UT Health Science Center San Antonio

Progress Report

HSC20060042H
Study Title: Stuttering Therapy and Neurophysiological Interaction

REQUEST FOR RE-APPROVAL

Click here for Form Instructions. Do not submit double-sided documents for the original and do not delete any tables on this form.

1. **Date: 06/30/08**

2. **Name and Address of Principal Investigator (PI):** *(This is the primary contact information used by the IRB. Indicate where mail can most reliably reach the PI. If research is part of a multi-center study, the PI listed here should be the investigator responsible for the research conducted locally.)*

PI Name *(Last Name, First Name, MI):* Fox, Peter T.
Employer(s): *Example: UTHSCSA 50%, VA 50%)* UTHSCSA – 100%
Department: Research Imaging Center
Room # & Bldg: 2nd Floor, McDermott Building
Mail Code #: #6240

3. **Additional Contact Information**
PI's Telephone#: 567-8150 PI's Pager Number: N/A
PI's e-mail address: fox@uthscsa.edu PI's FAX Number: 567-8152
PI's Position Title: Director, Research Imaging Center
PI's Point of contact name & e-mail: Jean Hardies hardiesl@uthscsa.edu Point of Contact Phone Number: 78181

4. Please attach to this report a current copy of your **Study Personnel List** (Form B-2).	
☑	Copy of current Study Personnel List is attached
☐	N/A – PI listed above is the only person conducting research.

5. During this review period, **have there been any changes**, no matter how minor, to any part of this research project, including the IRB approved forms?			
☐	**No.** Go to Question 7.		
☑	**Yes.** *If yes, select one.* ***For either choice, complete question 6.***		
	☑	All changes implemented have been previously reported to and approved by the IRB.	
	☐	The changes described below have been implemented but were not submitted to or approved by the IRB.	
		a. Give a brief description of the change(s) made	b. Explain why IRB approval was not obtained prior to making the change(s)

Stuttering Therapy and Neurophysiolgical Interaction

a summary of **previously approved amendments** or modifications since the last review using the table below:

ent	Brief Summary of Changes
07	New Flyer
07	New Flyer/same text to be used on website
07	Add 3 team members to the protocol
8/07	Increase the number of subjects to recruit 20 controls; consent form reflect changes
1/07	Shorter version of consent, have fMRI but no therapy
01/10/08	New text for advertising
02/04/08	Revise consent form to include UTSA IRB as a contact for info on subject's right, and to mention the UTSA IRB in the Authorization for use of PHI as an entity that could review records

7. Have you identified minor revisions (e.g., update study personnel, correct telephone numbers on consent forms, etc.) that you would like to make as part of this progress report? *(Do not include changes that require immediate action, these should be submitted as a separate amendment request)*

☐	**No.** Go to Question 8.
☑	**Yes.** The changes are detailed in the attached amendment form and revised documents as required. Submit appropriate number of copies if submitting for full Board review.

Locally Enrolled Subject information

NOTE: **You should compare all information entered in this report with what has been previously reported to the Board. If you discover that there are discrepancies with or errors in previously reported information, please attach a separate cover letter explaining the differences.**

8. Choose the statement that best describes the **human research activities** being performed. *Select only one.*

This study:		
☑	Involves interacting/intervening with living individuals for research purposes	*Answer all questions in item 9, below*
☐	Is limited solely to use of identifiable private information (data, records, specimens, etc.) (Does not involve interacting with living individuals for research purposes)	*Answer questions in item 9 below--**some questions may not be applicable***

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What is the **current status** of your study? *Check all that apply*

Research activities related to human subjects and identifiable private information	Yes	No	N/A *and provide reason (edit text as needed)*
The study is permanently closed to new subject enrollment	☐	☑	☐ Does not involve living subjects
Data, private information, and/or clinical specimens continue to be collected for research purposes (not to include long-term follow-up)	☑	☐	
Subjects are currently being treated	☑	☐	☐ Does not involve living subjects or treatment or no subjects enrolled
Research assessments or procedures are currently being performed	☑	☐	☐ Does not involve living subjects or no subjects enrolled
All subjects have completed all research-related procedures and treatments	☐	☑	☐ Does not involve living subjects or no subjects enrolled
The study remains active only for long-term follow-up of subjects and data analysis (no further procedures, treatments or interventions)	☐	☑	☐ Does not involve living subjects or no subjects enrolled
Remaining research activity is limited *only* to analysis of identifiable data/specimens locally	☐	☑	

