IRB# _____
(The above to be completed by the IRB Office)

Date Submitted:

SYRACUSE UNIVERSITY
INSTITUTIONAL REVIEW BOARD
Full Board Review or Expedited Review Application

Check which type of review is requested:

☒ Expedited Review- One signed copy of my application for **expedited** review.
Expedited review covers research that involves only minimal risk procedures. See Standard Operating Procedure 012. http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-012-Expedited.pdf for guidance.

☐ Full Board Review- One original signed hard copy plus 13 copies (14 total) of my application
Includes research that cannot be reviewed using the expedited process involving more than minimal risk to the participant and requires review by the full IRB. See Standard Operating Procedure 013.
http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-013-Full-Board.pdf for guidance.

Application Checklist:

☒ All questions on the application have been answered.

☒ The application has been signed by the investigator/faculty advisor and when appropriate, the student.

☒ Copies of all appropriate, consent and/or assent documents (written, electronic, or oral consent script) are included.

☒ Copies of any research instruments (surveys, questionnaires, interview questions, etc.) are included.

☒ Copies of all recruitment tools (flyers, emails, posters, newspaper ads, etc.) are included.

☒ All required appendices, including a list of references are included.

☒ Copies of other IRB approvals or letters of cooperation are included. When the investigation is to be carried out in cooperation with another institution or with an investigator at another institution, a letter indicating the willingness of the institution to cooperate in the study must be included with the proposal.

☒ The principal investigator/faculty member and student/research staff have completed the appropriate Collaborative Institutional Training Initiative (CITI) Web-based Training Program for Human Subjects required by SU.*

☒ All students/research staff or any other individuals listed in the application who will have direct contact with participants and/or identifiable human participant data have completed the appropriate Collaborative Institutional Training Initiative (CITI) Web-based Training Program for Human Subjects required by SU.*

* Submission of CITI Training Certificate is required **only** if CITI training was completed at another institution.

I/We assure the IRB that the following statements are true: All information provided in this form is correct. I have evaluated this protocol and determined that I have the resources necessary to protect participants, such as appropriately trained staff, necessary facilities and equipment. I will seek and obtain prior written approval from the IRB for ***any modifications*** including changes in procedures, investigators/research staff, consent forms, questionnaires, surveys, etc. I will promptly report any unanticipated problems that may occur in the course of this study. I will report any significant findings which may affect the risks and benefits to participation. I will not begin my research until I have received written notification of final IRB approval. I will comply with all IRB requests to report on the status of my study. I will maintain records of this research according to IRB standards. If any of the above conditions are not met, I understand that approval of this research may be suspended or terminated.

Faculty Member/Principal Investigator

Signed Jonathan Preston Date: 4/28/2017

Name (typed): Jonathan L. Preston

Student/Research Staff

Signed: Megan C Leece Date: 4/28/2017

Name (typed): Megan C. Leece

This application must be typewritten and all questions must be answered. To complete form, tab to each field. Incomplete forms will be returned to the investigator for additional information. Outdated applications will not be accepted for review.

To edit the content of the form -unprotect the document as follows:

For Office 2003 Users (or below)

- **Browse to View->Toolbars->Forms. The Forms toolbar will pop up.**
- **Click on the padlock icon on the right side. This will unlock the form.**
- **To protect the document again when you need to click on a checkbox, click on padlock.**

For Office 2007 Users

- **On the ribbon choose Review >Protect document>Restrict Formatting and Editing>Stop Protection.**
- **To protect the document again when you need to click on a checkbox, click on>Yes, Start Enforcing Protection>OK.**

1. Protocol Information

Title of Protocol: Treatments for childhood apraxia of speech

***NOTE* The Principal Investigator (PI) must be a person who holds a faculty appointment or other administrative position of Director or higher. If you have any questions regarding this IRB requirement call the IRB office at 315.443.3013 for guidance.**

Principal Investigator/Faculty Member Information

First Name: Jonathan	Middle Initial: L	Last Name: Preston
Title: Assistant Professor		
Department: Communication Sciences & Disorders	College: College of Arts & Sciences	
Campus Address: 621 Skytop Road, Room 1202G		
Campus Phone : 315-443-3143	Fax : 315-443-4413	
Email: jopresto@syr.edu	Cell Phone (optional):	

Student/Research Staff Information ☐ **NA**

First Name: Megan	Last Name: Leece
☐ Graduate Student ☐ Undergraduate Student ☒ Other: Project Manager	
Department: Communication Sciences & Disorders	College: College of Arts & Sciences
Local/Campus Address: 621 Skytop Road, Room 1181	
Local/Campus Phone: 315-443-5761	Fax: 315-443-4413
Email: mcleece@syr.edu	Cell Phone (optional):

2. Funding Information

2.1. Will/has the research been submitted as a grant or contract proposal? ☐ **No** ☒ **Yes**

Will/has the research been submitted through OSP? ☐ **No** ☒ **Yes**

If yes, who is the proposed sponsor and what is the title of the proposal submitted to OSP?

Sponsor: National Institutes of Health

Title: Motor learning considerations for impaired speech systems: Treatments for childhood apraxia of speech

2.2. Is this research currently being funded in part or in whole? ☐ **No** ☒ **Yes (indicate below)**

☐ **Internal Funding (check all that apply):**

☐ **Departmental Funds**	☐ **No cost study**	☐ **Personal Funds**
☐ **Gifts**	☐ **Other, specify:**	

☒ **External Funding (list all that apply and insert additional rows if needed):**

Agency/Sponsor	**Funding Mechanisms**	
NIH (NIDCD) R15 DC016426-01	☒ **Grant**	☐ **Contract**
	☐ **Grant**	☐ **Contract**

2.3. Has the research been reviewed before the IRB? ☒ **No** ☐ **Yes**
If yes, please give the date of the review:
and the IRB# (if known):

2.4. Is this research to be performed:

for faculty research	☐ **No**	☒ **Yes**
for a masters thesis	☒ **No**	☐ **Yes**
for a doctoral dissertation	☒ **No**	☐ **Yes**
as part of a course requirement	☒ **No**	☐ **Yes**
as an honors thesis	☒ **No**	☐ **Yes**

Other (explain):

3. Study Rationale

3.1. Using non-technical language, describe the objective of this proposed research including purpose, research question, hypothesis, etc. From your description, the IRB should be able to determine how this proposed study adds to the knowledge on the research topic in order to judge the risks and benefits to the research participants. NOTE: A reference list citing relevant background information must be provided as an appendix with this application.

Childhood apraxia of speech (CAS) is a pediatric speech sound disorder that may lead to persisting speech errors, often despite years of treatment. According to ASHA (2007), CAS is characterized by deficits in the production of accurate and consitent speech sounds, achievement of coordinated transition between speech sounds, and coordination of speech sounds (segmental aspects). Other impairments include difficulty with speech prosody, such as tone, rhythm, pitch and volume changes associated with emotional state and/or context (suprasegmental aspects). There are a variety of characteristics associated with CAS, although the presumed challenge is in planning and programming speech movements (ASHA, 2007; Preston, Molfese, et al., 2014). Such impairments may lead to social, academic, and vocational limitations. Thus, there is a need to explore alternate treatment approaches. This study will explore how to improve speech sound production in school-age children with CAS by modifying a standard speech therapy program. Two adaptations to speech therapy will be tested in a 2 x 2 randomized group design.

