

ALS REGISTRY SCREENING FORM

Study ID: _____

Date: _____

Initials of Screener: _____

Hello. This is (NAME) from the Durham VA Medical Center. May I speak to (name of individual who left the message on toll free phone line or name of veteran identified through medical records)?

1. Name of Veteran: _____

2. Name of Contact Person During Screening:

3. Relationship of Contact Person to Veteran:
 Self/Veteran Spouse Child Sibling Parent Partner Friend
 Health Care Provider Other (specify): _____

I am a research assistant with the national VA ALS registry. How may I help you today (if call is returned from phone line)?

Provide information about the registry:

We are currently developing a registry of U.S. veterans who have ALS, or Lou Gehrig's Disease. 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 the registry is to identify as completely as possible all living veterans with ALS, and to follow the health status of these veterans. The registry will also provide a way for the VA to inform veterans with ALS about clinical trials for which they may be eligible. (Enrolling in the Registry does not obligate you to participate in any future clinical trials.) Any living veteran who has received a medical diagnosis of ALS is eligible to enroll in this registry.

4. With your permission, I would like to ask you some questions to determine your (*the veteran's*) eligibility. The information you provide today will be documented as part of our database of individuals we have spoken with about the registry, and all of the information you provide will be kept confidential. May I proceed?

- Yes
 No (Refuse)
 No (Don't have ALS)
 No (Dead)
 Don't Know
 Call back

If YES (veteran or proxy): Go to Eligibility Form

If NO (refuse): Go to Refused Script

If NO (don't have ALS): Since you do not have ALS, I won't ask you to answer any further questions. Thank you for taking the time to speak with me today. (End call.)

IF DON'T KNOW:

The questionnaire will only take a few minutes, and the information you provide is confidential. You can refuse to answer any question or terminate this phone call at any time. May I proceed?

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If YES: Go to Eligibility Form

If NO: Go to Refused Script

If CALL BACK:

When would be a good time to call you back?

Date _____ / _____ / _____ Time _____ (EST)

ELIGIBILITY FORM

1. Have you (or the person being considered for eligibility) ever served in the US Army, Navy, Marine Corps, Air Force, or activated Reserves or National Guard Unit?

YES – Go to Q2 NO- Go to Ineligible Script (non-veteran) DK-go to Q2

2. Were you (was the veteran) ever told by a health professional that you (he/she) might have ALS or Lou Gehrig's disease?

YES -Go to 2a. NO - Go to Q3 DK-go to Q3

2a. Were you (was the veteran) clinically diagnosed with ALS?

YES -Go to Q5. NO - Go to Q3.

3. Is there another current diagnosis given by a health professional?

YES -Go to Q4. NO - Go to Q5.

4. What was the diagnosis (check all that apply)?

Possibly ALS (not yet determined/diagnosed) *If yes, go to Q5.*

Primary lateral sclerosis *If yes, go to Q5.*

Progressive bulbar palsy *If yes, go to Q5.*

Progressive muscular atrophy *If yes, go to Q5.*

Other (please specify): _____

Additional relevant/ "unusual" information: _____

If "other" diagnosis and there is no other unusual information (for example, veteran has a family member with ALS who had similar symptoms) *go to Ineligible Script (No ALS Diagnosis).*

If "other" and there is unusual information, continue with screener. Then inform the veteran that we will discuss his/her case with our study neurologist and call them back to let them know whether we will proceed with the consent process._

5. Have you been seen by a neurologist? YES NO

6. What was the date of diagnosis (if appropriate)? _____ / _____ / _____

7. Please describe your current symptoms? (Check all that apply)

Weakness in upper limbs

Weakness in the legs

Difficulty chewing/swallowing

Difficulty speaking

Other current symptoms: _____

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8. Have you had progression in muscle weakness? YES NO

If diagnosis is NOT possible ALS, primary lateral sclerosis, progressive bulbar palsy, or progressive muscular atrophy and patient does NOT have progression in muscles weakness, AND there is not unusual information, go to Ineligible Script (No ALS Diagnosis).

9. When was the onset of progressive muscle weakness? ____/____/____

10. Where did the muscle weakness start? _____

11. Has a family member/relative ever been diagnosed with ALS? YES NO
If Yes, Specify Family Member(s) _____

- **Complete Veteran/Proxy Information Form and go to Eligible Script**

VETERAN/PROXY INFORMATION FORM

1. Veteran's Contact Information:

Street address _____
City _____ State _____ Zip Code _____
Home Phone: _____
Work Phone: _____
Cell Phone: _____
Email Address: _____

2. In case we are unable to reach you, who should we contact as your proxy? For example, this may be the person who has your health care power of attorney.

Name of Proxy: _____

Relationship of Proxy to Veteran:

____ Self/Veteran ____ Spouse ____ Child ____ Sibling ____ Parent ____ Partner ____ Friend
____ Health Care Provider ____ Other (specify): _____

8. Proxy's Contact Information

Street address _____
City _____ State _____ Zip Code _____
Home Phone: _____
Work Phone: _____
Cell Phone: _____
Email Address: _____

9. Veteran's date of birth: _____

5. Veteran's Social security number ____ - ____ - ____

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6. Veteran's Gender : Male Female

7. Veteran's Ethnicity (mark all that apply):

Are you Spanish, Hispanic, or Latino?

