SUBJECT CONSENT TO TAKE PART IN A STUDY OF:
Stuttering Therapy and Neurophysiological Interaction

To be conducted at
The University of Texas Health Science Center at San Antonio
Research Imaging Center (RIC)

PURPOSE: We are asking you to take part in a research study about stuttering. We want to learn about the effectiveness of two different programs for treating adult developmental stuttering. For purposes of this study, it is necessary that we call them *Program A* and *Program B*. We want to compare these programs to find out which one is more effective. Both of these programs have been shown in other studies to be effective in treating stuttering, but no one has made a direct comparison of the programs to determine which one is *more* effective.

Both programs contain 5 phases, and these phases last about the same amount of time in each program. The amount of time you spend in each phase of either program will depend upon how much progress you make in meeting the stuttering reduction goals of each phase. The entire study will last between 28 and 40 months (about 2 to 3 1/2 years) and will require you to make 30 to 60 visits to the Research Imaging Center (RIC). On several of these visits, we will record your speech. You will also make recordings of your speech away from the RIC between visits. You will also have to fill out questionnaires.
If you don't live in San Antonio, you have the possibility to do part of the study at the University of California (Harder 1058, Santa Barbara, CA 93117). The imaging part (PET and MRI explained below) will always take place at the RIC.

This study also involves five magnetic resonance imaging (MRI) scans and five positron emission tomography (PET) sessions (a PET session consists of 6 PET scans). You will have one PET session and one MRI during each of the five phases. PET scans measure brain activity by measuring blood flow in the brain. We want to compare PET scans of people before treatment and after treatment (on both programs) to see what changes the treatments have on brain activity. We also want to compare the changes in brain activity of people who are on *Program A* versus people who are on *Program B*. We want to learn if the changes we see in brain activity using PET scans can help us predict how likely it is that either program will have long-term benefits for different people.

Dr. Peter T. Fox, MD, and Dr. Roger J. Ingham, PhD, are conducting this study. The National Institute on Deafness and Other Communication Disorders (NIDCD), a federal agency that promotes scientific research, is funding this study. This means that the NIDCD is providing money to the Research Imaging Center (RIC) so that the study doctors can conduct the study. Approximately 48 people who stutter will take part in this study. Half of these people will have *Program A* and half will have *Program B*. Another 24 people who do not stutter will also take part in this study. We will compare the PET scans of people who stutter to the PET scans of people who do not stutter to help us better understand changes in brain activity during the stuttering treatment programs.

We are asking you to take part in this study because you have stuttered since before age 10, are a healthy, right-handed person between the ages of 18 and 65, and have a home computer with

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internet access.

You cannot take part in this study if you

- have undergone treatment for your stuttering within the past three years,
- have any neurologic disorder other than stuttering,
- have any other current speech, language, cognitive, or behavioral disorder(s),
- use illegal drugs (we will ask you about this; there will be no drug testing done),
- are claustrophobic,
- have a cardiac pacemaker or cochlear implant.

You may not be able to take part in this study if you have metal in your body (surgical clips on aneurysms or intestines, pins, shrapnel, metal iron filings, etc.).

If you are currently pregnant or plan to become pregnant before the study is completed, you cannot take part in this study.

PROCEDURES: If you decide to take part in this study, the screening procedures, the first set of speaking tasks and the MRI and PET scan (described below) will be done after you sign this consent form.

SCREENING PROCEDURES:
To determine if you are eligible to participate in this study, we will have you:

- answer a metal screening form so that we can decide if it is safe for you to undergo the scans required for this study,
- answer a questionnaire to determine whether you normally use your left or right hand,
- complete a computer-based neuropsychological test, where you will answer questions about your current and past health (such as medical history, surgeries, allergies, prescription, over-the-counter, and illegal drug use) and respond to computer prompts that test things such as your reaction time, memory, and vocabulary,
- take a neurological physical exam, where we test your reflexes and coordination,
- take a screening test for hearing impairment,
- complete a central auditory processing test,
- answer a questionnaire to determine if you are anxious
- answer a questionnaire about your speech
- answer a questionnaire to evaluate your overall quality of life.
- take a speech assessment test (explained below).

Speech assessment:

We will ask you to read form a book aloud by yourself, read from a book aloud with another person reading aloud, read from a book aloud in rhythm with a metronome, read from a book while noise is played in the background and finally read from a book alone in a whispering

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voice. This assessment is done to determine if the fluency of your speech can be shaped.