In Aim 1, we will compare a standard treatment schedule of 2 one-hour sessions per week vs. a treatment sequence beginning with an intensive therapy schedule (10 hrs of treatment in one week), which will then transition to a more distributed practice schedule. This treatment modification is intended to minimize erred practice between training sessions in the early stages of learning, then foster generalization through increased time between practice sessions. Prior studies suggest that distributing speech therapy sessions in a more intense schedule may be beneficial to learning (Namasivayam et al., 2015; Thomas et al., 2014)

In Aim 2, we will compare a standard treatment that includes only verbal feedback to the client during speech practice vs. a treatment sequence that initially includes real-time ultrasound visual feedback of the tongue during speech, which will be faded over the course of treatment. Ultrasound visual feedback is designed to train articulatory movements. It may enhance children's understanding of the articulatory goals of speech

movement patterns by comparing executed tongue movements with intended movements. Prior case reports and single subject experimental designs have shown that speech sound production may be enhanced by including ultrasound visual feedback (Preston, Brick & Landi, 2013; Preston, Leece, McNamara, & Maas, in press), although no prior randomized group studies have been conducted.

All 4 of these treatment conditions (e.g., intensive/distributed, ultrasound visual feedback/no ultrasound visual feedback) have been proven effective in treating childhood apraxia of speech; however, no study to date has compared these treatments to see which treatment (or combination of treatments) is most effective.

Beside these modifications, the other aspects of treatment will be held constant. Outcomes will be evaluated by tracking changes in percent consonants correct from a large speech sample, scored by individuals who are blind to treatment status. The four groups will be compared to determine the extent to which speech sound therapy can be enhanced through a treatment sequence that begins with intensive practice and/or with ultrasound visual feedback.

4. Methods

4.1. Provide a detailed description of what participants will be required to do; including any technical terms or procedures.

All behavioral testing and treatment will take place at the Speech Production Laboratory (621 Skytop Road, Suite 165).

Evaluation Visit 1 (Baseline 1; ~2 hrs.)

Following consent and assent, the following research procedures will be followed to determine eligibility for the study

1. Hearing screening. ~5 minutes. Quiet beeps are presented through headphones. The child raises their hand if they hear the beep. 25 dB at 500Hz and 20 dB at 1000, 2000, 4000 Hz in each ear. Participants must pass the hearing screening at all frequencies in both ears to be included in the study.
2. Matrix Reasoning subtest of the Wechsler Abbreviated Scale of Intelligence – Second Edition (Wechsler, 2011). ~10 minutes. Child is asked to select the picture (from a set of 5-6) which best completes the pictured pattern. Inclusionary Criteria: t-Score of 37 or better (-1.33 SD from the mean).
3. Goldman-Fristoe Test of Articulation – Third Edition (Goldman & Fristoe, 2015). ~10 minutes. Child is asked to name various pictures which evaluate speech sound production. Inclusionary Criteria: Score less than the 5th percentile.
4. Peabody Picture Vocabulary Test (PPVT-4; Dunn & Dunn, 2007). ~15 minutes. The examiner says a word and the child points to a picture that corresponds to the word, from an array of 4. Complexity of vocabulary increases as children progress through the test. Inclusionary Criteria: Standard Score of 80 or better (-1.33 SD from the mean)
5. Following Directions subtest of the Clinical Evaluation of Language Fundamentals – 5th Edition (CELF-P2; Wiig, Semel & Secord, 2013). ~15 minutes. The examiner gives a direction and the child points to pictures to execute the direction given (e.g., "Point to the black circle that is to the right of the square."). Complexity of directions increases as children progress through the test. Inclusionary Criteria: Scaled score of 6 or better (-1.33 SD from the mean).

**CAS Criteria: to confirm a diagnosis of CAS, participants must meet CAS criteria on 2 of the 3 tasks described below:*

6. *Maximum Performance Tasks (Rvachew et al., 2005; adapted from Thoonen et al., 1999). ~20 minutes. Maximum length of phonation duration and fricative duration will be collected. Additionally, alternating motion diadochokinetic rates (MRRmono) (e.g., [pʌ pʌ pʌ pʌ pʌ pʌ pʌ] and sequential motion diadochokinetic rates (MRRtri) (i.e., [pʌ tʌ kʌ pʌ tʌ kʌ pʌ tʌ kʌ] will be collected. CAS Criteria: Apraxia score of 2, Dysarthria score of 0 or 1. Exclusionary criteria: Dysarthria score of 2.
7. *Syllable repetition task (Shriberg et al 2009). ~5 minutes. Children repeat nonsense syllables that contain the sounds /ba ma da na/ ranging from 2-4 syllables in length (e.g.,/daba/ or /mabadana/). Number of items with additions will be recorded. CAS Criteria: 4 or more additions present out of 18 items.

8. *Polysyllabic Naming Task (Murray, McCabe, Heard, et al, 2015; adapted from Gozzard et al, 2004). ~15 minutes. Children will name 80 researcher-selected multisyllabic words presented via pictures on PowerPoint slides (e.g., vegetable, umbrella). Children's productions will be rated for accuracy of lexical stress, percent consonants correct, and number of segregated syllables (e.g., um----brella).

Following the first visit, participants who are eligible will be invited to continue the study. They must agree to be randomized to one of the treatment conditions. If they agree, they will be randomized (through concealed envelopes) to one of four treatment groups, and scheduling will be discussed. The second evaluation visit will be scheduled within one week of the start of treatment.

<u>Evaluation Visit 2</u> (Baseline 2; ~1.5 hours)

1. 3 subtests comprising the Phonological Awareness Composite of the Comprehensive Test of Phonological Processing – Second Edition (Wagner et al., 2013). ~20 minutes. Subtests include: Elision (e.g., "Say *cowboy.* Now say it again, but don't say boy."), Blending Words (e.g., "What word do these sounds make? /m/ --- /u/ --- /n/), and Sound Isolation (e.g., "what is the second sound in *toast*?"). Subtest scaled scores, percentiles and the Phonological Awareness Composite score, percentile will be obtained.
2. The Recalling Sentences subtest of the Clinical Evaluation of Language Fundamentals – 5th Edition (CELF-P2; Wiig, Semel & Secord, 2013). ~10 minutes. Participants will be asked to repeat sentences of increasing length and complexity immediately after hearing them once. Subtest scaled score will be obtained.
3. Nonword Repetition Task (Dollaghan & Campbell, 1998). ~5 minutes. Participants will be asked to repeat 1 – 4 syllable non-words after the word is presented via computer. Percent consonants correct will be obtained.
4. Structural Oral Mechanism Evaluation. ~5 minutes. The structure and function of oral anatomy will be observed using passive (e.g., observe symmetry of facial structures) and active tasks (e.g., wag tongue from side to side).
5. Multisyllabic Rapid Automatic Naming (Preston & Edwards, 2009). ~5 minutes. Participants will be asked to name a set of 6 randomly-presented multisyllabic pictures across 48 trials. Time of task will be recorded.
6. Multisyllabic Word Repetition Task (Preston & Edwards, 2007). ~10 minutes. Participants will repeat multisyllabic words of 2-5 syllables after the word is presented via computer. Percent consonants correct, percent lexical stress correct, and number of syllable segregations will be obtained.
7. Word Inconsistency Task from the Linguisystems Articulation Test (Bowers & Huisingh, 2011). ~5 minutes. Participants will repeat multisyllabic words three times after an examiner prompt (e.g., "Say *lifeguard* three times." Percent consonants correct, percent lexical stress correct, and number of syllable segregations, and number of different productions will be obtained.
8. Multisyllabic Picture Naming. ~5 minutes. Participants will name 30 researcher-selected multisyllabic words presented via pictures on PowerPoint slides. Percent consonants correct, percent lexical stress correct, and number of syllable segregations will be obtained.
9. Word Inconsistency subtest of Linguisystems Articulation Test (Bowers & Huisingh, 2011). ~5 minutes. Participants will name 12 multisyllabic pictures 3 times each following an initial model (e.g., "Say *eyelashes* three times). Productions will be evaluated on whether the 3 trials are consistent (C) or inconsistent (I). Additionally. Percent consonants correct, percent lexical stress correct, and number of syllable segregations will be obtained from the first production of each set.
10. Phrase repetition task. ~10 minutes. Participants will repeat phrases and short sentences containing multisyllabic words after the phrase/sentence is presented via computer (e.g., "factual discussion;" "Renew my newspaper subscription."). Percent consonants correct, percent lexical stress correct, and number of syllable segregations will be obtained.
11. Three Individual Phrase Probe Lists. ~5 minutes each, 15 minutes total. Based on speech sound errors observed in Baseline 1, specific error patterns will be identified. Individual probes addressing an error pattern will be administered. Participants will read a list of 20 phrases containing the target pattern (e.g., for onset /l/ examples might be: "please go left" and "light the flame"). Percent accuracy will be collected on number of target sounds produced correctly out of 40 using a binary scoring system (i.e., incorrect = 0; correct = 1).

