# SYRACUSE UNIVERSITY

#### **Department of Communication Sciences and Disorders**

#### **Oral Consent for Parents of Child Participants**

Protocol Title: Alternative Service Delivery Model for Treatment of Rhotic Speech Errors

# Principal Investigator/Key Research Personnel:

Name and Title	Role	Contact Information
Jonathan Preston, PhD CCC-SLP Director, Speech Production Lab 621 Skytop Road Suite 1200, Syracuse, NY 13244	Principal Investigator – responsible for coordinating the research project	jopresto@syr.edu
Benedette Herbst, M.S.Ed. CCC-SLP Doctoral Student Syracuse University 621 Skytop Road Suite 1200, Syracuse, NY 13244	Will assist PI Preston in conducting research. Will conduct all assessment and treatment sessions.	<u>bmherbst@syr.edu</u>

#### Introduction:

The purpose of this form is to provide you with information about participation in a research study and offer you the opportunity to decide whether you wish to participate. You can take as much time as you wish to decide and can ask any questions you may have now, during, or after the research is complete by contacting the researchers at <u>bmherbst@syr.edu</u> or at 315-443-1351. Your participation is voluntary.

#### What is the purpose of this research study?

We are interested in learning about different ways of treating speech problems. In this study, we are researching if an alternative treatment schedule of four, 10-minute sessions provided weekly can be used to help children learn to produce the /r/ sound more consistently. We estimate that approximately 20 participants will take part in this study.

#### What will I be asked to do?

If you agree to have your child participate in this study, you and your child will be asked to participate in the following:

<u>Screening and Consent/Technology Set-Up Visit:</u> If your child passes the online screening, we will schedule a Zoom meeting to discuss the requirements for this study and obtain your consent to audio recording of assessment and treatment sessions. We will also ask your child to assent to their participation at this time. You and your child will have the opportunity to review



this information and ask questions of the study staff prior to the assessment visit. The assessment session will be scheduled after the consent/technology set-up Zoom session.

It's important to note that all assessment and treatment sessions for this study will be conducted via video chat using Zoom. You must have a laptop or personal computer and wired broadband internet connection to participate in this study.

If you agree to have your child participate in this study, we will ask you to provide some information about your child's developmental, speech/language, and educational history. We will also ask you to provide information regarding your technology set-up at home.

## Assessment Session:

During the assessment session, your child will be asked to participate in several standardized tests of speech and language that involve naming pictures, repeating words and sentences, following directions, answering questions, and listening for sounds in words. We will also make sure your child has adequate range of motion of their tongue by asking them to stick their tongue out of their mouth and move it from side to side. These tasks will be completed in about an hour and a half. These tests will be used to determine eligibility for the remainder of the study; it is possible that, based on the results of the tests, your child might not be eligible to participate in the remainder of the study.

## Orientation to "R" Session:

All children, regardless of whether or not they are considered eligible for the remainder of the study, will also be invited to attend a 30-minute "orientation to correct /r/ production" speech session. During this orientation session, your child will learn and discuss the proper tongue movements needed to produce an accurate /r/ sound. Additionally, your child will have the opportunity to practice producing /r/ with cues and feedback provided by the clinician.

# Recording Session 1:

If your child qualifies for the remainder of the study, and you and your child choose to continue with the study, we will need to make several recordings of your child saying "R" syllables, words, phrases, and sentences. The pre-treatment recording session (Recording Session 1) should take about 30 minutes and will be completed during a Zoom call with the researcher. You will be asked to audio record your child completing these tasks using the recording instructions we will have provided you.

#### Treatment Sessions:

All participants will receive a total of 32 ten-minute speech sessions (4 sessions per week for 8 weeks) to improve the clarity of their speech. These speech sessions will be based on Speech Motor Chaining, a treatment approach that has previously shown to be effective in helping some children improve their /r/ sounds. Each session will have elements that are similar to traditional speech therapy. Your child will be prompted to say a word or phrase with the /r/ sound out loud. The clinician will provide cues and feedback to help your child recognize and produce a clear /r/ sound. Your child may also be asked to rate the accuracy of their own productions of /r/.

You must agree to be willing to have your child participate in any treatment schedule to which he or she is assigned. Unfortunately, you do not get to choose which treatment schedule your child will receive - the researchers will randomly assign your child to one of the two treatment schedules, either the immediate treatment schedule or the delayed treatment schedule. These two schedules are displayed in the table below.

Week	Immediate Treatment Group	Delayed Treatment Group
1	Consent/Assent Session	Consent/Assent Session
	Assessment Session	Assessment Session
	Orientation Session	Orientation Session
	Recording Session 1	Recording Session 1
2	Four 10-minute treatment sessions	No sessions
3	<ul> <li>Four 10-minute treatment sessions</li> </ul>	No sessions
4	Four 10-minute treatment     sessions	No sessions
5	Four 10-minute treatment     sessions	No sessions
6	Four 10-minute treatment     sessions	No sessions
7	Four 10-minute treatment     sessions	No sessions
8	Four 10-minute treatment sessions	No sessions
9	<ul> <li>Four 10-minute treatment sessions</li> <li>Recording Session 2</li> </ul>	Recording Session 2
10	No sessions	Four 10-minute treatment sessions
11	No sessions	Four 10-minute treatment sessions
12	No sessions	Four 10-minute treatment sessions
13	No sessions	Four 10-minute treatment sessions
14	No sessions	Four 10-minute treatment sessions
15	No sessions	Four 10-minute treatment sessions
16	No sessions	Four 10-minute treatment sessions
17	Recording Session 3	<ul><li>Four 10-minute treatment sessions</li><li>Recording Session 3</li></ul>

If your child has to miss a session for any reason, we will attempt to make-up the missed session that week. If you are unable to make-up the missed session that week, we will not be able to make-up the session in a following week. We cannot extend treatment past 8 weeks.