If the table above does not fully describe the status of research activities, **please explain here →**

10. **Drugs/Biologics/Devices** - Indicate the items below which apply to your research. *Check ALL that apply.*

☐	**Not applicable** – this research does **not** involve the investigational use of a drug or device. Go to Question 11
☐	FDA Approved **Drug(s)** being used in an **approved** manner
☐	FDA Approved **Device(s)** being used in an **approved** manner
☐	Approved **Drug** being used in an **unapproved** manner/indication (different dose, route, population, etc.)
☑	Investigational New **Drug** (unapproved drug)
☐	Approved **Device** being used in an **unapproved** manner/indication
☐	Investigational New **Device** (unapproved device)
☐	Humanitarian Use **Device**
☐	Use of **Placebo** in place of standard therapy

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Number of subjects (or records/specimens) **accrued.**
ote for studies only accruing data/specimens – for this section, obtaining an individual's information or specimens is onsidered enrolling subjects. Please include these numbers in the table below.

	Local *(AT THIS SITE)*	Total Number
A.	What is the total number of subjects **authorized/approved** by IRB?	92
B.	How many subjects have you enrolled (*consented*) **since last IRB review?**	45
C.	How many subjects have you enrolled (*consented*) **since the study started?** *[If this is the first progress report, this number should be the same as B, above. If not the first report, this number should equal the total from your last report plus B above]*	65
D.	How many subjects are **currently** active?	25
	Major Categories of Withdrawals Since the Last IRB Review *(AT THIS SITE)*	**Total Number**
	Check here if study only involves accruing data/specimens (does not involve interacting with subjects). Skip to Question 13.	
E.	How many subjects were Screen failures *(signed consent & completed only part or all of screening)?*	3
F.	How many subjects discontinued due to an Adverse Event (AE), *except death*?	0
G.	How many subjects withdrew by their choice?	11
H.	How many subjects were withdrawn by PI (i.e., subject non-compliance, disease progression, etc.)?	1
I.	How many subjects died during their participation period?	1
J.	How many subjects have completed the study **since the study started**?	21
	Total Withdrawals	
K.	Total Number of Withdrawals **since the study started.**	19

12. **Detailed description** of the reason for **subject withdrawal** noted above **since the last IRB review**.

N/A – No subjects have withdrawn from the research since the last IRB Review. Go to Question 13.

Detailed Description of the Reason for Withdrawal	Total number per reason
For example, for subjects who discontinued due to AE – describe the actual AE(s) experienced that lead to withdrawal; for those who withdrew by choice, describe their stated reason(s), describe the screen failure	*How many subjects withdrew for each reason listed?*
Subject did not meet the speech criteria required to participate	2
Withdrew due to amount of time needed to complete training	7
Uncomfortable with scanning	3
Deceased (airplane accident/not related to study)	1
Withdrawn due to non-compliance	1
Subject did not wish to continue in study	2

Consent

NOTE: **Please enter information related to the consent process and documentation.**

13. Does this study involve **obtaining consent?**

No. Consent was waived by the IRB for all subjects participating. Go to Question 16.

Yes. **If yes,** answer the following questions:

	Yes	No	N/A No subjects enrolled

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11. Number of subjects (or records/specimens) **accrued.**
Note for studies only accruing data/specimens – for this section, obtaining an individual's information or specimens is considered enrolling subjects. Please include these numbers in the table below.

