Department of Veterans Affairs	VA RESEARCH CONSENT FORM Social and Behavioral Research

Title of Study:	DESIPHER Speech Degradation as an Indicator of Physiological Degeneration in ALS		
Principal Investigator:	Samuel Phillips, PhD	VAMC:	Tampa-673

Informed Consent to Participate in Research: Social and Behavioral Research

University of South Florida, the IRB of record for the James A. Haley Veterans' Hospital
Information to Consider Before Taking Part in this Research Study

IRB Study # Pro00023666

Researchers at the James A. Haley Veterans' Hospital study many topics. Our goal is to find better ways to help treat patients. To do this, we need the help of people who agree to take part in a research study.

We are asking you to take part in a research study that is called: **DESIPHER Speech Degradation as an Indicator of Physiological Degeneration in ALS**

The person who is in charge of this research study is Samuel Phillips, PhD**.** This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge. The person explaining the research to you may be a study staff member other than the Principal Investigator.

The research will be done at James A. Haley Veterans' Hospital.

This research is being paid for by VA Rehabilitation Research and Development. .

Should you take part in this study?

This form tells you about this research study. This form explains:

- Why this study is being done.
- What will happen during this study and what you will need to do.
- Whether there is any chance you might experience potential benefits from being in the study.
- The risks of having problems because you are in this study.

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

Before you decide:

- Read this form.
- Have a friend or family member read it.
- Talk about this study with the person in charge of the study or the person explaining the study. You can have someone with you when you talk about the study.
- Talk it over with someone you trust.
- Find out what the study is about.
- You may have questions this form does not answer. You do not have to guess at things you don't understand. If you have questions ask the person in charge of the study or study staff as you go along. Ask them to explain things in a way you can understand.
- Take your time to think about it.

It is up to you. If you choose to take part in this study, you will need to sign this consent form. If you **do not** want to take part in this study, you should **not** sign the form.

Why is this research being done?

The purpose of this study is to find out The purpose of this study is use automatic speech recognition (ASR) and machine learning software to identify speech pathologies and use them to predict other aspects of physiological degradation associated with ALS (e.g., respiratory difficulty or inability to swallow); improve speech recognition for those with speech impairments; and (ultimately) improve the quality of life for patients through conversation with a computer.

Why are you being asked to take part?

We are asking you to take part in this study because you are a Veteran with ALS that appears to meet the inclusion/exclusion criteria.

What will happen during this study?

You will be asked to spend about two years in this study.

Subject's Name: _____

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A study visit is one you have with the person in charge of the study or study staff. You will need to come for 8 study visits in all. Most study visits will take under an hour. At each visit, you will be asked to read four preselected passages, repeat a short word and have your tongue strength measured via a soft bulb-shaped device that will be placed in your mouth.

In addition to this consent form, you will be asked to sign two other documents: a consent form for use of picture and/or voice and an authorization for use and release of individually identifiable health information.

The consent form for use of picture and/or voice will allow us to record your readings. Recordings will not include any identifying information other than a study code. They will be kept indefinitely and used for training the speech recognition system. Recordings are digital in nature and will be stored in a secure folder on the VA's shared drive.

The authorization for use and release of individually identifiable health information (HIPAA) form which will provide the research team permission to access your electronic medical record for this study. You will also be asked for permission to store the data you provide as part of this study in a research data repository for future studies.

During the course of the study, if a participant is deemed at high risk for harm/suicide, study personnel will do the following:

- Stay with patient until they can be 'handed off' to appropriate medical staff (name the staff person).
- If the patient is an outpatient, this will involve taking the patient to the Emergency Room for evaluation.
- If the patient is an inpatient, this will involve calling the patient's primary treatment team and/or escorting the patient to such providers.
- All study personnel who work directly with research participants will be given the names and phone numbers of the patient's medical care team. After the patient has been 'handed off' to the appropriate staff, the PI will be alerted.

How many other people will take part?

About 20 people will take part in this study at James A. Haley Veterans' Hospital.

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

What other choices do you have if you decide not to take part?

If you decide not to take part in this study, that is okay. Participation in this research study is entirely voluntary. In other words, you do not have to participate in this study. If you do not want to participate in this study, the rights and health care benefits you are entitled to will not change (i.e., including VA benefits and access to standard medical care). Any new significant findings developed during the study that may change your decision about participating will be provided to you.

Instead of being in this research study you can choose not to participate.

Will you be paid for taking part in this study?