***The 2 least accurate of the 3 individual phrase probes will be selected as therapy targets.*

Progress monitoring Assessment (~40 minutes): Conducted after 5 weeks, 10 weeks, and 15 weeks.

1. Multisyllabic Word Repetition Task (Preston & Edwards, 2007). ~10 minutes. Participants will repeat multisyllabic words of 2-5 syllables after the word is presented via computer. Percent consonants correct, percent lexical stress correct, and number of syllable segregations will be obtained.
2. Multisyllabic Picture Naming. ~5 minutes. Participants will name 30 researcher-selected multisyllabic words presented via pictures on PowerPoint slides. Percent consonants correct, percent lexical stress correct, and number of syllable segregations will be obtained.
3. Word Inconsistency subtest of Linguisystems Articulation Test (Bowers & Huisingh, 2011). ~5 minutes. Participants will name 12 multisyllabic pictures 3 times each following an initial model (e.g., "Say *eyelashes* three times). Productions will be evaluated on whether the 3 trials are consistent (C) or inconsistent (I). Additionally. Percent consonants correct, percent lexical stress correct, and number of syllable segregations will be obtained from the first production of each set.
4. Phrase repetition task. ~10 minutes. Participants will repeat phrases and short sentences containing multisyllabic words after the phrase/sentence is presented via computer (e.g., "factual discussion;" "Renew my newspaper subscription."). Percent consonants correct, percent lexical stress correct, and number of syllable segregations will be obtained.
5. Three Individual Phrase Probe Lists. ~5 minutes each, 15 minutes total. Based on speech sound errors observed in Baseline 1, specific error patterns will be identified. Individual probes addressing an error pattern will be administered. Participants will read a list of 20 phrases containing the target pattern (e.g., for onset /l/ examples might be: "please go left" and "light the flame"). Percent accuracy will be collected on number of target sounds produced correctly out of 40 using a binary scoring system (i.e., incorrect = 0; correct = 1).
6. Ultrasound Safety Form (for those receiving US biofeedback). ~5 minutes. Administer a short questionnaire to participant and parent to ensure that procedures and methods continue to be safe and are without adverse effect.

Treatment Design

Aim 1: In addition to the above assessment visits, participants will be randomized to one of four treatment conditions.

Table 1: Four groups to which children will be randomized in a 2 x 2 Factorial design

Distribution Conditions	Biofeedback Conditions	
	Sequenced Biofeedback (Biofeedback → No biofeedback)	No biofeedback
Sequenced Distribution (massed→distributed)	n=10	n=10
Distributed Practice	n=10	n=10

We will randomize children with CAS to one of four groups. We will test generalization effects in a x 2 (Mass→Distributed vs. Distributed only Practice Schedule) x 2 (Sequenced Biofeedback→No biofeedback vs. No biofeedback) factorial treatment design.

Participants will be randomly assigned to either Distributed Practice or Sequenced Distribution (massed→distributed practice). In both conditions, the cumulative treatment dose will be 20 hours of treatment. Half of our participants (n=20) will receive treatment following a distributed model of twice per week for 60 minutes for 10 weeks, for a total of 20 hrs of therapy. The remaining participants (n=20) will receive treatment following a sequenced approach of massed then distributed practice, with 10 hrs occurring in the first week (2 hrs per day for 5 days, with a 10 minute break in between sessions each day), then 3 one-hour sessions per week for 2 weeks, and finally 2 one-hour sessions per week for 2 weeks.

Table 2: Overview of Aim 1 Schedule by Group: Operationalized Definitions

	Wk 1	**Wk 2**	**Wk 3**	**Wk 4**	**Wk 5**	**Wk 6**	**Wk 7**	**Wk 8**	**Wk 9**	**Wk 10**	**Wk 15**
Distributed Practice Group (n=20)	1 hr x 2 visits	1 hr x 2 visits	1 hr x 2 visits	1 hr x 2 visits	1 hr x 2 visits & Assess	1 hr x 2 visits	1 hr x 2 visits	1 hr x 2 visits	1 hr x 2 visits	1 hr x 2 visits & Assess	Assess
Sequenced Distribution Group (n=20)	2 hr x 5 visits	1 hr x 3 visits	1 hr x 3 visits	1 hr x 2 visits	1 hr x 2 visits & Assess	-	-	-	-	Assess	Assess

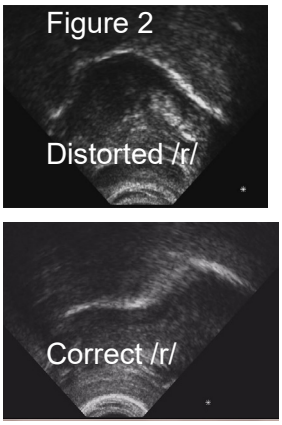
Aim 2: In addition to the above randomization based on schedule, half of the participants (n=20) will be randomized to receive treatment without ultrasound visual feedback and half (n=20) will be randomized to receive treated with ultrasound. The practice structure described above (see *Overview of Treatment Procedures*) will be identical, and the difference between conditions therefore will be whether or not the clinician and client have access to a visual referent during speech production to describe aspects of both erred and correct tongue movements.

In the Sequenced Biofeedback→No biofeedback condition, participants begin treatment such that ~50% of the session includes ultrasound feedback of the tongue. Each session will be divided into four 13 minute Time Periods (A, B, C, D). The ultrasound will be available for practice in Time Periods A and C, whereas practice will continue without ultrasound for periods B and D. When the ultrasound is used in Time Periods A and C, it will be available only when the participant is practicing at treatment Levels 1 (syllables), 2 (monosyllabic words), 3 (multisyllabic words) and 4 (phrases). However, after 8 hrs of treatment, *ultrasound use will be faded* such that it is only available as children are at practice Levels 1 and 2 to encourage independent practice without visual support at more complex levels. During the final 4 hours of treatment, no visual feedback will be available.