	Local *(AT THIS SITE)*	Total Number
A.	What is the total number of subjects **authorized/approved** by IRB?	92
B.	How many subjects have you enrolled (*consented*) **since last IRB review?**	45
C.	How many subjects have you enrolled (*consented*) **since the study started?** *[If this is the first progress report, this number should be the same as B, above. If not the first report, this number should equal the total from your last report plus B above]*	65
D.	How many subjects are **currently** active?	25
	Major Categories of Withdrawals Since the Last IRB Review *(AT THIS SITE)*	**Total Number**
	Check here if study only involves accruing data/specimens (does not involve interacting with subjects). Skip to Question 13.	
E.	How many subjects were Screen failures *(signed consent & completed only part or all of screening)?*	3
F.	How many subjects discontinued due to an Adverse Event (AE), *except death*?	0
G.	How many subjects withdrew by their choice?	11
H.	How many subjects were withdrawn by PI (i.e., subject non-compliance, disease progression, etc.)?	1
I.	How many subjects died during their participation period?	1
J.	How many subjects have completed the study **since the study started**?	21
	Total Withdrawals	
K.	Total Number of Withdrawals **since the study started.**	19

12. Detailed description of the reason for **subject withdrawal** noted above **since the last IRB review**.

N/A – No subjects have withdrawn from the research since the last IRB Review. Go to Question 13.

Detailed Description of the Reason for Withdrawal	Total number per reason
For example, for subjects who discontinued due to AE – describe the actual AE(s) experienced that lead to withdrawal; for those who withdrew by choice, describe their stated reason(s), describe the screen failure	*How many subjects withdrew for each reason listed?*
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Deceased (airplane accident/not related to study)	1
Withdrawn due to non-compliance	1
Subject did not wish to continue in study	2

Consent

NOTE: Please enter information related to the consent process and documentation.

13. Does this study involve **obtaining consent?**

No. Consent was waived by the IRB for all subjects participating. Go to Question 16.

Yes. **If yes,** answer the following questions:

	Yes	No	N/A No subjects enrolled

			enrolled
A. Was consent obtained for all subjects enrolled **since the last IRB review**?	☑	☐	☐
If **No, explain here** →			
B. Did all subjects enrolled **since the last IRB review** receive a copy of the signed consent form?	☑	☐	☐
If **No, explain here** →			

14. Is this study approved for **surrogate consent** of adult subjects?

☑ No. Go to Question 15.

☐ Yes. **If yes,** answer the following questions:

	Number	N/A No subjects enrolled
How many subjects were enrolled by surrogate consent **since the last IRB review?**		☐
How many subjects who were enrolled by surrogate consent have subsequently **consented to continue** in the study since the last IRB review?		☐
How many subjects who were enrolled by surrogate consent have subsequently **decided not to continue** in the study since the last IRB review?		☐

Describe the reasons why subjects enrolled by surrogate consent later **did not agree to continue** in **the study.**

Describe here →

15. Have you enclosed a copy of each **current** approved version of the Consent Form(s)?

☐ **N/A.** The research is permanently closed to enrollment and no new risks have been identified during this approval period. Go to Question 16.

☐ **N/A.** The IRB approved a waiver of the requirement to use a consent form. Go to Question 16.

☑ **Yes.**

If yes, how many different consent forms are approved? **4**

☐ **No. Explain here** →

Summary of Study Progress

NOTE: Provide a summary of the progress you have made since the last IRB review.

DO NOT restate information provided elsewhere – this section is intended to provide the IRB with information on how the study is progressing.

16. Summary of **Study Progress and activities** at this site ***since last IRB review.***

Summarize your study's progress toward achieving the objectives of the study. *NOTE: If you are experiencing problems or delays, explain the situation and your plan for resolving the problems/delays.*

We are continuing to enroll subjects as they become available and meet the criteria as outlined in the protocol. We are showing marked improvement in the stuttering subject's speech.

17. **Subjects' response** to the study since the last IRB review. Please describe how subjects have responded to and tolerated their participation in this research project. ***Your Answers should be substantive.***

Were any subjects actively participating in this study during the period of time since the last IRB review?

Choose one

☐ **N/A** – Study only involves accruing data/specimens (does not involve interacting with subjects). Go to Question 18.

☐ **No.** If **No**, explain the lack of research activity since the last review. *You should describe whether or not your study will still meet its recruitment goal. Provide justification for the study remaining open if no activity occurred in the last year.*

Explain here →

☑ **Yes.** If **Yes**, answer the following questions:

(a) How has the study **affected** the subjects since the last IRB review?

Stuttering subjects have shown marked improvement in speech.