The tests and questionnaires will take about 2 hours to complete. After this, you will complete the first set of speaking tasks (described below). The speaking tasks will take about 1 hour to complete.

SPEAKING TASKS: This study will measure the effect on your speech of these treatment programs. This means that it will be necessary to record your speech prior to starting treatment, regularly during treatment, and for a year after you have completed your treatment program. We will be making audio and audiovisual recordings of your speech. The recordings will be evaluated by the study team to determine if the treatment you are receiving is reducing your stuttering, and if so by how much.

The audiovisual recordings will be made at the Research Imaging Center in a sound-proof room. You will be seated before a digital video camera and a computer monitor displaying a clock that shows how long you have been speaking. You will wear a lapel microphone and a Velcro neckband that holds an accelerometer (a harmless device that measures vocal vibrations from the surface of your throat). The initial speaking tasks used in the study consist of oral reading (you will read continuously from a book), monologue (you will speak continuously on a topic of your choice), and telephone conversation (with research assistants at the RIC). For each speaking task, we will record five minutes of your speech. Each time your speech is recorded at the RIC, we will also ask you to fill out questionnaires regarding your speech.

The audio recordings will be made by you away from the RIC. You will send the recordings to us via the internet ("upload" the files onto a secure website at the RIC). We will train you to use the digital audio recorder, that we will provide, so you can make the audio recordings of yourself away from the RIC. We will show you how to code the audio recordings and upload them to the website. The three speaking tasks for the recordings you make away from the RIC will be selected based upon conversations you have with the investigators. The tasks may be similar to the in-clinic speaking tasks and will include one speaking task that usually causes you a lot of difficulty because of your stuttering. For each speaking task, you will need to record at least five minutes of your speech.

What you choose to record (the topic you read or speak about) is not important, but you should use your normal way of speaking. We will be evaluating your frequency of stuttering, speaking rate, and the naturalness of your speech. Please try not to record content that you would prefer remains private. However, if the recording does contain content that you prefer remains private, you may always erase it and make a replacement recording.

MRI SCAN: Magnetic resonance imaging (MRI) gives us pictures of the structure of the brain. During the scan you will lie on a padded table with your head resting on a padded head holder that will hold your head still during the scan. The upper half of your body will be inside a large, metal cylinder (the MRI scanner). The MRI scanner makes loud knocking noises during scanning, so you will be asked to wear earplugs. You will also wear large headphones, like if

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you were listening to music, so that you can hear the MRI technician. The MRI technician will also be able to hear you when you speak. You will be asked to lie very still for the scan.
During the study you will have 5 MRI scans. One before treatment starts and one scan during treatment phase 2 to 5. Each scan will take about 1 ½ hour.
It is possible that the first scan session will be spread over 2 days. If that is the case, we will ask you to undergo a MRI scan that takes about 1 hour on every day. The total amount of scanning will be the same whether we ask you to do it in 1 or 2 days.

PET SCAN: Positron emission tomography (PET) is used to measure brain activity. You will have five PET sessions during this study, one session before the treatment starts and one session during treatment phase 2 to 5. Each PET session contains six PET scans. This adds up to 30 PET scans for the entire study (6 scans per session; 5 sessions). The first PET session (6 scans) will be on your first study visit, the same day as the MRI scan.

During PET scanning you will lie on a padded table. Your head will rest in a padded head holder and a plastic mask with holes for eyes, ears, nose, and mouth will be placed over your face to hold your head still during scanning. The upper third of your body (chest up) will be inside a large, metal cylinder (the PET scanner), which is a little bigger than the MRI scanner. A plastic catheter, or tube, (an "i.v. line") will be inserted in a vein in your arm, and medical saline (salt water) will flow in slowly. Saline is used to keep the catheter from clotting. At the start of each scan, about a teaspoon of radioactive water (which gives off x-rays) will be injected into the tube in your vein. The radioactive water will flow in your blood up to your brain. The parts of the brain that are more active will use up more of the radioactive oxygen in the water. The PET machine will identify the active brain regions by measuring the locations of higher levels of radioactivity. After each injection we will scan your brain. Each scan will take about two minutes. There will be a ten-minute rest period between scans. You will have 6 scans during each session.