Table 3: Structure for a 60-min Session: Operationalized Comparison of Ultrasound use for Aim 2

Sequenced Biofeedback → No Biofeedback Group (n=20)				
Time Period:	**A**	**B**	**C**	**D**
Treatment target	Target 1	Target 1	Target 2	Target 2
Ultrasound available: First 8 hrs of therapy	Used on Levels 1: Syllables 2: Monosyllabic words 3: Multisyllabic words 4: Phrases	None	Used on Levels 1: Syllables 2: Monosyllabic words 3: Multisyllabic words 4: Phrases	None
Next 8 hrs of therapy	Used on Levels 1: Syllables 2: Monosyllabic words	None	Used on Levels 1: Syllables, 2: Monosyllabic words	None
Last 4 hrs of therapy	None	None	None	None
No Biofeedback Group (n=20)				
Time Period:	**A**	**B**	**C**	**D**
Treatment target	Target 1	Target 1	Target 2	Target 2
Ultrasound use	None	None	None	None

When biofeedback is required, we will use an EchoBlaster 128 ultrasound with PV 6.5 probe to provide real-time visual display of the tongue. When it is available, *all verbal feedback* by the clinician will be expected to reference the visual display. For example, when treating /-ks/ sequences, feedback can be provided to the client about elevation of the tongue body and lowering of the tongue tip for /k/, followed by elevation of the tongue tip/blade for /s/. The participant's attention will therefore be drawn to these movements on the screen and participants will be instructed to visually monitor their speech movements and make corrections based on the visual feedback. As an example, **Figure 2** shows ultrasound images for /r/ (anterior is right, posterior left). The distorted /r/ (top) has a low tongue tip/blade (right side of the image) and high tongue body, whereas the correct /r/ (bottom) has a high tongue tip/blade and a lowered tongue body.



When no biofeedback is required, practice will be similar to traditional speech therapy. Feedback will be based on the clinician's percept of the child's production unaided by technology. However, the practice and feedback structure will still follow that which is outlined in Table 3.

Overview of Treatment Session Procedures

A manual is posted on our website outlining practice procedures (speechproductionlab.syr.edu). The general structure involves a pre-practice stage and a practice stage in each session. During ***pre-practice***, target sound sequences (e.g., /lo-/) are elicited through frequent phonetic cues, shaping strategies, and verbal descriptions of articulation. When biofeedback is available, and visualization of is used to encourage the child to modify shape and position and to properly sequence movements for acceptable productions. A pre-established criterion (i.e., 12 correct productions of the target) must be met to progress from the pre-practice stage to the practice stage. For clients with significant difficulty producing the target sound sequences, pre-practice may take the majority of a session (during the early stages of therapy); for clients who have developed the ability to successfully perform the task (during the later stages of therapy), pre-practice may be completed in 1-2 minutes.

During the ***practice*** stage, there are multiple levels of practice with target stimuli that are chained. Chains involve a target sound sequence (e.g., /lo-/) produced first in syllables then in more complex environments. Each practice level involves 6 blocked attempts at the target. If at least 5 of 6 productions are correct, practice continues on the same chain the next highest level; if fewer than 5 are correct, practice returns to the Level 1 on a different target (e.g., /kl-/). The first practice level is at the syllable level, followed by monosyllabic words, multisyllabic words, phrases, and sentences. For each sound sequence that is targeted, 8 chains will be used for treatment in each session. The table below outlines the practice parameters.

Table 3: Practice Stage: Operationalized Parameters for Blocks of 6 Attempts (all sessions)

Practice Level	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**
Targets	Syllables	Monosyllabic word	Multisyllabic word	Set phrase	Client-generated sentence
Example chain	/lo/	*Load*	*Loading*	*Loading the truck*	[*Loading* in sentence]

Each hour of therapy will address two different sound targets, with the first half of the session addressing one sound target and the second half addressing another; the order will be counterbalanced each session. Targets are selected as a phoneme in a syllable position, and four exemplars are selected for that sound target. For example, /l/ in onset could be addressed with sound sequences such as /li-/, /lo-/, /kl-/, /pl-/ during the first half hour, and /k/ in coda could be treated with sound sequences such as /-ɪk/, /-ʊk/, /-ks/, /-sk/ during the second half hour. Targets will be selected based on the lowest percent accuracy before treatment based on the sound-specific Probes. Two targets will be treated per session; however, new targets will replace previous targets if the participant successfully completes Level 5 for 2 chains during 2 consecutive sessions.

The above components of treatment are held constant, allowing for manipulation of other parameters (distribution of sessions for Aim 1 and exposure to visual feedback for Aim 2). These standard components to treatment, as well as the manipulated components for Aim 1 and 2, will be monitored and reported for treatment fidelity and to ensure replicability.

4.2. Describe how you will have sufficient time to conduct and complete the research?

The grant provides one course release per year for Dr. Preston, along with summer salary. The grant also covers 50% of Ms. Leece's time as well as paid time for research assistants. We will devote time for weekly lab meetings with research assistants throughout the year to ensure the progress progresses.

4.3. Surveys, interviews, questionnaires will be conducted:

☐ **No (Skip to 4.4)**

☒ **Yes Include all research instruments including surveys, questionnaires, sample interview questions, etc. as separate appendices. If the survey instrument is commonly used in your discipline, only provide a citation to the instrument.**

4.4. Community Based Participatory Research (CBPR) is described as research that is conducted as an equal partnership between traditionally trained "experts" and members of a community. Is this research categorized as CBPR?

☒ **No. (Skip to 4.5)**

☐ **Yes. Please explain:**

4.4.1. In CBPR research studies, the community participates fully in all aspects of the research process including conception, design, and analysis.
With this in mind, describe how you plan to engage community members in your research study:

4.4.2. Describe how you plan to provide community members with appropriate training for human subjects research? Include in your description what training will be provided.

4.4.3. Describe your plan to disseminate research findings with members of the community throughout the course of your study.

4.5. Will this research be conducted by SU investigators in foreign countries?

☒ **No. (Skip to 4.6)**

☐ **Yes. An International Research Form must be completed and submitted with this application.**
http://researchintegrity.syr.edu/wp-content/uploads/2016/10/International-Research-Form-2013.doc

4.6. Will this research involve genetic testing?

☒ **No. (Skip to Section 5)**

☐ **Yes. A Genetic Research Form must be completed and submitted with this application.**
http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Genetics.doc

5. Performance Site Information

5.1. Describe how you will have adequate facilities to conduct your study.

The Speech Production Laboratory (PI, Dr. Preston) at 621 Skytop Road, Suite 165-00 was designed for clinical data collection from children. Dr. Preston has been running studies with children for 3 years. He currently has the equipment required (ultrasound, recording devices, testing materials, etc.) to conduct this project.

5.2. List all Performance Sites Other than SU *(insert additional rows if needed).*
(*This may apply when a SU investigator collaborates with a non-SU investigator or institution. Please check all that apply and add additional sites. Each will require a letter of cooperation and/or IRB approval.*)

Check all that apply	Name of Performance Site (list all participating sites below)	IRB Approval and/or Letter of Cooperation
☐	SUNY Upstate Medical University	☐ Attached ☐ Pending
☐	*Syracuse City Schools	☐ Attached ☐ Pending
☐	*Other, specify site:	☐ Attached ☐ Pending

**The following additional information is required: contact information for the site, if the site has an IRB, and whether the IRB has approved the research, or plans to defer review to SU's IRB:*

5.3. Will this research be conducted in a school or is it funded by the US Department of Education?

☒ **No (Skip to 5.4)**

☐ **Yes. If yes, complete the form found at:**
http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Department-of-Education-Schools-Form.doc

5.4. Is this a multi-center research project in which Syracuse University will function as the coordinating center/lead institution? (*A multi-center study is one where different PIs at different institutions are conducting the same study*.)