(b) Have subjects had any **comments or complaints** about the study since the last IRB review? ☐ Yes ☑ No

If **yes**, provide details here→

18. Were all **study procedures** conducted as described in the protocol?

☑ **Yes.**

☐ **No.**

If **No, explain here** →

☐ **Not applicable.**

If N/A. explain here →

19. Is this a **multi-center study** where the UTHSCSA IRB is the reviewing IRB for the study operations center?

☑ **No.**

☐ **Yes.** Have there been any oversight problems at the satellite study sites? ☐ Yes ☐ No

If yes, explain here →

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Events, Other (non-AE) Problems and Unexpected Problems Involving Risks to Subjects and Others (UPIRSO)

Review your study records related to adverse events, other (non-AE) problems and UPIRSOs since the last IRB review and also for the entire study to answer the following questions.

Taking into consideration all safety-related information, have any adverse events occurred since the last IRB review?

☐ **No.** Skip to Question 23

☐ **Yes.**

If yes, have the adverse events been of the nature and occurred at the frequency and severity that were anticipated?

(in order to determine frequency, you should consider all AE's that have occurred since the study started)

☐ Yes, the adverse events have occurred as **anticipated** (in frequency or severity as compared to research documents or as previously recognized in the subject population(condition (risk profile)). Skip to Question 23

☐ No, there have been **unanticipated** adverse events (Unanticipated - Not previously identified, occurred more often or more seriously than expected by research documents or not expected or not expected as often or as serious considering the subject population (underlying condition (risk profile))). Go to Question 21

21. Were any of the unanticipated adverse events identified in question 20, at least possibly related to the research?

☐ **No.** Skip to Question 23

☐ **Yes.** There have been unanticipated AEs that are at least possibly related.

If yes, have the unanticipated and possibly related adverse events been **serious or do they suggest a greater risk than previously known**?

☐ Yes. Go to Question 22

☐ No. Skip to Question 23

22. Were all the unanticipated adverse events that were at least possibly related and were either serious or suggest a greater risk identified in question 21, previously reported to the IRB as possible Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs)?

☐ **No.**

If No, explain why prompt reporting was not accomplished.

A. **Explain here →**

B. Attach a new "Notification of Possible UPIRSO" to this progress report. Go to Question 23

☐ **Yes.** List the UPIRSO's previously reported below. Then Go to Question 23

Date Reported	Brief description of the UPIRSO

23. Have there been any other problems that were not adverse events since the last IRB review?

☑ **No.** Go to Question 25

☐ **Yes. If yes**, were the non-AE problems of a nature that may have placed subjects (or others) at greater risk? *(For example the loss of confidential data, dosing error with no detectable harm, etc.)*

☐ Yes, the non-AE problems may have placed subjects at greater risk. Go to Question 24

☐ No. Go to Question 25.

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. Were all the non-AE problems identified in question 23, previously reported to the IRB as possible Unanticipated roblems Involving Risks to Subjects or Others (UPIRSOs)?

☐ **No. If No**, explain why prompt reported was not accomplished.

A.	**Explain here →**
B.	Attach a new "Notification of Possible UPIRSO/ Non-Adverse Event" to this progress report. Go to Question 25

☐ **Yes.** List the non-AE UPIRSO's previously reported below. Then Go to Question 25

Date Reported	Brief description of the non-AE UPIRSO

Special Populations

25. Is this study approved to recruit any of the following **special populations?**

☑ No.

☐ Yes. **If yes,** complete the **Vulnerable Population** table below:

Vulnerable Population	Yes	No	Number since last review	Number since study start
Children	☐	☐		
Pregnant women/fetuses	☐	☐		
Non-viable neonates / neonates of uncertain viability	☐	☐		
Prisoners	☐	☐		
Cognitively impaired (adult surrogate consent)	☐	☐		
Inclusion criteria **targets** economically disadvantaged	☐	☐		
Inclusion criteria **targets** educationally disadvantaged	☐	☐		
Other: **Describe here →**	☐	☐		
Other: **Describe here →**	☐	☐		

26. Breakdown of enrolled **Subjects' self-identification**

Race/Ethnicity	Number since last review		Total for entire study	
	Male	Female	Male	Female
American Indian/Alaskan Native	0	1	0	1
Asian or Pacific Islander	1	0	1	0
Black-non Hispanic	1	0	1	0
Hispanic	8	6	12	6
White-non Hispanic	19	8	35	8
Other	1	0	1	0
Not available	0	0	0	0

If subject breakdown data is not available, provide an explanation here →

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Repository Information

Note: Data management centers (data centers) and human specimen repositories (e.g., registries, banks, or libraries) are defined to store data and/or specimens for future research use.