During each PET session, you will read aloud from a television screen during two scans, speak on a topic of your choice during two scans, and lie quietly with your eyes closed during two scans. Your speech will be audiovisually recorded during the four PET scans where you are speaking. Each PET session will take about 2 hours.

Also on each PET session day, we will ask you to update the list of medications you are taking and tell us if you have used any illegal drugs. If you start taking medications or other therapy to treat your stuttering or report that you have used illegal drugs, you will not have the PET scans and your participation in the study will end. Women of childbearing potential will also have a pregnancy test the day of each PET session. If the test shows you are pregnant, you will not have the PET scans, and the investigators will discuss your continued participation in the study with you (see the Reproductive Risks section on page 8).

It is possible, depending on machine availability or due to lack of time, that we will ask you to come in for one or two additional visits to make the necessary scans.

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AFTER SCREENING PROCEDURES: If the results of the screening procedures show that you are eligible for participation in this study and you decide to continue taking part, we will assign you to be trained in either *Program A* or *Program B*. Which program you are trained in will depend only on the order in which you join the study (1st person – A, 2nd person – B, 3rd person – A, 4th person – B, etc.). You will be told which program we assign you to when you come in for your second visit of the study. The second visit will be 6-10 weeks after the screening procedures are done. This visit will be the beginning of the Pre-Establishment Phase of the treatment program you are assigned to receive.

On each day you visit the RIC we will audiovisually record your speech and ask you to repeat the following tests and questionnaires you did during screening:

- complete a central auditory processing test
- a questionnaire to determine if you are anxious
- a questionnaire about your speech
- a questionnaire to evaluate your overall quality of life.

What follows is a description *Programs A* and *B* (how long they last, how many visits you will make to the RIC, etc.).

TREATMENT PROGRAMS *A* and *B*:

Pre-Establishment Phase: The purpose of the Pre-Establishment Phase is to allow the study staff to collect information about your stuttering that they will use in the rest of the study to determine if the treatment is decreasing your stuttering. Your visits to the RIC during the Pre-Establishment phase will each be approximately 2 weeks apart. The first visit of this phase will be your second study visit. This phase will last at least 8 weeks (3 visits), and could last as long as 10 weeks (6 visits). Between visits, you will audio record your speech and send us the audio recordings. The results of the audio and audiovisual recordings of your speech will determine how many visits (3, 4, 5, or 6) you make during this phase. Each of these visits will last about 1 hour.

Establishment Phase: The purpose of the Establishment Phase is to give you training on the program to which you are assigned (A or B) and to establish the behavioral/speaking changes that are the focus of that program. On your first visit during the Establishment phase, you will be given a manual describing the program, and we will begin training you in the program. We will answer any questions you may have about the program. This phase of both programs is mostly self-directed, meaning you choose how much time and effort you wish to put into the program. You can work on the program at your home, and you can schedule as many appointments as you wish at the RIC to work with the study staff (depending upon the staff schedule). The Establishment Phase requires about five 2-3 hour sessions per week for approximately 4 weeks (at your home or at the RIC), but the actual length of this phase will depend upon how much time you put into the program and how well you progress in the program. This phase may last up to 10 weeks.

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In this phase of both programs, we will teach you how to control the frequency of your stuttering under carefully controlled conditions. We will give you a copy of a computer program and a portable voice signal recorder (a device similar to the accelerometer used during the speech recording tasks at the RIC). We will teach you how to use the program and how to install the program on your home computer. We will show you how to use the portable voice signal recorder, and you will wear it while working with the computer program at your home. You can work on the program at the RIC as often as the study staff schedule allows and at your home as often as you want.

On two of your visits to the RIC during the Establishment Phase, we will make audiovisual recordings of your speech (described above, 1 hour each visit). On one of these two visits, we will make the second set of PET scans (2 hours) and the second MRI (1 ½ hour). Between visits to the RIC, you will make audio recordings of your speech (described on page 3) and upload them to the study's website. The *Program A* or *B* manual will give you information about how often you will need to make and send us audio recordings of your speech.

If you are in *Program A* and your speech is not improving by the end of the Establishment Phase, we will offer to train you in *Program B*. The same will apply if you are in *Program B* to begin with; we will offer to train you in *Program A*. This will result in you going through the other program's Establishment Phase, which will add another 4-10 weeks to your participation in this study. If you choose not to be trained in the other program, your participation in the study will end.

