

VERBAL INFORMED CONSENT VIA TELEPHONE
National Registry of Veterans with ALS

PATIENT ID: _____

NAME: _____

SSN: _____ - _____ - _____

We are asking you to volunteer to take part in a nationwide registry of veterans with amyotrophic lateral sclerosis, or ALS. This registry is being developed by the Department of Veterans Affairs (VA) under the direction of Dr. Eugene Oddone and his research team. The purpose of this registry is to identify all living veterans with ALS and to collect data that will be important for future studies examining the causes of ALS. In addition, the registry will provide a way for the VA to inform veterans with ALS about clinical trials for which they may be eligible.

I would like to know if you are willing to take part in this registry. If you agree to participate, we will obtain copies of your medical records from your doctor(s). A neurologist with expertise in ALS will review these medical records to determine if you qualify for the registry. Following this review, we will contact you to tell you whether you qualify.

Veterans, or their representatives, who participate in the registry will be asked to complete a brief telephone interview when they enroll in the registry. This interview will take no more than one hour and will include basic questions about your illness and medical care. Once you are enrolled in the registry, we will also contact you by telephone approximately every six months to ask you a short series of questions about your current health and medical care. These phone interviews will take no more than one hour.

Once you are enrolled in the registry, we may contact you about clinical trials and other studies for which you may be eligible. This may include trials that are examining new drugs for the treatment of ALS. Enrolling in the registry does not commit you to being involved in any additional studies. It simply means that the registry team will be able to notify you about specific studies that you may want to consider. A special registry advisory committee will evaluate each of these studies, and you will only be notified about studies that are scientifically sound and important for the treatment or understanding of ALS.

Your willingness to receive information about clinical trials is voluntary. If you choose not to allow the VA to contact you with this information, you may still be enrolled in the registry.

Do you give the VA permission to contact you by telephone or mail if there is a study related to ALS for which you/the veteran may be eligible?

_____ YES _____ NO

Because we will be asking you questions only, participation in the registry is not believed to have any risks for your health. Taking part in this study may not personally help you, but your participation may lead to knowledge that will help others.

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As part of this study we are asking you to authorize Dr. Oddone and his research team to access the following information about you: Your name, social security number, demographic information, military history, and your responses to survey questions dealing with symptoms related to ALS. We will also access your previous VA and non-VA medical records, including: clinic data, hospital visit data, results of neurological tests (such as electromyograms and nerve conduction tests) and results of other laboratory tests that may be used to diagnose ALS.

We may disclose your information to the Veterans ALS Registry Scientific Review Committee (a committee of expert researchers that oversees Registry procedures and use of Registry data), the Veterans Benefits Administration, the Institutional Review Boards that oversee this project (Lexington, KY VAMC, Durham, NC VAMC, and University of Kentucky), and government agencies as required by law. We will not share any information with any groups outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these groups may no longer be protected under federal law.

You do not have to authorize the use of this information. If you decide not to authorize the use of this information, it will not affect your regular medical care or your rights as a VHA patient, but you will not be allowed to participate in the Registry. This authorization has no expiration date. You can withdraw this authorization at any time by writing to Dr. Oddone or asking a member of the research team to give you a form to withdraw the authorization. If you withdraw this authorization, Dr. Oddone and his research team can continue to use information about you that has been collected, but no additional information will be collected.

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.

You need to be aware that:

- You are not required to participate in the Registry; your participation is strictly voluntary.
- You can refuse to participate now or you can withdraw from the study at any time after giving your verbal consent. You can refuse to answer any question or stop the interview at any time. These actions will not interfere with your regular medical treatment, if you are a patient.
- Eligibility for medical care is based upon the usual VA eligibility policy and is not guaranteed by participation in this or any other research study.
- The investigators will let you and your physician know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study.
- If our questions reveal information concerning suicidal intent, depression, or other major clinical findings, your primary physician will be notified immediately.
- There will be no costs to you for being part of this research study nor will you be paid for taking part in this study.
- If results of this study are reported in medical journals or at meetings, you will not be

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identified by name, by recognizable photograph, or by any other means without your specific consent.

If you have questions about this study, you may call Dr. Oddone at (919) 286-6936 during the day and at (919) 401-4403 after hours or to leave a message on the toll free line, 1-877-DIAL ALS (1-877-342-5257).

Are you willing to participate in the ALS Registry and authorize the use of your information as described?

_____ YES

_____ NO

I certify that the veteran consented verbally to participate in the Registry and permit use of their personal health information:

Name of Person Obtaining Verbal Telephone Consent
And HIPAA Authorization

Date