	Yes	No
Does this study **collect** specimens/data for inclusion in a Repository or data center?	☐	☑ Skip to question 28
Is the specimen repository or data center located at an institution under the oversight of the UTHSCSA IRB?	☐	☐ Skip to question 28
Is the repository / data center established and operations approved under this protocol?	☐	☐ Skip to question 28

Details on Repository Activity	Recipient Study Information
List other research studies (including IRB study #) given data and/or specimens from your repository **since the last review here** →	

Other Sources of Relevant Information

28. Does this study have an **independent safety monitoring** entity?

(for example a data safety monitoring board (DSMB) or independent medical monitor)

- ☑ **No.**
- ☐ **Yes.** If yes: Was a report received since the last IRB review?
  - ☐ **No.**
  - ☐ **Yes.**
    If yes, summarize here →
  - ☐ A report is not available.
    Indicate a date when a report will be available or indicate that no written report will be generated:
    Enter Date here →

29. If this is a **multi-centered trial**, have there been any other **multi-center reports or notices** relevant to your study since the last review?

(For example a study sponsor safety alert or black box warnings, annual updates, or other memorandums)

- ☑ **N/A.** Not a multi-center trial.
- ☐ **No.**
- ☐ **Yes.** ***If yes:*** The following is a brief summary of the substantive safety issues contained in the report:
  Enter Summary here →

30. A search of the **recent literature that may be relevant to the research** is *required*. How was the search completed?

- ☐ The study sponsor was contacted for an update on the literature.
- ☑ The local PI performed a search of the relevant literature
  Enter date performed here → 07/01/08

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Summarize the **recent literature that may be relevant to the research.**

☐ There has not been new literature published.

☐ There has been new literature published.

Provide a summary and implications for subjects →

32. Is there any **other new information** that alters the risk/benefit ratio of this study?

☑ No.

☐ Yes.

Provide a summary and implications for subjects →

33. **Risks and Benefits** of this study

Considering all relevant information related to this study, including all internal and external adverse events/unanticipated problems involving risks to subjects, information about the safety of any drugs or devices (as applicable), in your opinion:

A. Do the research related **risks continue to be minimized** to the extent possible given the nature of the study?

☑ **Yes.**

☐ **No.**

Explain here →

B. Do the research related **risks** continue to be **reasonable** in relation to the potential **benefits** to the subjects and/or the importance of the knowledge that may reasonably be expected to result from the research?

☑ **Yes.**

☐ **No.**

Explain here →

34. **Roles and Responsibilities of study staff** – *Only Select One*

I have reviewed the roles and responsibilities for all members of the study staff in relation to their level of training, specific license, and clinical credentials. **I certify that the members of the study staff remain qualified by training and experience as appropriate to their responsibilities in this study.**

In addition, institutional approval for study staff to perform research (Research Scope of Practice) is: *Only Select One*

☐ N/A. All members of the study staff are not subject to the Research Scope of Practice policy.

☑ current and approved at the appropriate institution(s) for all personnel who require this certification.

☐ pending approval for one or more staff at the applicable institution(s). I understand re-approval will be conditioned on my certification that approved Research Scope of Practice forms are approved for all research staff who require this certification.

35. **Conflict of Interest** – *Only Select One*

I understand as the Principal Investigator, I am responsible to ensure all members of the study staff declare any potential conflicts of interest or commitment related to this study and that they report these to the Conflict of Interest Committee. I **certify that:**

☑ There have been **no changes** to the status of possible financial conflict of interest for **any of the study staff members**, or their families, with respect to this study.

☐ There **have been changes** relative to possible financial conflict of interest. I have submitted the required COI Form X for review by the COI Committee.

