OMB 2900-0649
Estimated Burden: 30 min.

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): G*o 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?
O YES – *Go to Q2* O NO- G*o to Ineligible Script (non-veteran)* O 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?
O YES -*Go to 2a*. O NO - *Go to Q3* O DK-*go to Q3*

2a. Were you (*was the veteran*) clinically diagnosed with ALS?
O YES -*Go to Q5*. O NO - *Go to Q3.*

3. Is there another current diagnosis given by a health professional?
O YES -*Go to Q4*. O NO - *Go to Q5.*

4. What was the diagnosis (check all that apply)?
O Possibly ALS (not yet determined/diagnosed) *If yes, go to Q5.*
O Primary lateral sclerosis *If yes, go to Q5.*
O Progressive bulbar palsy *If yes, go to Q5.*
O Progressive muscular atrophy *If yes, go to Q5.*
O 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? O YES O NO

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

7. Please describe your current symptoms? (C*heck all that apply*)
O Weakness in upper limbs
O Weakness in the legs
O Difficulty chewing/swallowing
O Difficulty speaking
O Other current symptoms:_____

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8. Have you had progression in muscle weakness? O YES O 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? O YES O 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):_____

3. Proxy's Contact Information

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

4. Veteran's date of birth: _____

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

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6. Veteran's Gender : O Male O Female

7. Veteran's Ethnicity (mark all that apply):
   Are you Spanish, Hispanic, or Latino?
   O No
   O Yes If Yes, O Mexican, Mexican American, or Chicano
   O Puerto Rican
   O Cuban
   O Other Spanish/Hispanic/Latino: _____

8. Veteran's Race (check all that apply):
   O White
   O Black or African American,
   O American Indian or Alaska Native Principle Tribe_____
   O Asian
   If Yes, O Asian Indian
   O Chinese
   O Filipino
   O Japanese
   O Korean
   O Vietnamese
   O Other Asian: _____
   O Native Hawaiian or other Pacific Islander
   If Yes, O Native Hawaiian
   O Guamanian or Chamorro
   O Samoan
   O 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:

Branch	Type Duty A*ctive, ActiveReserves,* R*eady/inactive Reserves*	Begin Date	End Date
_____	_____	___/___/____	___/___/___
_____	_____	___/___/____	___/___/___
_____	_____	___/___/____	___/___/___
_____	_____	___/___/____	___/___/___

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.? _____

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

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

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