Form Approved
OMB No. 0923-0041
Exp. Date xx/xx/201x

National Amyotrophic Lateral Sclerosis (ALS) Registry Research Application Form:

Type of request ☐ Research notification ☐ Data ☐ Biospecimens or tissues (mark all that apply)

Before submitting your application, please attach a copy of the following required materials in the web form on the application page. All materials received by the Agency for Toxic Substances and Disease Registry (ATSDR) have to be in pdf format.

- Research Application Form and signed Researcher Agreement.
- Cover letter with a brief overview of the project, highlighting the importance of the research proposal.
- PI CV or Biosketch.
- Full study protocol, including consent form if applicable.
- Confirmation of IRB approval of full protocol and informational materials.
- Additional supporting documents.
  - For clinical notifications include the recruitment letter and/or informational materials to be sent to potential study participants and complete Part A.
  - For specimens include completed specimen request form(s) (Part B and/or Part C) including types and number of specimens requested.
  - For data only complete Part D.

Date (mm/dd/yyyy):

Title of Study or Project: _____

Principal Investigator (or Project Director): _____

Short Title: _____ Organization: _____

Co-Principal Investigator (if any): (if there are no Co-PI's enter "None.")

Name(s)	Organization(s)	Business Phone Number	Business Email Address

Funding source and any declared (to the IRB) financial conflicts of interest:

Funding source: List the source(s) of funding for the project and this sample, the amount of funding anticipated from each source, and indicate the type of support provided: i.e., grant, contract, cooperative agreement, interagency agreement, other (specify), and note if the funding is current or is pending.

Declared conflict of interest: For each investigator please list any financial conflicts of interest declared to the IRB.

Summary of Proposed Study Protocol or Project Activities:
Provide a brief summary of your proposed study or project activities. Provide sufficient detail to describe your study or project. If you are requesting data and/or biospecimens or tissues obtained from the National ALS Registry describe how they will be used. Include in this summary the ALS study population in which you are interested, describe the benefit of this study to the community or individuals involved, demonstrate an understanding of the scientific merit of your proposed study, include a description of the hypothesis to be tested and some background information to support why the study or project is being proposed, and include a brief description of your proposed methods and analytic plan. (The summary should be limited to 7000 characters.)

Background:

Specific Aims:

Methods:

Population:

Measures:

Analysis:

Institutional Review Board (IRB) for the Protection of Human Subjects:

(As defined by the U.S. Department of Health and Human Services in the Code of Federal Regulations, Title 45, Part 46): **Evidence of a current IRB approval is required prior to the ATSDR contacting ALS registrants.**

Please provide the following information on the IRB to review this project outside of ATSDR:

Name and address of the IRB:

IRB Federal Wide Assurance (FWA) number:

Does this study have current approval from this IRB? ☐ Yes ☐ No

If Yes, Date of the IRB approval (mm/dd/yyyy):

Please provide a lay summary of not more than 250 words that describes the purpose of your research, what information you hope to obtain, who can participate, number of participants, and what participants must do to take part including time commitment. Remember the average high school graduate reads at the 8th grade level so use simple declarative sentences and avoid scientific jargon.

Researcher Agreement

Name of Institution: _____

Name of Research/Study Covered by this Agreement:
_____

The researcher will maintain IRB approval at their institution.

The researcher will not attempt to re-identify the samples or data.

The researcher will only use the samples or data for the approved project.

The researcher understands that only approved project staff will be permitted to use samples or data approved for the project.

The researcher will submit an annual update.

The researcher will submit any abstracts or manuscripts before submission and allow ATSDR time to review for accurate description of the data/samples and limitations.

The researcher will submit a copy of each published abstract or manuscript describing the results of such research with the annual update.

The researcher will submit a copy of the abstract or executive summary of any thesis or dissertation that includes analysis of Biorepository samples or data with the annual update.

The researcher understands that any project not updated by the deadline will be considered terminated.

The researcher will submit a final update when the project is completed.

The researcher understands that ATSDR will contact the Principal Investigator with instructions for handling residual samples and/or data when the project is completed and these instructions must be followed within three months of receipt.

The researcher will provide results to ATSDR in the requested format.

The researcher understands that the National ALS Registry and the National ALS Biorepository should be acknowledged in any publication based on analysis of its samples or data.

Researcher Signature: _____ Date _____

Print Name: _____ Degree(s): _____

Part A - Research Notification

Will any of the information (obtained from the National ALS Registry, or from the request for ATSDR to inform ALS registrants about the proposed study) be used as a basis for legal, administrative, or other actions which may directly affect particular individuals or establishments as a result of their specific identification in this project?

☐ Yes ☐ No ☐ Maybe

If Yes or Maybe, please explain:

Will any of the information (obtained from the National ALS Registry, or from the request for ATSDR to inform ALS registrants about the proposed study) be used as a basis for marketing purposes, including, but not limited to, marketing of pharmaceutical drugs?

☐ Yes ☐ No ☐ Maybe

If Yes or Maybe, please explain:

The following variables are available for all registrants and can be used to prescreen registrants for notification about your study. Please indicate which variables you would like us to use and specific criteria.