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36. List of Institutions Under UTHSCSA IRB Jurisdiction – Check All That Apply

Institutions Affiliated with the UTHSCSA IRB (IRB of Record)		"UTHSCSA IRB Affiliated Institutions"	
		Choose one	
Check all that apply	Name of Institution / Study Site (list all participating sites below)	Employees of this institution are "engaged" in this research	Employees of this institution are not "engaged" in this research"
	UTHSCSA Including any of the following: School of Medicine, CTRC at UTHSCSA (IDD or SWOG), FIRST Program / GCRC (Carrington Bldg.), Dental School, School of Nursing, Graduate School of Biomedical Sciences, School of Allied Health, Research Imaging Center (RIC), College of Pharmacy, UT Austin, UT Medicine, Regional Academic Health Center (RAHC) click here to type Other	Engaged	Not engaged; This will be a study site but the institution will not be considered engaged in research (AKA-Study Site Only).
	South Texas Veteran's Healthcare System (STVHS) Including any of the following: Audie Murphy Medical Center, General Clinical Research Center (GCRC), Outpatient Clinics Division, Kerrville	Engaged	Not engaged; (Study Site Only).
	University Health System (UHS) Including any of the following: University Hospital, University Health Center Downtown, University Center for Community Health (UCCH), UCCH/Texas Diabetes Institute (TDI), University Family Health Centers, UHS Breast Imaging Ctr / CTRC, Correctional Health Care Services	Engaged	Not engaged; (Study Site Only).
	Christus Santa Rosa Health Care (CSRHC) **(UTHSCSA PI only)** Including: CHART Center / GCRC	Engaged	Not engaged; (Study Site Only).
	Wilford Hall Medical Center (WHMC) **(Children's Oncology Group studies only)**	Engaged	Not engaged; (Study Site Only).
	Southwest Foundation for Biomedical Research (SFBR)	Engaged	Not engaged; (Study Site Only).
	Southwest Research Institute (SwRI)	Engaged	Not engaged; (Study Site Only).
	Other Institution(s) **Covered by UTHSCSA IRB Sharing Agreement** **Insert Name(s):** click here to type (names)	Engaged	Not engaged; (Study Site Only).

37. List of **Collaborating** Institutions or Study Sites **Not** Under UTHSCSA IRB Jurisdiction – Check All That Apply	
	A. N/A Not Collaborating with Institutions Not Under UTHSCSA IRB Jurisdiction
	B. Collaborating Institutions with an Assurance and IRB ("Assured Institution")
If yes, insert name(s) here →:	University of California
	C. Collaborating Institutions without an Assurance or IRB ("Non-Assured Institution")
If yes, insert name(s) here →:	

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	Which items are being attached to this Progress Report? *Check all that apply.*
	Abstract / Project Summary - **Required** – the template is available on next page of this report **or** if you have previously submitted Form C – Research Description, the abstract is the same, you can cut and paste to the progress report.
☑	Study Personnel List Form B-2
☑	Most recently approved Consent Form(s)
☐	DSMB report or independent medical monitor report
☐	Sponsor reports or notifications
☐	New information on risk/benefit ratio
☑	Amendment Form with applicable attachments
☐	Notification of Possible UPIRSO form
☐	Form X – Conflict of Interest
☐	Publication(s) or meeting proceedings
☐	Other: (describe)

Print a copy of this form and: (1) Type ***and*** sign your name below.

(2) Make a copy of the ***signed*** report for your regulatory file.

Signature of Principal Investigator: _____

Peter T. Fox, M.D.

Abstract / Project Summary

e a succinct and accurate description of the proposed research. State the purpose/aims. Describe concisely the rch design and methods for achieving the stated goals. This section should be understandable to all members of the scientific and non-scientific. This summary will also be needed in future IRB Progress Reports.