☒ **No**

☐ **Yes. If yes, describe the plans to manage information obtained in multi-site research that may be relevant to the protection of research participants such as: unanticipated problems involving risks to participants or others, interim results, and protocol modifications:**

6. Research Qualifications

CITI training is required for the faculty member listed below and all researchers and research staff who have direct contact with participants and/or identifiable human participant data. NOTE: If training is not completed at the time of submission, approval of your application will be delayed.

6.1. List the names and research qualifications of the primary investigator/faculty advisor listed in Section 1 of this application.

Dr. Jonathan Preston, PI, is a licensed speech-language pathologist and is an expert in childhood speech sound disorders. He has provided clinical speech services for 14 years and has conducted research with over 200 children with speech sound disorders, including children with childhood apraxia of speech. He has successfully completed numerous projects and has experience managing participants, research teams, and data sets. Dr. Preston has completed CITI and Good Clinical Practice training for clinical research studies.

6.2. List the names and research qualifications of the student/research staff listed in Section 1 of this application.

Ms. Megan Leece is a licensed speech-language pathologist who has been practicing for over 18 years. She supervises graduate students in the Gebbie Speech-Language-Hearing Clinic part-time and works as Dr. Preston's lab manager part time (50% effort). She will conduct the assessments and treatment sessions. She has extensive experience managing sensitive data in both clinical and research environments. Her expertise is in working with children with speech sound disorders and is therefore sensitive to the needs of both children and their parents. Ms. Leece has completed CITI and Good Clinical Practice training (supporting documentation attached) for clinical research studies.

6.3. List the name(s) and research qualifications of all other individuals who will be involved in this research and will have direct contact with participants and/or identifiable human participant data.
Jaclyn Storto will serve as a research assistant who will have contact with data. She has 15 years of experience as a special education teacher and is therefore familiar with some of the particular needs of working with confidential data. She is enrolling in the Master's program in Speech-Language Pathology and has completed CITI and Good Clinical Practice training.

6.4. How will you ensure that all persons listed above are adequately informed about the protocol and their research related duties and functions?
A manual has been developed outlining the protocols that are to be followed. All members of the team will be required to read the manual to ensure familiarlity with technical and procedural issues. We will hold weekly lab meetings to review both procedural/compliance issues as well as scientific issues. We will outline responsibilities at each meeting (currently using the web-based system ASANA) and we will keep a running log of the status of recruitment, participation, data collection, data safety/confidentiality, and data analysis. All members are CITI-certified and will be instructed to immediately bring to the PI's attention any Human Subjects related issues.

6.5. Explain how you will have adequate numbers of qualified staff to conduct your study.
The staff listed above are sufficient to collect and manage data from approximately 15 children per year and to conduct data management/coding activities for those participants.

7. Characteristics of Participants

7.1. Approximate Number of Participants to be recruited: 40

7.2. Sex: **M** ☐ **F** ☐ **Both** ☒

7.3. Age Range-Check all that apply:
- ☐ **0-6 (Include parental consent form)**
- ☒ **7-17 (Include parental consent form and child assent form)**
- ☐ **18-64**
- ☐ **65 and older**

Exact ages to be included: 9;0 – 17;11

7.4. When the age range indicates an upper limit, provide justification: This age range is chosen as it is sufficiently restrictive to enable homogeneity of participants, with all participants beyond the age of typical acquisition of speech sounds (approximately age 8-9 yrs, Smit et al., 1990); additionally, prior work has shown that children below the age of 8 may show less growth with biofeedback treatments (Sjolie et al., 2016). Because participants may be randomized to a treatment condition with an intensive component (e.g., 10 hours of therapy over 5 consecutive days), participants need to be old enough to maintain attention to cognitively demanding tasks over long durations.

7.5. Does this study target one gender or specific social/ethnic group(s)?
- ☐ **No. (Skip to 7.6)**
- ☒ **Yes. If yes, answer 7.5.1. and 7.5.2. below.**

7.5.1. If yes, check all that are targeted/vulnerable populations (Code of Federal Regulations: http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr46_00.html).

***These additional forms can be found on the IRB Website under Special Populations: http://researchintegrity.syr.edu/human-research/forms/**
- ☒ **Children/minors - *Requires additional form***
- ☐ **Cognitively impaired - *Requires additional form***

☐ **Prisoners - * Requires additional form***
☐ **Pregnant women - *Requires additional form***
☐ **Legally restricted, non-prisoner**
☐ **Educationally disadvantaged**
☐ **Economically disadvantaged**
☐ **Elderly/aged**
☐ **Other, specify:**

***NOTE*:** **These additional forms can be found on the IRB Website (under Special Populations):** http://researchintegrity.syr.edu/human-research/forms/

7.5.2. Explain the rationale for using this particular group(s): This is the age at which most children have typically acquired speech sounds; therefore, any errors present are unlikely to resolve due to maturation effects. Also, children over the age of 9;0 are more likely to sustain attention during tasks which are cognitively demanding.

7.6. List the inclusion criteria:

Participants must be native English speakers who hear English as the dominant language in their home setting. Participants must be in the age range of 9;0 – 17;11. In the initial evaluation, all participants must pass a hearing screening. Additionally, participants must score at or better than -1.3 standard deviations from the mean on the Matrix Reasoning Task of the Wechsler Abbreviated Scale of Intelligence – 2nd Edition (WASI-2; t-score ≥ 37), Peabody Picture Vocabulary Test – 4th Edition (PPVT-4; standard score ≥ 80), and the Following Directions subtest of the Clinical Evaluation of Language Fundamentals – 5th Edition (CELF-5; scaled score ≥ 6). Speech sound errors will be confirmed by the administration of the Goldman-Fristoe Test of Articulation – 3rd Edition (GFTA-2; percentile ≤ 5th). A diagnosis of CAS will be verified using three research supported tasks which assess the participant's the ability to plan/program complex speech movements. The 3 primary tasks described below, which have been part of our assessment battery to date, have been independently developed in previous studies in Sydney, AU, Nijmegen, NL, and Madison, WI. Based on published procedures, we will require that participants meet CAS diagnostic criteria on at least 2 of the 3 tasks described below.

Task	**Description**	**Measures**	**Published Sensitivity/ Specificity**
Polysyllable task (Murray, McCabe, Heard, et al., 2015)	Naming of 80 polysyl-labic words (e.g., kangaroo)	Percent Consonants Correct, Percent of words with appropriate lexical stress, Percent syllable transitions with segregation.	97% / 100% (when combined in a model with DDK task be-low, Murray et al., 2015)
Diadochokinetic task (Thoonen et al., 1999)	Rapid sequences of /pʌtʌkʌ/	Rate and accuracy of tri-syllables	100% / 91 %
Syllable Repetition Task (Shriberg et al., 2009; Shriberg et al., 2012)	Participant repeats nonsense words of 2-4 syllables (e.g., /bamadana/	Number of items (out of 18) with phoneme additions	74.6% / 93.4%

7.7. List the exclusion criteria:

Participants will be excluded if parent report or direct evaluation reveals oral-facial structural abnormalities (e.g., cleft palate). We will not study participants whose parents report known genetic syndrome, neurobehavioral disorders (e.g., autism spectrum disorders, ADHD, obsessive-compulsive

disorder), or vision problems that are corrected with glasses/contacts.). We will also exclude individuals who fail a hearing screening during the eligibility visit. These restrictions are put into place to enhance the internal validity of the study. In order to avoid confounding interpretation of the relations between treatment outcomes and language or cognitive abilities, we will exclude individuals with low nonverbal abilities (as identified as being below the inclusionary criteria on the Matrix Reasoning subtest of the WASI-2, PPVT-4, or Following Directions Subtest of the CELF-5). Participants will also be excluded if they do not meet the CAS diagnostic criteria on 2/3 of the tasks described above. A Dysarthria Score of 2 on the Maximum Performance Tasks is also considered exclusionary (to avoid confounding interpretation of treatment outcomes). Participants who are not in the target age range during the entire range of their participation (9;0 – 17;11) will also be excluded.