No

Yes If Yes, Mexican, Mexican American, or Chicano

Puerto Rican

Cuban

Other Spanish/Hispanic/Latino: _____

8. Veteran's Race (check all that apply):

White

Black or African American,

American Indian or Alaska Native Principle Tribe _____

Asian

If Yes, Asian Indian

Chinese

Filipino

Japanese

Korean

Vietnamese

Other Asian: _____

Native Hawaiian or other Pacific Islander

If Yes, Native Hawaiian

Guamanian or Chamorro

Samoan

Other Pacific Islander: _____

9. Veteran's Military History:

9a. Branch(es) of the Military (mark all the apply):

____ Army

____ Air Force

____ Navy

____ Marines

____ Other

____ Army Reserves

____ Navy Reserves

____ Marine Reserves

____ Air Force Reserves

____ Army National Guard

____ Air National Guard

____ Army Guard

____ Coast Guard

____ Air Force Guard

____ Refused

____ Don't Know

____ Missing

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9b. Dates of service:

<u>Branch</u>	<u>Type Duty</u> <i>Active, ActiveReserves, Ready/inactive Reserves</i>	<u>Begin Date</u>	<u>End Date</u>
_____	_____	___/___/___	___/___/___
_____	_____	___/___/___	___/___/___
_____	_____	___/___/___	___/___/___
_____	_____	___/___/___	___/___/___

9c. Were you in the Gulf War ALS Study?

Mark NA if dates do not overlap GW period (08/02/90-07/31/91).

- ___ Yes
- ___ No
- ___ NA
- ___ Refused
- ___ Don't Know
- ___ Missing

9d. Have you ever been stationed at or worked at Kelly Air Force Base?

- O YES O NO

9e. While in the military, did you (*did the veteran*) serve outside the continental U.S.?

- ___ Yes
- ___ No

If Yes,

i. Did you serve in:

- Afghanistan ___ Yes ___ No
- Europe ___ Yes ___ No
- Korea ___ Yes ___ No
- North Africa ___ Yes ___ No
- Pacific Islands ___ Yes ___ No

- Persian Gulf ___ Yes ___ No

If Yes:

In what location(s): _____

Dates: From ___/___/___ to ___/___/___

- Vietnam ___ Yes ___ No
- Other ___ Yes ___ No

Specify: _____

ii. Number of months served outside the continental U.S.? _____

10. **Are you a current patient of a VAMC?** (if so, list location of primary VA) _____

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11. How did you find out about this registry (if self-referred)? (Mark all that apply.)

- ALS Brochure- Specify source: _____
 - Muscular Dystrophy Association
 - ERIC Website
 - Other Website -Specify _____
 - ALSA referral
 - Neurologist
 - Friend or family member (word of mouth)
 - Press release -Specify _____
 - Other – Specify _____
 - DK
- If not self-referred:*
- Received Letter
 - VA Database -Specify _____
 - VBA records
 - Other – Specify _____

12. Are you a member of a Veterans' Service Organization? Yes _____

No _____

If Yes, please list _____

SCRIPTS

REFUSED SCRIPT:

If you change your mind regarding your participation in our study, you can reach us at any time by calling 1-877-DIAL-ALS (1-877-342-5257).

INELIGIBLE SCRIPTS:

Not Veteran:

Because you are not a U.S. veteran, you are not eligible to enroll in this registry. There are other studies dealing with ALS among non-veterans, and we would encourage you to contact the ALS Association (1-800-782-4747 or www.alsa.org) for more information. Thank you for taking the time to answer our questions.

No ALS diagnosis:

Because you have not been diagnosed with ALS by a physician, you are not eligible to enroll in this registry at this time. If you are diagnosed with ALS at a later date, please re-contact us via the toll-free ALS call line (1-877-342-5257). Thank you for taking the time to answer our questions.

ELIGIBLE SCRIPT:

We would like to send you a packet that will contain a copy of the verbal consent form for you to keep, and a Release of Medical Information form. We will need you to sign and date the medical release form and return it to us in the postage paid envelope included so we may obtain a copy of your medical records.

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Once we have received the form back from you, we will request a copy of your medical records from your physician(s). A study neurologist who is an expert in ALS and other motor neuron diseases will then review your records to confirm your diagnosis.

If veteran reports diagnosis of ALS, Possible ALS, PLS, PBP, PMA, say: If the neurologist confirms your diagnosis, you will be eligible to participate in the Registry and we will contact you by telephone to conduct a brief interview.

If veteran has no specific diagnosis but has progressive muscular weakness, say: If the neurologist believes you may have ALS, you may be eligible to participate in the Registry immediately, or we may request that we review your medical records again in six months to determine whether you are eligible to participate. If you are eligible to participate, we will contact you by telephone for a brief interview.

This interview will include basic questions about your health. We will also contact you every six months to complete a similar interview and monitor your health status.

You should be receiving the information packet from us soon. If you have any questions about these materials or the registry, please call us on our toll-free line: 1-877-DIAL-ALS (1-877-342-5257). Thank you for taking the time to speak with me today.