Department of Veterans Affairs	VA PUGET SOUND HEALTH CARE SYSTEM (663) RESEARCH CONSENT FORM
SUBJECT NAME	
TITLE OF STUDY	**A Prospective, Controlled Study of Rehabilitation of Anomia in Aphasia**
PRINCIPAL INVESTIGATOR	**Diane Kendall, PhD**

LAY TITLE: Speech therapy for aphasia

Researchers:

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24-hour emergency contact: Please call Diane Kendall at (206) 369-3558

You are being invited to participate in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide whether you want to be in the study. You are free to discuss this with friends or family. This process is called "informed consent." We will give you a copy of this form once it is signed for your records.

1. Purpose of research study and how long it will last: The purpose of this study is to give speech therapy to individuals who have suffered a stroke and have difficulty speaking, a condition called "aphasia." The study will compare two different treatments for aphasia, one which is based in sounds and one which is based in words (see Section 2 Step 4 for further details).

This study has been funded by a grant from the VA Rehabilitation Research and Development Service (RR&D). There will be 80 total individuals with aphasia who will participate in this study. Forty individuals will be recruited and enrolled from the VA Puget Sound Health Care System (Seattle), and 40 will be recruited and enrolled from the University of Washington (Seattle).

2. Description of the study including procedures to be used: If you participate in this study, the following five steps will take place.

Step 1: Screen

If you are signing this consent form, you have already gone through Step 1. You have been asked several questions about your medical history. This was an initial screening to see if you met basic criteria for the study. You were asked to provide information regarding where you received medical care following your stroke. We have a document (called a "waiver") that allowed us to view your medical records to confirm the location of your stroke. This waiver allowed us to get your medical records with your verbal permission only, before you came in to sign this form. Since you passed the initial screen and the CT/MRI screen, you are now on the next step (Step 2).

Step 2: Randomization

You will be randomized (like a flip of a coin) to one of two treatment groups, Group A or Group B:

- Group A: Phonological (treatment based in sounds)
- Group B: Semantic (treatment based in words)

Step 3: Pre-Treatment Testing

You will meet with a speech-language pathologist over the course of 1 week to receive pen/paper aphasia testing for a total of 10-15 hours. Ideally, testing will be broken up into smaller periods (2-3 hours) over the course of the week, with breaks scheduled every 30-60 minutes or at your request. You will be video and audio recorded. We will have you sign a separate consent form for audio and video recording.

Step 4: Treatment Phase

You will receive speech therapy for 60 total hours (1-hour sessions two times a day for 5 days a week for 6 weeks).

- **Group A:** "Phonological treatment" is training individual sounds (consonants and vowels) and sound sequences (strings of consonants and vowels used in 1-syllable, 2-syllable, and 3-syllable words). Using "talk therapy," the therapist will teach you these sounds and sequences through your senses: visual (looking in a mirror), auditory (hearing the sounds), tactile-kinesthetic (feeling the sounds in the mouth), and speech motor (saying the sounds).

- **Group B:** "Semantic treatment" is training whole words (such as nouns). Using "talk therapy," the therapist will teach you nouns by showing you a picture (for instance, a hammer) and then ask you a series of questions about that noun (for example, *"What do you do with it?"* and *"Where do you store it in your home?"* and *"Show me how you hold it."*). You will then be asked to name that picture ("hammer"). After naming the picture, the therapist will show you a new picture and repeat the same procedures.

Step 5: Post-Treatment Testing

Immediately following treatment and again 3 months later, you will need to meet with a speech-language pathologist to receive the same pen/paper aphasia tests you received in Step 3. Over the course of 1 week, you will need to meet with the speech-language pathologist four or five times for testing. The sessions will be video and audio recorded.

You have the option of returning 1 year from the end of treatment for another testing session. If you decide to complete this testing, you will need to meet with the speech-language pathologist two or three times over the course of 1 week for testing. Again, the sessions will be video and audio recorded.

You do not have to answer any questions or test items that make you uncomfortable. Any audio or video recordings we take of you will only be used for two purposes: (1) We will use the recordings to listen to your test responses to determine changes in your language before and after therapy; and (2) We may use the recordings for education purposes (for example, showing graduate students what someone with aphasia might sound like). You will be able to review any recordings and choose whether or not you want them to be used for education.

All procedures will be performed at a site that is most convenient for you. This can be your home, the VA Puget Sound Health Care System (Seattle), or the University of Washington.

3. Description of any procedures that may result in discomfort or inconvenience: You may feel fatigued during the speech therapy sessions and the aphasia tests. In the event of fatigue, you may take a break from therapy at any time. Also, 10-minute breaks will be scheduled after every 50 minutes of testing or treatment.

You may find the intensive schedule of treatment to be inconvenient. The therapist can come to your home if that will aide in travel.

4. Potential risks of the study: You will be given an opportunity to review any audio and/or video recordings we make of your speech and erase any portion. Please note that your voice is technically identifiable according to patient privacy rules, so we will do everything possible to protect your voice identity. For information as to how we will protect your identity to the best of our ability, please refer to Section 7.

The particular treatments or procedures in this study may involve risks that are currently unforeseeable. We will contact you as soon as possible if new findings occur during this research that may pose a risk to you.