7.8. Does this research involve participants likely to be vulnerable to coercion or undue influence?

☒ **No. (Skip to 7.9)**

☐ **Yes. If yes, describe the additional protections included in the protocol to protect their rights and welfare.**

7.9. General state of Health: ("Unknown"- ***unless you will obtain health data on participants prior to beginning the study.*****)**

"[Suspected] childhood apraxia of speech" The clinical diagnosis is inconsistently applied; therefore, we will use our own criteria to make this determination.

8. Recruitment of Participants

8.1. Describe in detail how participants will be identified and recruited. Include in your description how you will have access to a population that will allow recruitment for the number of participants required for your research. Do not merely state "Volunteers".

Participants will be identified and recruited through flyers, informational letters, and emails that will be distributed to local speech-language pathologists who will be invited to share information about the study with parents of children who might benefit from participation in the study. In addition, flyers and online postings will be used to reach out to parents in the surrounding communities. Online postings will consist of a link to the flyer available via the (1) CSD department website (csd.syr.edu); (2) Speech Production Lab Website (speechproductionlab.syr.edu); (3) SU Today; (4) the American Speech-Language Hearing Association's CLARC program (Clinicians and Researchers Acting Together; community.asha.org/clarc) of which Dr. Preston is a member; and (5) the Childhood Apraxia of Speech Association of North America (CASANA.org). The research team will also contact the Gebbie Clinic (621 Skytop Road, Suite 1200), and private speech-language clinics (with publicly available addresses) and invite personnel at these locations to post/share a copy of our flyer; they are free to decline. An announcement will be placed in the SU CSD Alumni newsletter and flyers will be passed out at Continuing Education events for speech-language pathologists throughout the year. We will pay to put an ad in the Central New York Speech-Language Hearing Association newsletter. Additionally, links to information on the website will be tweeted (@JPrestons_SLP, @meganleece, @SyracuseCSD) and posted to Facebook (Dr. Preston's page, CNYSHLA page).

Additionally, we will coordinate with speech-language pathologists at various schools. Letters of support are attached.

8.2. Describe who will recruit participants.

Dr. Preston, Ms. Leece, Ms. Storto

8.3. Identify all applicable recruitment methods that apply: NOTE:Copies of all advertising materials including flyers, posters, ads, letters, scripts or detailed descriptions; including graphics MUST be provided with your application. (See SOP 036 for Recruitment/Advertising).

☒ Flyers	☒ Mass E-mail Solicitation	☒ SU Today News Service
☒ Internet	☐ Posters	☐ Television
☒ Letter	☐ Newspaper	☒ Departmental Research Boards
☐ Telephone	☐ Radio	☒ Social Media
☐ Other (describe):		
☐ Not applicable		

8.4. Will participants be compensated?

☐ **No. (Skip to Section 9)**

☒ **Yes. If yes, answer 8.4.1. and 8.4.2. below.**

Note: All information regarding compensation must be included in consent/assent documents.

8.4.1. If Yes, specify the method of compensation (e.g. monetary, course credit, gift card, toy, etc.), the amount of compensation, and how the compensation will be awarded (per task, per session, etc.).

Participants' parents will be compensated at $20/hr for all assessments (Visits Baseline 1, Baseline 2, 5-Week, 10-Week, 2-Month). Participants' parents will also be compensated $5 per visit to defray travel costs; this applies to both assessment and treatment visits. Participants' parents would therefore be paid a total of approximately $215 for the entire study. While separately obtaining assent, participants will be reminded that they may withdraw from the study at any time, and that they don't have to participate in the study (even if their parents want them to).

8.4.2. Describe how compensation will be awarded if the participant withdraws after beginning the study. Compensation must be pro-rated in a manner that recognizes the time and effort of the participant prior to withdrawal.

For any participant who withdraws part-way through an evaluation session, compensation will be pro-rated at $5 per quarter hour of time spent. Similarly, we will provide compensation at $20/hr ($5 per quarter hr) for individuals who are evaluated for eligibility, but are excluded from the study due to a failure to meet eligibility criteria.

9. Informed Consent Procedures

Consent is required for all human subject participants. Final copies of ALL consent/assent documents (including electronic or oral scripts) must be provided for IRB approval and date stamping. Informed consent/assent documents must be on *official SU departmental letterhead.* For guidance regarding informed consent, consult SOP 017-Documentation of Informed Consent http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-017-Document-of-Informed-Consent.pdf **. For consent form instructions/sample visit:**
http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Consent-Form-Guidelines.doc
http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Consent-Form-Sample.doc
For assent form instructions/sample visit: http://researchintegrity.syr.edu/wp-content/uploads/2016/10/How-to-Prepare-a-Child-Assent-Document-and-Assent-Sample.doc

9.1. How many consent documents are included with this application? 1

9.2. How many assent documents are included with this application? 1

9.3. Is more than one consent/assent document included with this application?

☒ **No. (Skip to 9.4.)**

☐ **Yes. If yes, follow instructions below (9.3.1 and 9.3.2).**

9.3.1. Assign form numbers to each individual document and add it to the footer of the document-e.g. Consent form 1, Consent form 2, Assent form 1, etc.

9.3.2. Create a separate log as an appendices identifying each document-e.g. Consent form 1-parental consent, Consent form 2-adult participant consent; Assent form 1-child assent, etc.)

9.4. Indicate the type of consent you will obtain for your study (check all that apply).

9.4.1. Written Consent ☒ (ATTACH COPY)

Provide a brief statement of what will be said when the consent process is initiated:

Anytime we do research, we have to get permission. Before we ask for your permission, we want you and your parents to be aware of what will happen in the study and why. The Assent document that we read to you and the Consent document for your mom/dad explain the details. I'll read the Assent to you and let your mom/dad look through the Consent document, and you'll have a chance to ask questions before you decide if you want to participate or not.

9.4.2. Electronic Consent ☐ (ATTACH SCRIPT) *(This is a request to waive the required element of documentation of written consent, e.g. internet studies.)*

9.4.3. Oral Consent ☐ (ATTACH SCRIPT)

Provide the justification for the waiver of written consent:

9.4.4. N/A ☐ Data Analysis Only, no consent form required.

9.5. Who will conduct the consent interview?

Megan Leece, Jonathan Preston

9.6. How will you ensure that prospective participants have sufficient opportunity to consider whether or not to participate in your study?

We will conduct a phone screening with all parents/guardians (see Phone Screening) and will describe the study at the time and will answer questions. We will also send an electronic copy or a mailed copy of the consent form before they attend the first visit and will allow them to ask questions before signing the consent.

