech and language disorders.

☐ Recordings may be used <u>for teaching</u> purposes.

As part of their training, current and future clinicians must learn about different types of speech and language disorders. If you check this box, we may play recordings to current and future clinicians to illustrate different speech and language disorders.

☐ Recordings <u>may **NOT** be used</u> for any other purpose except for data analysis.

What are my responsibilities if my child takes part in this research?

If your child takes part in this research, you will be responsible for:

- arranging transportation for your child to and from the study location (Temple University)
- providing lunch for your child during camp weeks
- providing any other items you think your child will need during the study
- completing questionnaires during pre-camp and weeks 1, 4, and 7

Could being in this research hurt my child?

The things that your child will be doing have no more risk than in daily life. The most important risks or discomforts that your child may expect from taking part in this research include:

- becoming tired from evaluation, testing, or treatment tasks
- becoming bored with some of the tasks that are repetitive
- becoming frustrated with some of the tasks during evaluation, testing or treatment that may be difficult

Breaks will be offered throughout all sessions to minimize fatigue, boredom, and frustration. Assessment sessions may also be discontinued and rescheduled for continuation at a later date. During treatment, targets will be selected that are personally relevant and/or engaging to minimize frustration, boredom, and fatigue. The treatment procedures are designed to be adaptive to children's performance as a way to minimize frustration.

These risks are temporary and are expected to go away when the tasks are stopped. Although we have tried to avoid and minimize risks, your child may nevertheless feel that some procedures may be stressful or upsetting. If this happens, we can take a break, or reschedule evaluation or testing for another time, or you and your child can stop participating altogether.

Your child will be evaluated, tested, and treated individually. However, because the study is conducted in the format of a camp, children and parents will interact with other children and parents. We will use names for pragmatic reasons, but we will not share other private information with other children or parents. To ensure that children stay in study locations, children will be supervised at all times and will be escorted by a trained research assistant when leaving the group or individual rooms (for example to go to the bathroom).

Because we collect identifiable information, there is always a risk of loss of confidentiality. See the section below (*What happens to the information collected for this research?*) for details about how we have tried to minimize this risk.

Will it cost me money for my child to take part in this research?

Taking part in this research may lead to added costs to you. These costs include transportation costs to attend study visits, as well as costs to provide lunch for your child during camp weeks.

Will being in this research benefit my child?

We cannot promise any direct benefits to your child or others from your taking part in this research. However, possible benefits to your child include improvements of your child's speech, and social benefits from participating in group activities with other children with childhood apraxia of speech (CAS).

You may also gain a better understanding of your child's speech abilities. If you like, we will provide you with a report that summarizes the evaluation results. This evaluation is performed for research purposes and not intended for clinical purposes beyond the study.

Findings from this study will also provide important information about CAS, and will help in developing better treatments for children with CAS.

What other choices do I have besides having my child take part in this research?

You may choose not to have your child participate without penalty or loss of benefits to which you or your child are otherwise entitled.

What happens to the information collected for this research?

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy. Your child's private information may be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor (National Institutes of Health)
- People who work with the research sponsor
- Government agencies, such as the Department of Health and Human Services
- The Institutional Review Board (IRB) that reviewed this research
- Temple University

Only members of the research team who are trained in protecting personal information will see the records we collect in this study. No one from the team will disclose this information to third parties unless one of the organizations listed above requests this information, or unless you provide written permission. Your child will be identified in records only by a number code and not by name. Records will be kept in locked cabinets in restricted, locked rooms and/or on a firewalled server that is accessible only via computers that are protected with passwords. Any electronic file that contains personally identifying information will be encrypted and password-protected. We will keep the personal information you give us separate from these records.