5. Potential benefits of study: You may not benefit from taking part in this study. You may, however, be able to speak better after completing 60 hours of speech therapy. Information that we gain through this study may be of future benefit to patients with aphasia.

6. Other treatment available: Should you decide not to participate in this research speech therapy study, you may continue with your usual care clinical speech therapy sessions or participate in your community social groups.

7. Use of research results / Confidentiality: The information obtained about you will be held confidential. However, for purposes of this study, the following list of people or groups may know that you are in this study. They will have access to your records, which may include your medical records:

- Research team members
- Portland State University Speech & Hearing Department – Aging and Adult Language Disorders Research Lab
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research)
- Federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), and the VA Office of the Inspector General (OIG), Government Accountability Office (GAO)
- The VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies
- The VA Puget Sound Fiscal Department will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study
- The UW committees that oversee research, including the UW Institutional Review Board and supporting staff, will have access to your study records but not your medical records

The purpose of this access is to review the study and make sure that it meets all legal, compliance, and administrative requirements. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to appropriate authorities.

To protect the confidentiality of the information obtained about you during this research study, we take many preventative measures. Only a code number will identify your research records. The master list linking names to code numbers will be kept separately from other research records. Part of your research records will be stored on paper in locked file cabinets, and part will be stored in electronic format on password-protected computers. The file cabinets and computers will be housed in rooms that are locked when unoccupied, except when the records are in use by authorized members of the research team.

There may be publications about this study in the future. If so, your identity will be held confidential. No personal information will be given in a publication without your approval in writing.

Your study information will be used only for research purposes and will not be sold. Information gained from this research may be used commercially for the development of new ways to diagnose or treat diseases. However, neither you nor your family will gain financially from discoveries made using the information that you provide.

We use a video and/or audio recorder to record part of your study visits. These files are used to verify that the tester accurately wrote down your response word for word, or for further analysis of your speech. To protect your identity, the recorders will only be used within the VA Seattle, University of Washington Aphasia Research Laboratory, or your home during testing sessions. The video and/or audio recorders used to record interviews or test responses will be kept with the research staff or stored securely at all times. The video and/or audio recorder will be kept in a locked desk when not in use. The video and/or audio files will be stored on a secured computer server protected by a VA firewall in password-protected folders. The files will be accessible only to the researcher staff listed on the first page of this consent form.

We will need to send some of the recordings of your speech to Portland State University in Portland, Oregon. The recordings will only be of your conversational samples. In other words, not all of your data will be sent to Portland State University; only the conversation samples and only the audio version (we will not send videos). All recordings will be burned to encrypted CDs and will be mailed via the United States Postal Service.

Once this study is completed, we will not use your audio, video, or transcript data (or the code linking it to you) for any additional research. Your data and code will be held in a secure database until VA receives authorization to destroy them in accordance with federal records regulations. It may be several years before the data and code are actually destroyed, but they will not be used for research after this study is completed.

8. Special circumstances: The VA requires some Veterans to pay co-payments for medical care and services. This study will not require you to pay any co-payments. However, you will still have to pay any co-payments that are not related to this research study (your regular doctor visits).

You will be compensated for your time and costs associated with this study, such as gasoline and bus fare. A check for $300 will be sent to you within 8 weeks of completing the study. If you do not complete all study procedures, you will be paid a partial payment at the time of your withdrawal. You may receive an Internal Revenue Service (IRS) Form 1099. If so, your social security number will be used for this purpose.

9. Withdrawal from the study: You do not have to take part in this study. If you are in this study, you can withdraw at any time. You will not be penalized for your decision to not participate or withdraw nor will you lose your VA or other benefits if you decide to do so.

Your doctor has the right to terminate your participation in this study if he or she feels that it is not in your best interest. This termination will not require your consent.

We may need to terminate your participation if we feel you have developed any medical symptoms unrelated to the study that require medical care. In this case, we would refer you to your physician and any other relevant specialty services (such as neurology or psychology).

If you decide to withdraw, or if you are terminated from the study, a person from the study team will then need to meet with you to discuss the necessary steps that you may need to take to end your participation in the study.

10. Questions or concerns related to the study: Please call Diane Kendall at (206) 369-3558 *immediately* if:

- You think you may have been harmed or injured as a direct result of this research; and/or
- You have any questions regarding your medical care issues.

You may contact the Institutional Review Board (IRB) – VA Office at (206) 277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study;
- Have questions, concerns, or complaints about the research;
- Would like to verify the validity of the study; or
- Have questions about your rights as a research subject.

An IRB is an independent body made up of medical, scientific, and non-scientific members, whose job it is to ensure the protection of the rights, safety, and well-being of human subjects involved in research.

11. Research-related injury: Medical treatment will be provided, if necessary, by the VA if you are injured by being in this study. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

You do not waive any legal rights by signing this consent form.

12. Research subject's rights: I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or

discomforts, possible benefits of the study, and other choices of treatment available to me. My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

I agree to participate in this research study as you have explained it in this document.

_____ _____
Subject Signature **Date**

_____
Print Name of Subject

_____ _____
Signature of Person Obtaining Consent **Date**

_____
Print Name of Person Obtaining Consent