Transfer Phase:
The purpose of the Transfer phase of both programs is to demonstrate that the treatment gains (reductions in stuttering) you experience during the Establishment Phase speaking tasks can be duplicated in other speaking conditions. You will con tinue practicing with the three speaking tasks assigned during the Establishment phase, and three new speaking tasks will be added. The Transfer phase will last 8 – 16 weeks and you will have 2 – 4 visits to the RIC where we will audiovisually record your speech. On one of these visits, we will make the third set of PET scans (2 hours) and the third MRI (1 ½ hour). You will continue to make audio recordings of your speech and send them to us via the internet throughout this phase of the treatment program.

Maintenance Phase: The purpose of this phase is to demonstrate that the treatment gains that you achieved during the Transfer Phase can be maintained. You will continue trying to improve your speech on the final three speaking tasks from the Transfer Phase. At each visit to the RIC during this phase, we will audiovisually record your speech. You will continue to make audio recordings of your speech send them to us via the website throughout this phase of the treatment program. The number of weeks between visits to the RIC will be based upon how well you do on these recordings. When you maintain the same level of non-stuttered speech or your speech improves, the time between visits will be extended. To complete this phase, you must maintain the same level of non-stuttered speech for a minimum of 32 weeks (8 months). It is expected that the Maintenance phase will last 12 – 19 months. On one of the visits during the Maintenance Phase, we will make the fourth set of PET scans (2 hours) and the fourth MRI sca

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(1 ½ hour).

Successful completion of these four phases indicates successful completion of the program you were assigned. The next phase (Follow-up) will determine how well and how long the treatment works after you have stopped coming to the RIC to work with the staff on the treatment program.

Follow-up Phase: During the Follow-up phase, you will have two visits to the RIC; the visits will be at 6 months and at 12 months after finishing the Transfer Phase. We will make audiovisual recordings of your speech at these two visits to see how well your speech is doing following the completion of treatment. On one of the two visits during the Follow-up Phase, we will make the fifth (last) set of PET scans (2 hours) and the fifth (last) MRI scan (1 1/2 hour). You will make two sets of audio recordings during this phase and send them to us via the website. You will need to return the audio recorder that we loaned you for the study once these recordings are completed.

RISKS:

SPEECH RECORDING: This part of the study has no physical risk. However, you may accidentally record content that you would prefer to be kept private. You will always have the right to erase such recordings.

PET and MRI SCANS: *Claustrophobia.* Being inside the PET scanner while wearing a face mask and inside the MRI scanner with your head in a padded head holder are unusual experiences. In some people this will cause anxiety and even claustrophobia (fear of being in a confined space). Very few people become claustrophobic when inside the PET, as the inside of the PET is far from the face (about 18 inches). Claustrophobia is more common in the MRI scanner, as the walls of the MRI cylinder are close to the face (about 8 inches away). Conversation and reassurance with the MRI or PET technician usually will calm any anxiety. You will be able to speak to and hear the MRI or PET technician during all scans. If you experience severe anxiety during this study and do not feel reassured by the staff, you may end the session.

MRI SCAN: There are no known complications of MRI in most persons. Although there are no known long-term side effects associated with the use of MRI, there is the possibility of unknown risks. No needles will be used. No X-ray exposure will occur. People with heart pacemakers cannot enter MRI areas because the magnetic field can interfere with the function of the pacemaker. People with metal in their bodies (such as surgical clips, bone pins, shrapnel, or metal iron filings) might not be allowed to enter MRI areas, as the magnetic field may cause metal objects to move with force and could result in serious injury. Whether you can undergo the MRI will be decided by the study doctor and the MRI technician. Occasionally a person may experience slight dizziness or other minor sensations during a MRI scan due to the magnet or the loud noises which are part of the MRI process. If you experience discomfort or anxiety during this study, you are free to ask us to end the session.

PET SCAN: There are no serious risks of PET scanning. Minor risks include:

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i.v. pain and bruising. Catheter placement in the vein can cause a small amount of pain and bruising. There is a slight risk of infection. If the research staff at the Research Imaging Center discovers an infection, proper medical care will be provided. If you see swelling or a red color at the place where you had an i.v. several hours after the scan, call one of the persons listed on page 13. These risks are present whenever the skin is punctured with a needle.

Lying still. Some people find it uncomfortable to lie still for an entire PET session (2 hours).