9.7. What steps will be taken to minimize the possibility of coercion or undue influence?

Assent is obtained separately from consent (thus, parent/guardian may sign consent, but participant may choose not to assent). Prior to signing the assent, participants will be told that they are not required to participate and that they may withdraw at any time. We will make them aware of other options available for treatment (e.g., the Gebbie Speech Language Hearing Clinic at SU, school district, private speech therapy)

9.8. An ASSENT statement is required for participants who cannot legally give consent themselves. Assent statement:

☐ No (Skip to 9.9)

☒ Yes (ATTACH COPY)

9.8.1. From whom will consent be obtained and by what means for minors or the individuals considered to be cognitively impaired in their decision making ability? ☐ N/A

Parents/guardians will provide written consent. Children will provide written assent.

9.8.2. If subjects are minors, will they still be involved in the study when they reach the age of majority (18)?

☒ No

☐ Yes. If yes, outline your plan to re-consent these participants when they reach the age of majority.

☐ N/A

9.9. Will non-English speaking individuals be participants in the research?

☒ No (skip to Section 10)

☐ Yes If yes, indicate how consent will be documented from non-English speaking participants?

☐ **A translated written informed consent document in a language understandable to the participant. This should be an accurate translation of the full informed consent. (ATTACH COPY)**

Identify the name of the individual or translation service that provided the translation of the consent document.

List the qualifications of the individual or translation service that provided the translation of the consent document.

☐ **Orally, using a qualified translator to translate the English informed consent document to the participant, and a translated short form in a language understandable to the participant (ATTACH COPY)**

Identify the name of the individual or translation service that will provide translation for the consent process and during the conduct of the research.

List the qualifications of the individual or translation service that will provide translation for the consent process and during the conduct of the research.

☐ **A confidentiality statement from**

10. Potential Financial Conflict of Interest

A conflict of interest exists when any investigator or personnel listed in this research protocol's financial interests may reasonably be affected by research, scholarship, educational or other externally funded activity. Or, when the immediate family* of anyone in such a role, have significant financial interests that may compromise, or have the appearance of compromising, an investigator's professional judgment that could directly and significantly affect the design, conduct, or reporting of the research, proposed or funded.

Federal Guidelines emphasize the importance of assuring there are no conflicts of interest in research projects that could affect the welfare of human participants. If this study involves or presents a potential conflict of interest, additional information will need to be provided to the Vice President for Research.

The following significant financial interests must be disclosed if interest is in the sponsor of the research or the product being tested:

Anything of monetary value - aggregated for the Investigator and the Investigator's spouse, domestic partner, and dependent children - including but not limited to the following:

a. Salary or other payment for services (e.g. consulting fees) of $10,000 or greater in the past year when aggregated for the immediate family;
b. Any equity interest (e.g. stocks, stock options or other ownership interests) unless it meets the following three tests:
    i. less than $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value (e.g. most recent sales price recognized by the company),
    ii. constitutes less than a 5% ownership interest in any single entity, or
    iii. publicly traded on a national stock exchange,
    iv. no arrangements have been made where the value of the interest will be affected by the outcome of the research.
c. Intellectual property rights (e.g. patents, copyrights and royalties from such rights).
d. Services as an officer, director, or in any other executive position in an outside business, whether or not remuneration is received for such service.
e. Any compensation or equity interests that may be influenced by a particular outcome in sponsor-funded research, even if the identified thresholds are not met.

Syracuse University Policy on Conflict of Interest for Research Investigators:

http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-032-Institutional-Conflict-of-Interest.pdf
Immediate family means a spouse, domestic partner or dependent children.

10.1. Do any of the investigators or personnel listed in this research protocol, or members of the immediate family of the investigators or personnel, have a financial interest associated with this study that requires disclosure?

☒ **No (Skip to question 10.3)**
☐ **Yes; If yes, identify the individual(s):**

10.2. Has this financial interest been disclosed and managed?

☐ **Yes. The Office of Research Integrity and Protections will verify that a management plan is in place with the Vice President for Research.**
☐ **No. If the Vice President for Research does not have an approved management plan for this research, complete Parts I and II of the Disclosure of Significant Financial Interest Form (http://osp.syr.edu/forms%20and%20pages/Forms/COI%20-%20Disclosure%20of%20Financial%20Interests%20Form.PDF) and submit it to the *Office of the Vice President for Research, 304 Lyman Hall*.**

10.3 To your knowledge, did the University, or your School/Department receive a gift or equipment donation, or promises thereof, from commercial sponsors of this research project?

☒ **No**
☐ **Yes; If yes, identify the sponsor:**

Final IRB approval cannot be granted until all potential conflict matters are settled. The IRB requires a recommendation from the Vice President for Research regarding disclosure to participants and management of the conflict.

11. Data Collection, Storage of Data and/or Confidentiality

Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

11.1. Specify the individually identifiable data you will obtain, use or disclose to others.

Because this study involves many visits, we obtain data to be able to contact the participant/parent. This includes participant name, parent name, date of birth (to accurately score standardized tests), home address, and parent's phone number and email. As part of the data collection for the study, audio recordings of treatment sessions will be collected and ultrasound images of the tongue may be collected (depending on randomization condition). Video images of a participant's face may or may not be collected based on whether or not consent is obtained to collect these images (participants may opt in to video recording of the face).

11.2. Describe how data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop oe other portable device); how you will maintain the confidentiality and data security, (e.g., password protected computer, encrypted files, locked cabinet and office); and who will have access to the data (e.g., research team, sponsors, consultants).

All paper-based study data will be stored in locked file cabinets in the principal investigator's office and laboratory space. All electronic materials will be stored in a password-protected database on a secure server shared accessible only to the members of the research team. Participants will be assigned a unique code that does not retain any personal information that could link the identifier to the participant. All data collected during study activities will be recorded on a data sheet that contains only subject identifier codes, with no personal information such as name, birthdate, address, or contact information.

The following individuals will have access to identifiable private information about human subjects:

- Dr. Jonathan Preston, principal investigator
- Megan Leece, Project/Lab manager, treating SLP
- Jackie Storto, research assistant

For the purpose of data rating, blinded outside listeners may listen to audio recordings of single words produced by participating children during probe measures. However, these single words will be presented in random order and will not be paired with names or any other identifying data. The parent/guardian is specifically asked to consent to this sharing of audio data. Likewise, audio recordings of participants may be shared in academic audiences with the express consent of the participant and his/her guardian (see consent form).

11.3. If you will be sharing data with others, describe how data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit.

We provide a summary of standard scores from the testing, but we only provide a copy of this to the parent. They may share this with other professionals if they choose to do so. For participants who sign to agree to allow us to use their ultrasound recordings of the tongue for educational purposes, we will select short video recordings (about 1 minute) of the child speaking words as illustrative examples to train speech-language pathologists to interpret the images. Images of faces will not be publically available, only ultrasound images of the tongue. Parents may decline to share this information for the training website but may still have their child participate in the study.

11.4. If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code.

Participants will be assigned an ID number and all data stored (hard copies of test forms, audio/video files, etc) will be filed by the ID number. The key linking ID number with identifying information will be stored in a password-protected database that Dr Preston and Ms. Leece can access.