We will pay you for the time you volunteer while being in this study. You will receive $25 for each voice recording visit. The total payment will be up to $200.00, if all visits are completed. Payment will be by Electronic Funds Transfer (EFT) or check. Payment is made through the U.S. Department of Veterans Affairs Financial Services in Austin, TX. Payments made through the Austin Financial Services Center generate an Internal Revenue Service (IRS) Form 1099, regardless of amount. We will need your social security number and your bank account number (for the EFT) in order to pay you.

What will it cost you to take part in this study?

It will not cost you anything to be part of the study.

As a VA patient, there may be co-payment costs for some of the non-research procedures for which the VA may not pay even if these occur while you are participating in this research. Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study and that you would receive as part of your regular medical care.

What are the potential benefits if you take part in this study?

We do not know if you will get any benefits by taking part in this study.

What are the risks if you take part in this study?

The following risks may occur: The etiology of ALS frequently creates other health issues. These anticipated issues that may require medical intervention and hospitalization include, but are not limited to: respiratory insufficiency, sleep apnea, malnutrition, dehydration, tracheotomy, frontotemporal dementia and falls.

If you have any of these problems, call the person in charge of this study right away at (813) 558-3995 Unforeseen risks: A previously unknown problem could result from your taking part in this research. It is not possible to estimate the chances of such problems or how serious the problems could be. Any new findings will be given to you that may affect your willingness to take part in this study. If new findings are discovered, you will be asked to sign a new (updated) informed consent form to document that new information provided in the updated Consent Form has been explained to you. If you have any of these problems, call the person in charge of this study right away at (813) 558-3995.

Throughout the study, the researchers may notify you (via telephone or in person at a scheduled visit) of any new information that may become available and which might affect your decision to remain in the study.

What if you are injured while you are in the study?

You are participating in a research project approved by a Research and Development Committee and conducted under the supervision of one or more VA employees. Every reasonable safety measure will be used to protect your well-being. If you are injured because of your participation as a research subject in this research study, the VA medical facility will provide you with necessary medical treatment.

If you need emergency care:

- **Go to your nearest hospital or emergency room right away. Call 911 or for help.** It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.
- Call the person in charge of this study as soon as you can. They will need to know that you are hurt or ill. Call Dr. Samuel Phillips at (813) 558-3995.

If you need emergency care in a private hospital, have a friend or family member contact the VA immediately at (813) 972-2000, extension 6197 or 6198, and your study doctor so that they can

coordinate care with a private hospital. If an eligible veteran requires admission to a non-VA hospital as a result of an emergency, the Department of Veterans Affairs will not be responsible for the cost incurred unless the Department of Veterans Affairs is involved immediately.

If it is not an emergency, and you get hurt or begin to feel bad: Go to your regular. Tell your doctor that you are taking part in this study. If you can, take a copy of this consent form with you.

If you are harmed while taking part in the study:

If you believe you have a medical concern related to this study, or have been hurt or became sick because of something that is done during the study, you should call the person listed below immediately.

DURING THE DAY:

Dr.: _Dr. Sam Phillips_____

Telephone number: __(813) 558-4995_____

AFTER HOURS:

Contact the hospital emergency department_____ Telephone number: *(813) 972-2000, extension 6197* _____
Emergency and ongoing medical treatment will be provided as needed.

Compensation for Research-Related Injuries

Financial compensation for research-related injuries, lost wages, discomfort or disability may be available. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

What happens if you decide not to take part in this study?

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study to please the study doctor or the research staff.

If you decide not to take part:

- You will not be in trouble or lose any rights you normally have.

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

- You will still have the same services you would normally have.
- You can still get your regular doctor.

What if you join the study and decide you want to stop later on?

You can decide after signing this informed consent document that you no longer want to take part in this study. **We will keep you informed of any new developments which might affect your willingness to continue to participate in the study.** However, you can decide you want to stop taking part in the study for any reason at any time. If you decide you want to stop taking part in the study, tell the study staff as soon as you can.

- We will tell you how to stop safely. We will tell you if there are any dangers if you stop suddenly.
- If you decide to stop, you can continue getting care from your regular doctor.

Are there reasons we might take you out of the study later on?

Even if you want to stay in the study, there may be reasons we will need to take you out of it. You may be taken out of this study if:

- We find out it is not safe for you to stay in the study. For example, your health may worsen.
- You are not coming for your study visits when scheduled.
- You fail to meet inclusion/exclusion criteria

Privacy and Confidentiality:

- Description of how the data and/or specimens will be **used**:
  Data collected from your VA medical record will be used to determine if changes in physiological functioning (Forced Vital Capacity, tongue strength, speech velocity, weight loss, aspiration risk, or psychological distress) are associated with different types of language/speech errors.