X-rays. This research study involves your getting radiation (like x-rays) from the water injected into your bloodstream for the PET scan. The amount of radiation you will get in this study from this procedure is small (2.5 rem, effective dose equivalent from no more than 600 mCi of $H_2{}^{15}O$ over a series of 30 injections). The amount of radiation you will receive in this study will be approximately 50% of the amount that a nuclear medicine worker may receive over a year. This radiation dose will be spread out over the course of the study, which lasts 28-40 months (about 2 – 3 1/2 years). However, you will get more than you would get if you were having most of the usual kinds of x-rays done on people when they are sick. The parts of your body that will get the most radiation are: testes/ovaries, red bone marrow, lungs, heart wall, kidneys, pancreas, spleen and liver. We do not know for certain what this type of low-dose radiation will do to you in the future, if anything. However, we believe that the chances are very small that you will have any bad effects.

If you have had radiation (like x-rays) before, please tell us now. We want to make sure that the amount of radiation you have received within the past year is within safe limits. If you need to have radiation like X-rays for routine medical procedures or because of broken bone(s), etc., while you are in this study, *please tell us as soon as you learn of this need.* We want to make sure that you do not get too much radiation.

REPRODUCTIVE RISKS: You cannot take part in this study if you *are pregnant now* or if you are *planning to become pregnant* during the time period of this study (28-40 months, or about 2 – 3 1/2 years) because we do not know what effect the radioactive water used in this study might have on a pregnancy. If you are a woman of childbearing potential, you will be given a urine or blood pregnancy test, free of charge, the day of *each* PET session to make sure that you are not pregnant. You will be asked to bring in your first urine of the morning for each test. If you do not bring in a urine sample, 2 mL (about 1/2 teaspoon) of blood will be drawn from a vein in your arm for a pregnancy test.

If you unexpectedly become pregnant during this study, please tell the study doctors immediately (phone numbers are on page 13). You will be given the option of continuing the speech therapy portion of the study (*Program A* or *B*). You will not have any more PET scans if you are pregnant. However, one of the goals of this study is to determine the changes in the brain that occur in persons who take part in the speech therapy portion of this study, and PET scans are required for this determination. Therefore, if you intend to become pregnant during the time period covered by this study, please do not sign this consent form. Instead, please speak with the investigators about alternative treatments you can receive without being enrolled in this study.

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about enrolling in this study at a later date.

CONFIDENTIALITY: The audio and audiovisual recordings of your speech will be heard/viewed by the study staff at the RIC involved in the study, and by researchers at the University of California, Santa Barbara (UCSB) and the University of Georgia, Athens (UGA) who are involved in analysis of the recordings. The staff at the RIC, the UCSB, and the UGA will review these recordings to determine how well the stuttering treatment programs are working. The audiovisual recordings we make at the RIC will be labeled with your initials, the date of the recording, and a code identifying which speaking task was recorded (oral reading, phone conversation, etc.). You will label the audio recordings that you send us via the study's secure website at the RIC with your initials, the date of the recording, and a code identifying which speaking task was recorded. Both the audio and the audiovisual recordings will be stored on the web server at the RIC and will only be accessible to researchers at the RIC, UCSB, and UGA who are involved in the study. The files stored on the web server will not include your name, address, date of birth, or any other written identifying information.

The audio and audiovisual recordings will be kept by the principal investigators at the RIC, UCSB, and UGA indefinitely so that the results of the study can be analyzed at any time and can be combined with newer data to be acquired from other studies in the future to get a complete picture of how and why these treatment programs work or do not work. The recordings will not be used in other ways (educational purposes, presentation at conferences, etc.).

All information obtained from you to determine eligibility for this study and all information gathered from you and about you during the course of this study will be placed in your study records at the RIC. No information will be placed in your medical records.

We will tell you about any significant new findings that develop during the course of this research that may relate to your willingness to continue taking part.

STUDY WITHDRAWAL: You may be withdrawn from the study before it is complete if you do not meet certain program criteria during the course of the program, if you report to us that you have used any illegal drugs, or if you start taking any other therapy or medicine for your stuttering. The specific program criteria to be met are detailed in the *Program A* and *B* descriptions that you will receive as part of the study at the beginning of the Establishment Phase. In the event of an early withdrawal from the study, we may either try to have you participate in the treatment program at another time or arrange for you to be assessed for possible therapy by a local private speech-language pathologist or clinic.