11.5. How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data collected.

Lab Meetings at the beginning of each semester will begin with a review of lab policies related to privacy and confidentiality. We will review possible scenarios in which confidentiality could be inadvertently compromised (e.g., failure to log off of the computer or to close the Excel file). We will review the process by which data are collected and stored (i.e., no written forms will have any private information, only password-protected files). We will discuss the need for all communications about participants to refer only to ID number, and the need to protect all private information. Any intended sharing of information with anyone outside of the laboratory must be cleared through the PI and will seek IRB approval. Fortunately, most individuals who will access data have clinical experience and are well trained in safe and confidential handling of identifiable data in clinical situations.

Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

11.6. Describe what provisions are in place to protect the privacy interests of participants, where "privacy interest of participants" refers to the participant's desire to limit interventions or interactions with others and to limit access of others to their private information. Examples include: location of data collection (private location vs. public location), method of data collection (focus groups vs. one-on-one interview,

questionnaires vs. interviews, telephone, email and mail communications), type of information (written vs. oral), recruitment methods and cultural norms.
Private data will be collected in one-on-one situations with the participant. Parents may observe these sessions via closed-circuit observation system (CORS). When observing via CORS, parents will wear headphones to ensure participant privacy.

They will wait in the Gebbie Clinic waiting area, which is a family-friendly environment, and others in the waiting area will likely be waiting for studies or for clinical services (though the specifics of these services are not disclosed). This would be similar to waiting in a doctor's office. However, all participant-researcher interactions, including consent/assent interviews and data collection activities will be obtained in one-on-one situations with the participant in the Speech Production Laboratory.

Communications with participants will be either email or phone, whichever the participant/parent prefers. Emails with identifying information are deleted once the information is stored in a password-protected database.

Recruitment will occur primarily through notices either on the CSD website, postings in the Gebbie clinic or other local speech-language clinics, and through speech-language pathologists.

11.7. Will audio, video or film recording be used?

☐ **No. (Skip to Section 12)**

☒ **Yes. If yes, specify type of recording:**

Audio recordings of all sessions (required)
Video recordings of ultrasound images (required)
Video backup recording of the session using a camera stationed on the wall (optional)

11.7.1. Describe the storage of the recordings. Include in your description who will have access to the recordings, as well as how and where they will be stored.
Recordings will be stored on a user-restricted lab drive available only to lab members who are granted access (following IRB approval). The password for the lab drive is changed via SU ITS (consult.syr.edu) whenever there is lab staff turnover (typically at the end of a semester). Students log-in to a restricted account in the laboratory and can only access files from the computers within the lab. Files will be stored by ID number.

11.7.2. How long will the recordings be kept and what is the disposition of the recordings once the research is complete.
It is required that all participants agree to audio recording as well as ultrasound video recording (no face) to track speech changes; no data would be usable without such recordings. However, parents will have opportunity to determine whether a video of the session (that includes the face) can be collected.

The recordings will be kept for 5 years after publication of final manuscripts, after which time they will be deleted.

If the parent provides permission to use videos of the tongue for educational purposes, we will store selected clips of ultrasound recordings (typically < 60 seconds in length) of the tongue indefinitely for for training purposes for speech-language pathologists.

NOTE: ***Specific permission for each type of recording must be sought in the consent form and should be indicated at the end of the document using checkboxes (_ I agree to be audio taped, _ I do not agree to be audio taped, _ I agree to be video taped, _I do not agree to be video taped, etc.)***

12. Risk to Participants

12.1. Describe in detail any possible physical, psychological, social, political, legal, economic, or other risks to the participants, either immediate or long range. Risk may be minimal but never totally absent. Do not say "No Risk".

Risks associated with the speech production and assessment components of this study are no greater than those in daily life. The ultrasound portion of this study likewise involves no more than minimal risk. Diagnostic ultrasound imaging is regarded as a safe and non-invasive technology (see Epstein, 2005, for a summary of this research). While a number of epidemiological studies have investigated the effects of ultrasound on various types of tissue, no negative effects have been documented as a consequence of exposure to diagnostic ultrasound of the type used in this study (Ziskin & Petitti, 1988; Barnett et al., 2000). Although certain types of ultrasound carry a slight risk that the temperature of the ultrasound probe may increase by 1-4 degrees Celsius during imaging, these thermal effects have never been associated with the type of imaging used in this study. Studies have demonstrated that the imaging mode used in this study (B-mode) is rarely associated with probe temperature increases of even one degree Celsius. Other risks associated with use of the ultrasound include transfer of communicable disease from one person to another (such as the common cold) if the ultrasound probe is not disinfected between participants.

Risks associated with the treatment portion of the study are those which would be associated with any speech-language therapy in schools. This includes frustration and/or boredom during completion of tasks.

12.2. Describe what procedures will be used to minimize each risk you have stated above. Also, include in your description the availability of medical or psychological resources that participants might require as a consequence of the research, if applicable. If participants need to be debriefed at the end of the study, a copy of the debriefing statement must be attached.

- To keep ultrasound exposure to an appropriately limited amount, we only expose the participant to ultrasound for approximately 13 minutes at a time, for less than half the session.
- To ensure that the risk of communicable diseases is reduced, we clean the ultrasound with approved products between users (before and after each session).
- To manage boredom/frustration, during assessments, breaks will be offered between tasks, approximately every 15-20 minutes. During treatment sessions, a 1-minute break will be scheduled every 13 minutes (after each period of practice) during which participants will be offered a drink of water, access to the restroom, or will be engaged in brief conversation.

12.3. Does this research involve more than minimal risks to participants?

☒ **No. (Skip to Section 13)**

☐ **Yes. If yes, please provide plan for monitoring the data collected to ensure the safety of participants. (Your data safety monitoring plan must include the following: Description of who will monitor the data, what data will be monitored, how frequently will it be monitored, what analysis will be performed on the data, what decision rules (e.g. stopping rules) will be considered, if unexpected harms will be detected promptly, if an increased frequency or severity of unexpected harms will be detected promptly, if the protocol will be stopped once harms are proven to outweigh benefits.).**

13. Benefits

Note: Course credit or payment is an inducement to participate in the study and should not be described as a benefit of the research.

13.1. Describe any benefits to the participants in general.

Some children with Childhood Apraxia of Speech (CAS) may improve the clarity (intelligibility) of their speech. Additionally, parents will receive a statement of the child's performance on standardized tests, which offer more information to them about their child's communication skills.

13.2. Society at large.

We may learn more about the utility of ultrasound for treatment of speech sound errors in children with CAS. Additionally, we may learn more about whether the intensity/distribution of therapy (regardless of whether or not ultrasound is used) has a positive effect on children's outcomes.

13.3. Explain how the benefits outweigh the risks involved.

The potential improvement in speech intelligibility for our participants, and the potential clinical impact of the findings related to (a) whether ultrasound is an effective therapy tool (versus no ultrasound) and (b) whether practice distribution (distributed versus intensive then distributed) facilitates generalization are judged to outweigh the minimal risks associated with the study.

A number will be assigned to your protocol. Please refer to it whenever calling or writing for information.

- **All supporting documentation including list of references, consent and/or assent form(s), survey instruments, interview questions, recruitment materials, letters of support, IRB approvals from other institutions, etc. must be included with the application.**

Return Completed Protocol To:

Office of Research Integrity and Protections
214 Lyman Hall
Syracuse University
Syracuse, NY 13244
Phone: 315-443-3013

Please send IRB notifications by:

☐ **Hard copy campus mail. All correspondence mailed to the PI/faculty member's address.**

☒ **Email notification (Only the original hard copies of date stamped consent/assent documents will be returned.)**