  The voice recordings will be transcribed and the transcripts along with the audio recording will be used to train a speech recognition system to adapt to increasingly more frequent language/speech errors of particular types, to produce an accurate textual transcript that will be readable by a caregiver or physician.

All of the data we collect will be treated as highly confidential. We will protect the data and it will not be seen by people outside of this study. Participants will be assigned a number at the time of enrollment in the study and will be identified by that number during the course of the study and data analysis. Identifiable personal information will be stripped from the database so as to protect confidentiality.

- Description of how/where the data will be **stored**.
  Data will be stored on the password-protected research server which sits behind the VA firewall. All data will be stored and maintained in a Microsoft SQL Server or Microsoft Access back-end database. The server is managed by VATAM OI&T and data are backed up on a nightly basis. The following staff members will have access to the data once it is saved on the research server: the PI and the project staff.

- Description of how the data and/or specimens will be **transmitted.**
  Data analysis will be conducted at the Florida Institute of Human and Machine Cognition (IHMC) in Ocala, Florida. De-identified data will be sent to IHMC via Credeon secure encrypted transfer.

- Description of how the data and/or specimens will be **destroyed.**
  Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule.

- Description of how the data will be **disclosed.**
  We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

Your Rights:

You can refuse to sign this form. If you do not sign this form:

- **You will not be able to take part in this research and therefore not be able to receive the research drug or procedure. However, you can receive other services that are currently available for your condition as part of your regular medical treatment**

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

- **This will not change your health care outside of this study.**
- **This will not change your health care benefits.**
- **This will not change the costs of your health care.**

How Do I Withdraw Permission to Use My Information?

You can revoke this form at any time. This means you can tell James A. Haley Veterans' Hospital to stop using and sharing your information. If you revoke this form:

- **You will no longer be a participant in this research study.**
- **We will stop collecting information about you.**
- **The information that we have collected before you tell us to stop may already have been used or shared, or we may need it to complete the research so you cannot withdraw that information.**
- **Staff may follow-up with you if there is a medical reason to do so.**

To revoke this form, you must tell us in writing. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study.

If you revoke this authorization, your research doctor or staff can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

While we are doing this research, we cannot let you see or copy the research information we have about you. After the research is done, you have a right to see and copy the information about you, as allowed by James A. Haley Veterans' Hospital policies.

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy or would like a copy of the Notice, the research team will provide one to you.

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

You can get the answers to your questions, concerns, complaints or issues.

If you have any questions, concerns or complaints about this study, call Samuel Phillips, PhD at (813) 558-3995.

If you have questions about your rights, general questions, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

If you would like to contact someone independent of the research study, or can not reach the research staff, you may contact the James A. Haley Veterans' Hospital Research Compliance Officer at 813-903-4422 or 813-903-4274.

Statement of Participation in Research

It is up to you to decide whether you want to take part in this study. If you want to take part, please read the statements below and sign the form if the statements are true.

I freely give my consent to take part in this study and authorize that my health information as agreed above, be collected/disclosed in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

_____ _____

Signature of Person Taking Part in Study Date

_____

Printed Name of Person Taking Part in Study

_____ _____

Signature of Caregiver of Person Taking Part in Study if Veteran cannot sign Date

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Print name of Caregiver of Person Taking Part in Study if Veteran cannot sign

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Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

Statement of Person Obtaining Informed Consent / Research Authorization

I have carefully explained to the person taking part in the study what he or she can expect.

I hereby certify that when this person signs this form, to the best of my knowledge, he or she understands:

- What the study is about.
- What procedures/interventions/investigational drugs or devices will be used.
- What the potential benefits might be.
- What the known risks might be.
- How the information collected about the person will be used.

I also certify that he or she does not have any problems that could make it hard to understand what it means to take part in this research. This person speaks the language that was used to explain this research.

This person reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her.

This person does not have a medical/psychological problem that would compromise comprehension and therefore makes it hard to understand what is being explained and can, therefore, give informed consent.

This person is not taking drugs that may cloud their judgment or make it hard to understand what is being explained and can, therefore, give informed consent.

_____ _____

Signature of Person Obtaining Informed Consent / Research Authorization Date

_____

Printed Name of Person Obtaining Informed Consent / Research Authorization

_____

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____