BENEFITS: There is a possibility that your stuttering will stop or will be reduced by the treatment programs used in this study. However, we cannot guarantee that you will benefit from either treatment.

You will not directly benefit from the PET and MRI scans. These scans are being done solely for purposes of the research study. If a suspected abnormality is found in your brain (such as a

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possible tumor), we will give you a copy of the MRI or PET film and recommend that you take it to your doctor for evaluation. We can also provide a referral if you do not have a primary physician.

ALTERNATIVES: There are alternative treatments for adults who stutter. In recent years the range of stuttering therapies recommended for adults and adolescents can be described as either behavioral treatments based on speech pattern modifications or drug treatments.

Behavioral treatments: The most widely used and effective treatments rely on a combination of regular practice and training in the use of a new speech pattern that is known as "prolonged speech". This is a sort of "drawly" sounding speech that with training can be made to sound reasonably normal and has little or no stuttering. Dramatic reductions in stuttering are reported from many programs that employ one or another variation of this procedure. A recent study reported that approximately 70% of adults treated by related procedures (under intensive conditions) achieve at least 85% reductions in stuttering that are maintained 10-18 months after treatment. However, relapse is common, and it is not always clear that patients ever actually achieve normal spontaneous speech, or speech that is free of constant self-monitoring. In fact, the success of many of these treatments appears to rely on the patient constantly practicing their "new speech pattern."

Some alternative behavioral approaches to treatment for adults have appeared recently, but most simply rely on a variation of the prolonged speech pattern. One much publicized device that is used to train this speech pattern is known as "SpeechEasy". This is a portable device that causes a person to hear his/her speech in a distorted way and with a slight delay. So far there is no research showing that this device produces maintained benefits, and its therapy benefits appear to require the patient use a new speech pattern.

Drug treatments: Almost every drug that relieves anxiety has been used in an effort to find a successful cure for stuttering. There is some evidence that the severity of occasions of stuttering during speech (how much someone stutters at one time) can be reduced somewhat by some drugs. But there is no convincing evidence that the frequency of occasions of stuttering during speech (how often someone stutters while speaking) is reduced by such drugs. In the past decade, there have been studies of *propranolol*, *carbamazepine*, *betaxolol*, *clonidine*, *verapamil*, and even of *botox* injections into the vocal folds. The fact is that, despite many attempts to develop drugs to treat stuttering, there is little evidence that any have been successful.

STUDY COSTS: You will not be charged for any of the study-related procedures, the digital audio recorder, the portable voice signal recorder, or the computer program. We will provide the digital audio recorder and the portable voice signal recorder to you for the time period of this study. You may keep any computer program provided to you, but you will need to return the digital audio recorder and the portable voice signal recorder at the end of the study. In the event that the audio recorder or the portable voice signal recorder stop working, please call one of the investigators (page 13) and we will arrange to have the device repaired/replaced. You will be responsible for the costs of your internet access.

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COMPENSATION: You will be compensated $25 for each MRI scan, and $ 100 for each PET session (2 hours each, five PET sessions). If you do not complete the study, you will be compensated $25 per MRI scan and $100 per PET scan session you complete. You will not receive compensation for the visits you make to work with the clinician on the speech program. The entire study is expected to require 28 – 40 months (2 – 3 1/2 years) and 30 – 60 visits to the RIC.

The compensation you receive may be taxable. When the total compensation paid to someone participating in one or more studies is $600 or more in one calendar year, the institution must report the amount to the IRS. The IRS considers it earned income and treats it like any other income. Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the compensation will be applied to that debt and you will not receive a check.

COMPENSATION FOR INJURY: If you are injured as a result of the research procedures, your injury will be treated. You will be responsible for all charges. We have no plans to give you money if you are injured. You have not waived any of your legal rights by signing this form.

CONFIDENTIALITY

What is Protected Health Information (PHI)?

Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. We will use the term "your PHI" as a shorter way of saying "your protected health information." According to the law, you have the right to decide who can see your PHI. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- information obtained from procedures used to determine your eligibility to participate in the study, including medical history and information about past surgeries, allergies, menstrual history, prescription, over the counter and other drug use,
- information that is created or collected from you during your participation in the study, including the results of computer tests and paper tests, the hearing screening, pictures of your brain from MRI and PET, and recordings of your speech,
- demographic information. Demographic information includes things like your age, your marital status, type of work you do and years of education completed.