NOT EXCEED THE SPACE PROVIDED.

he context for this study is an exhaustive empirical examination of a research-based and computer-managed treatment for adult developmental stuttering known as the Modifying Phonation Intervals (MPI) program. Within that context, the studies described in this proposal will test a number of hypotheses concerning the relationships among several critical factors: stuttering behavior, the neurology of stuttering, the cognitive and affective components of stuttering, stuttering treatment approaches, and the maintenance of stuttering treatment gains. Thus, this proposal simultaneously addresses two overwhelming needs: efficacious stuttering treatments for adults, and the integraton of basic knowledge, such as knowledge about the neurology of stuttering, with information from treatment research to develop comprehensive neurophysiologic and behavioral models of stuttering and stuttering teatment. It is hypothesized that (a) a necesaary prerequisite for durable treatment benefits is normalized cerebral blood flow within regions that constitute an emerging model of the neurophysiology of stuttering and (b) this result can be achieved by establishing a speech pattern that requires the production of speech with a reduced proportion of short phonated intervals (PIs). These aims will be met in a treatment comparison study that employs repeated behavioral, cognitive, and affective evaluations derived from the MPI program and a prolonged speech (PS) program that represents the current standard of care for adult stuttering. This evaluation format will be conjoined by repeated PET scanning, to identify specific speech-motor and neural system changes generated by these treatments and described by an empirically derived stuttering system model. Both treatments include identical transfer and maintenance components plus within and beyond-clinic assessments that extend over the course of treatment and 12 months after its cessation. Repeated performance-correlation analyses of the derived brain imaging data will test the prinicipal theoretic proposition that the system model regions functionally control the efficacy of stuttering treatment. The overall study also constitutes a Phase II treatment efficacy study that will determine the need for a Phase III treatment trial of the MPI program.

Subjects will have MRI scans during the study.

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or IRB Office Use Only: ☐ Check-in Complete Admin Reviewer Initials_____

Date Approval Expires:_____ VA ☐ Date/Time Admin Process Started:_____

Lapse in Approval? No Yes (Dates: from_____ to_____) Any terminations or suspensions by IRB? Yes No

Determination of Appropriate Review Process	Yes	No	N/A
Permanently closed to new subject enrollment	☐	☐	☐
Data, information, and/or clinical specimens continue to be collected	☐	☐	
Subjects are currently being treated	☐	☐	☐
Research assessments or procedures are currently being performed	☐	☐	☐
All subjects have completed all research-related procedures and treatments	☐	☐	☐
The study remains active only for long-term follow-up of subjects and data analysis	☐	☐	☐
Remaining research activity is limited *only* to analysis of identifiable data/specimens locally	☐	☐	

Total subjects:	Consents Dated:	Waiver?

	Minimal	Minor Increase	Greater Minimal
Original Risk Determination	☐	☐	☐

Vulnerable Populations	☐ Children	☐ Pregnant/fetus	☐ Nonviable neonate	☐ Prisoners

Administrative issues:_____

Date/Time 1st Contact:_____ Date/Time Resolved by PI:_____

☐ **All Administrative Issues Resolved** ☐ PIMS Updated: _____

☐ Copied to Shared Drive: _____ Date/Time Admin Process Completed:_____

IRB Determinations	Yes	No	N/A
Do the risks continue to be minimized?	☐	☐	
Do the risks to subjects continue to be reasonable in relation to the benefits?	☐	☐	
Does the selection of subjects continue to be equitable?	☐	☐	☐
Will informed consent be sought from each prospective subject?	☐	☐	☐
Will informed consent be appropriately documented?	☐	☐	☐
Are the provisions for protecting confidentiality/privacy appropriate?	☐	☐	☐
Is the plan for safety monitoring appropriate?	☐	☐	☐

IRB Action

☐ Approved	☐ Conditionally Approved	☐ Tabled/Deferred	☐ Disapproved
Risk Determination	☐ Minimal	☐ Minor Increase	☐ Greater than minimal
Approval period	☐ One (1) year	☐ Other (shorter) period:_____	

Comments/Conditions:

Review by Convened Meeting of the IRB

Chair: _____ Date: _____ ☐ Response to Stipulations Eligible for Expedited Approval

-OR- **Review by Expedited Review**

Expedited Category:	☐ 1 - 7	☐ 8A (F/U only)	☐ 8b (no enrollment & no new risk)	☐ 8c (data analysis only)	☐ 9 IRB voted

Expedited Reviewer: _____ Date: _____ ☐ Refer to convened IRB meeting