Recording Session 2:

After 8 weeks of treatment or 8 weeks of no sessions (depending on which treatment schedule you receive), we will complete another recording session. Your child will be asked to produce the same "R" syllables, words, phrases, and sentences they produced in Recording Session 1. This recording session should take about 30 minutes and will be completed during a Zoom call with the researcher. You will be asked to audio record your child completing these tasks using the recording instructions we will have provided you.

#### Recording Session 3:

During Week 17, once all treatment sessions have been completed, we will complete the third and final recording session. Your child will be asked to produce the same "R" syllables, words, phrases, and sentences they produced in Recording Sessions 1 and 2. This recording session should take about 30 minutes and will be completed during a Zoom call with the researcher. You will be asked to audio record your child completing these tasks using the recording instructions we will have provided you.

At this point, we will also ask you and your child what you liked or did not like about the short, frequent speech sessions.

It is very important for the study that we follow the prescribed schedules. We recognize that scheduling can be difficult, and we will work with you to identify a point at which we could start the speech lessons that would be convenient for you, such as a school vacation or summer, but would also meet the needs of the study. If your child meets all of the criteria for inclusion in our study, we will ask to schedule four 10-minute treatment sessions per week for 8 weeks. Participants may be withdrawn from the study if they are unable to adhere to the schedule agreed upon at the beginning of the study.

#### What are the possible risks of participation in this research study?

Because some of the speech and language tasks may be challenging, your child may experience some frustration. However, there are no known risks. Breaks will be offered, and your child may choose not to complete any of the tasks.

Whenever one works with email or the Internet, there is always the risk of compromising privacy, confidentiality, and/or anonymity. Your confidentiality will be maintained to the degree permitted by the technology being used. It is important for you to understand that no guarantees can be made regarding the interception of data sent via the Internet via third parties.

#### What are the possible benefits of participation in this research study?

The following benefits may be expected:

- As a result of the speech lessons, your child may improve the clarity of his/her speech production.
- The advancement of scientific knowledge may improve our understanding of speech difficulties and how to treat them.

#### How will my privacy be protected?

- All sessions will occur using a HIPAA-compliant Zoom account
- Only key study personnel will be in the Zoom session with your child

• The speech-language pathologist conducting the sessions will do so from a private, closed door space using a headset.

#### How will my data be maintained to ensure confidentiality?

- Only Benedette Herbst and Jonathan Preston will have access to your private information, such as name, date of birth, and contact information. This information will be stored digitally in a password protected environment.
- Your child will be assigned a numeric study ID (e.g., 1101). Only Benedette Herbst and Jonathan Preston will have access to the key that can link study identifiers with private information. This key is stored digitally in a password protected environment.
- Only Benedette Herbst and Jonathan Preston will have access to de-identified study information, such as the scores from the assessment tasks, which will be linked only to your child's assigned numeric study ID (and not their name). These files are stored digitally in a separate password protected environment than the private information. The researchers acknowledge that due to the nature of the audio recordings, this data cannot be made unidentifiable because of the sound of the participant's voice.
- All audio storage will happen on password protected platforms at Syracuse University.
- Identifiers might be removed from the identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional consent from the participant or the legally authorized representative.
- Under Syracuse University policy, faculty and researchers are considered mandated reporters. We will keep your study data as confidential as possible with the exception of certain information we must report for legal or ethical reasons such as child abuse, elder abuse, sexual misconduct, or intent to harm yourself or others.

#### Will photographs, audio, video, or film recording be used?

- We will audio record your child's speech during the assessment and treatment sessions. These recordings will be labelled with your child's study ID number as well as the session number and date. Your child's name will not be stored with the audio.
- The audio files will be stored on a password protected drive through Syracuse University and will only be accessible to Benedette Herbst and Jonathan Preston.
- Some of the audio recordings will also include video of the computer screen so the researchers can see the target and feedback assigned to each trial through the Speech Motor Chaining treatment. The video will not include your child's face.
- Our data analysis involves tracking improvements in speech clarity, and this requires collected recordings. By consenting, you agree to allow us to collect audio recordings for the purpose of listener judgements of speech sound correctness.
- You will be able to decide what happens with the audio recordings after the study is complete. The audio recordings will be retained by the Speech Production Lab for 12 years for future research purposes. You can decide whether or not to allow use of these audio recordings for instructional purposes (e.g., training students or other speech-language pathologists) as well. If you choose not to allow audio recordings to be used for instructional purposes, you may still have your child participate in this study.

#### Voluntary participation and withdrawal:

You and your child's participation in this study is voluntary. You or your child may decide not to participate or stop participating at any time, without penalty. If you decide to leave the study, please tell the study staff.

## What are my rights and the rights of my child in research?

- Your participation, and the participation of your child, is voluntary.
- You or your child may skip and/or refuse to answer any question for any reason.
- You are free to withdraw from this research study at any time without penalty.

#### Whom may I contact with questions now, during, or after the research is complete?

- For questions, concerns, or more information regarding this research you may contact Benedette Herbst at bmherbst@syr.edu or at 315-443-1351 or Dr. Jonathan Preston at jopresto@syr.edu or at 315-443-3143.
- If you have questions or concerns about your rights as a research participant, you may contact the Syracuse University Institutional Review Board at 315-443-3013.

Do you have any questions?

Are you 18 years or older?

Do you understand that all assessment and treatment sessions will be audio recorded?

Will you allow us to use audio recordings of your child saying short words or phrases (without his/her name) in academic contexts to train current speech-language pathologists or students (e.g., in a classroom, at a conference)?

Do you agree to have your child participate?

How can I provide you with a copy of this consent script?