We will get this information by asking you personally for information, by having you fill out questionnaires, by recording your speech, and by making MRI and PET scans.

How will your PHI be shared?

Because this is a research study, we will be unable keep your PHI completely confidential. W

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may share your health information with people and groups involved in overseeing this research study including:

- The sponsor of this study, the National Institute on Deafness and Other Communication Disorders (NIDCD), and representatives of the sponsor, or other agents designated by the NIDCD to monitor or inspect study data;
- Researchers at the University of Texas Health Science Center at San Antonio, at the University of California - Santa Barbara (UCSB), and at the University of Georgia (UGA),
- Representatives of the University of Texas Health Science Center at San Antonio Institutional Review Board (IRB), the UTSA IRB, the UCSB IRB, the UGA IRB, the UTHSCSA Compliance Office, and representatives of other groups that have the responsibility of monitoring and overseeing research studies;
- In addition, in order to review the study findings, the U.S. Food and Drug Administration (the FDA), may review your PHI.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax.

The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

If you decide to participate in the study, you will be giving your permission for the groups named above, to see and share your health information. If you choose not to let these groups see and share your health information as explained above, you will **not** be able to participate in the research study.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use codes and your initials instead of your name in order to identify your PHI on any photocopies of your study records, MRI, or PET scans that are sent outside of the RIC for review. Audio and audiovisual recordings stored on the web server at the RIC will have your initials, the date of the recording, and a code number on them. These files will only be accessible to researchers at the RIC, UCSB, and UGA who are working on this study for review and testing. If the results of this study are reported in medical journals or at meetings, your personal identity will remain confidential.

Do you have to be in this study?
Being in the study is voluntary. You are free to choose not to be in this study or to stop being in this study at any time. You are also free not to let the researchers and other groups see and share your health information. If you choose not to be in the study or not to let the researchers and other groups use your health information, there will be no penalties. In other words, you will still be able to get medical treatments without being in the study and it will not affect your eligibility for any health plan or any health plan benefits or payments for which you may be eligible.

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What if you change your mind?
You may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Jean Hardies, Ph.D., Research Imaging Center, University of Texas Health Science Center, 7703 Floyd Curl Dr., San Antonio, TX 78229-3900. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study at any time in the future. There is no expiration date because we do not know how long it will take us to finish doing all of the analyses and we will need to use your health information for as long as it takes.

If you have questions now, feel free to ask us now. If you have additional questions later or you wish to report a medical problem which may be related to this study, please call Dr. Peter Fox, Dr. Shalini Narayana, Dr. Jean Hardies, or Dr. Roger Ingham:

	Daytime	Evening
Dr. Peter Fox	210-567-8100	210-493-5282
Dr. Shalini Narayana	210-567-8100	210-326-2637
Dr. Jean Hardies	210-567-8100	210-694-4707
Dr. Roger Ingham	210-567-8100	

(Dr. Ingham resides in California. When he is not in San Antonio, we will take a message and have him call you back.)

The University of Texas Health Science Center committee that reviews research on human subject (Institutional Review Board) (567-2351) and the University of Texas Institutional Review Board (210-458-6473) will answer any questions about your rights as a research subject.

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SUBJECT CONSENT TO TAKE PART IN A STUDY OF:
Stuttering Therapy and Neurophysiological Interaction

You will be given a signed copy of this form to keep.

SIGN THIS FORM ***ONLY*** IF ALL OF THE FOLLOWING ARE TRUE:

-YOU HAVE VOLUNTARILY DECIDED TO TAKE PART IN THIS RESEARCH STUDY

-YOU AUTHORIZE THE COLLECTION, USES AND DISCLOSURES OF YOUR PROTECTED HEALTH INFORMATION AS DESCRIBED IN THIS FORM.

-YOU HAVE READ THE ABOVE INFORMATION.

-YOUR QUESTIONS HAVE BEEN ANSWERED TO YOUR SATISFACTION AND YOU BELIEVE YOU UNDERSTAND ALL OF THE INFORMATION GIVEN ABOUT THIS STUDY AND ABOUT THE USE AND DISCLOSURE OF YOUR PHI.

Signature of Subject	Date & Time Signed by Subject
Printed Name of Subject	
Signature of Witness	Printed Name of Witness
Signature of Person Obtaining Consent	Printed Name and Title of Person Obtaining Consent

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