We may publish the results of this research. However, we will keep your child's name and other identifying information confidential. Your child's name will not appear in any publications or presentations based on this research. Data collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

In order to better understand the relation between clinical findings and our study findings, we also seek your permission to obtain previous medical records relevant to your child's

neurological status and speech/language history. Records from your child's school, such as Individualized Education Programs (IEPs), are governed by the Family Educational Rights and Privacy Act (FERPA). Federal law provides additional protections of your personal information. These protections, and the information we seek to obtain, are described in an attached document titled "Authorization to use and disclose your protected health information." By signing both forms (this one and the "Authorization" form) you give us permission to receive these records such as IEPs from your child's school. These documents will not be disclosed to anyone outside our research team.

Data and records will be kept until you or your child ask that we destroy your child's data, or until 7 years after the final publication resulting from this research or until 7 years after your child turns 18, whichever comes later. This includes audio and video recordings. We will keep your child's data and records stored in locked cabinets in locked rooms, and on a firewalled server accessible only via password-protected computers to which only the research team has access. Any electronic file that contains personally identifying information will be encrypted and password-protected. Please indicate below which option you prefer:

☐ Do NOT keep my child's data and records. Selecting this option means that we will destroy your child's data and records 7 years after the final publication from this research or 7 years after your child turns 18, whichever comes later.

☐ Keep my child's data and records until I or my child ask that data and records are destroyed by contacting the Investigator at:

Edwin Maas, Ph.D.
Department of Communication Sciences and Disorders, Temple University
1701 N. 13th Street
Philadelphia, PA 19122
e-mail: emaas@temple.edu

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

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt your child or made your child sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (215) 707-3390 or irb@temple.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team.

- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Can my child be removed from this research without my approval?

The person in charge of this research can remove your child from this research without your approval. Possible reasons for removal include:

- if your child develops or has a medical condition that makes it difficult to continue or may be contagious
- if your child repeatedly fails to follow study procedures or experimenter directions (such as repeatedly refusing to follow the clinician's directions)
- if your child repeatedly cancels or fails to keep scheduled appointments

We will tell you about any new information that may affect your child's health, welfare, or choice to stay in this research.

What happens if I agree for my child to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team so that the investigator can keep track of how many children withdraw from this research and why. The investigator may ask you for the reason for withdrawal for reporting and planning of future studies. You are not required to give a reason. Withdrawal from this study or failing to give a reason will not preclude you or your child from participating in future studies in our lab or others at Temple University, nor will it jeopardize any other relationship with Temple University you may have now or in the future (including clinical services through the Speech-Language-Hearing Center in the Department of Communication Sciences and Disorders).

If you wish to withdraw only from the treatment part of the study (the camp in weeks 2-3 and 5-6) but are willing to return for follow-up testing, please let the investigator know, so that we can schedule a follow-up visit for testing at a time that is convenient to you.

If you stop being in this research, already collected data will be retained and may be used for research purposes and the uses indicated above.

Will I or my child be paid for taking part in this research?

You and your child will not be paid for taking part in this research. Your child may receive small prizes (e.g., toys, stickers) as rewards for participation, and your child may take home any art projects created during camp activities. During camp weeks, we also offer small snacks and water. The intervention and camp are provided free of charge.

Statement of Consent:

I have read (or someone has read to me) this form, and I am aware that my child is being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I understand that I may ask more questions whenever I want. I voluntarily agree to allow my child to participate in this study. I am not giving up any legal rights by signing this form. I have received a copy of this form.

By signing below, I agree to have my child participate in this research

- All children are required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted.
- If assent is obtained, have the child sign the consent form, unless the investigator determines that the child is not capable of signing.

Signature of child's parent or individual authorized to consent to the child's general medical care	Date
Printed name of child	Date
Signature of person obtaining consent	Date
Printed name of person obtaining consent	Date

❑ I have explained the study to the extent compatible with the child's capability, and the child has agreed to be in the study.

OR

❑ The child is not able to assent because the capability of the child is so limited that the child cannot reasonably be consulted.

Signature of person obtaining assent	Date
Signature of child	Date