Specific Age Range at Diagnosis (e.g. 40-50, 50-60, 60-75):

Specific year/years of diagnosis (e.g. 2012 - current):

Specific Sex (e.g. female only, male only):

City and / or State(s) of residence or region of the United States (e.g. Los Angeles, CA, Dallas, TX, State of Arizona, State of Georgia and Florida):

*Additional variables are available on a subset of the population, such as registrants with a history of military service, smoking / alcohol consumption or specific ALSFRS score. If you wish to use these as eligibility requirements, please contact the ALS Research Notification System Administrator.

☐ **I do not want to prescreen for eligibility (e.g. I want to have research materials sent to all participants taking part in the notification process.).**

* Requests to have ATSDR identify additional variables for eligible participant(s) may delay the distribution of research materials. If you have questions or concerns about the application process or status of your application, please contact the ALS Research Notification System Administrator at 877-442-9719 (Monday through Friday, 9am to 5pm ET). You may also send us an email at ALSResearch@cdc.gov.

ATSDR kindly requests that researchers include the following acknowledgement in any publications deriving from the study:

"Recruitment for this study was in part made possible by ATSDR's National ALS Registry Research Notification Mechanism (http://wwwn.cdc.gov/ALS/ALSClinicalResearch.aspx)" and that they forward such publications to ATSDR (ALSResearch@cdc.gov).

Part B- National ALS Biorepository

Date of Request:

SAMPLES					
SAMPLE TYPE	**ALIQUOT SIZE**	**PRICE/ ALIQUOT**	**NUMBER OF INDIVIDUALS REQUESTED**	**REQUESTED NUMBER OF ALIQUOTS/INDIVIDUAL**	**TOTAL ALIQUOTS**
PLASMA	0.5 ml				
BUFFY COAT					
RED BLOOD CELL	1.0 ml				
WHOLE BLOOD (metals free)	1.8 ml				
SERUM	0.5 ml				
RNA	2 ug				
DNA	2 ug				
URINE	1 ml				
URINE (Hg preservative)	1 ml				
HAIR					
NAILS					

Comments/Special Instructions:

SURVEY DATA	CONTACT INFORMATION
*All specimen requests include demographics when available, including: age at diagnosis; age at first	Protocol #

symptoms; age at death; race; sex; family history of ALS; family history of other NGD; state of residence; ALSFRS closest to collection; and survival time.

Are you interested in additional Survey Data? Note, not all survey data may be available at this time.

☐ **Yes** ☐ **No**

If yes, please select from the options below:

- ☐ Demographics
- ☐ Occupational History
- ☐ Military History
- ☐ Smoking/Alcohol History
- ☐ Physical Activity
- ☐ Disease Progression (ALSFRS)
- ☐ Family History of Neurological Diseases
- ☐ Clinical Data (e.g. devices used, body onset)
- ☐ Lifetime Residential History
- ☐ Lifetime Occupational History
- ☐ Residential Pesticide Use
- ☐ Hobbies with Toxicant Exposures
- ☐ Caffeine Consumption
- ☐ Reproductive History (women)
- ☐ Health Insurance Status
- ☐ Trauma History

Title of Study or Project

Principal Investigator or Project Director

Organization

Contact Phone Number

Email Address

SHIPPING INFORMATION

LAB CONTACT:

LAB TELEPHONE:

LAB CONTACT EMAIL:

LAB SHIPPING ADDRESS:

Sample Request Form

Part C- National ALS Biorepository Postmortem Sample Request Form

Date of Request:

SAMPLES				
SAMPLE TYPE	**PRICE/SAMPLE**	**NUMBER OF INDIVIDUALS REQUESTED**	**REQUESTED NUMBER OF SAMPLE/INDIVIDUAL**	**TOTAL SAMPLES**
Frozen tissue (0.5-1g)				
Precentral motor cortex	$80			
Cervical spinal cord	$100			
Thoracic spinal cord	$100			
Lumbar spinal cord	$100			
Other:				
Parafin-embedded fixed tissue sections (5 sections at 5um)				
Olfactory bulb	$60			

Midbrain at level of red nucleus	$60			
Midbrain at decussation of the superior cerebellar peduncle	$60			
Precentral motor and postcentral sensory cortex (Brodmann area (BA) 4, 3, 2, 1)	$40			
Precentral motor cortex	$40			
Inferior parietal cortex (BA 39,40)	$40			
Anterior cingulate (BA 24)	$40			
Superior frontal (BA 8)	$40			
Inferior frontal cortex (BA 10,11,12)	$40			
Middle frontal cortex (BA 8,9) at level of CAP	$40			
Caudate nucleus, putamen, and nucleus accumbens (CAP)	$40			
Anterior temporal (BA 38)	$40			
Superior temporal (BA 20, 21,22)	$40			
Amygdala, with entorhinal cortex (BA 28)	$60			
Globus pallidus, putamen with claustrum, insula and substantia innominata	$60			
Anterior hippocampus	$60			
Hippocampal formation at level of lateral geniculate body, tail of caudate	$60			
Superior temporal posterior (BA 41,42)	$40			
Thalamus with centromedian, dorsal medial, lateral dorsal and lateral posterior nuclei	$60			
Thalamus with subthalamic nucleus, mammillary body	$60			
Posterior cingulate (BA23, 31)	$40			
Calcarine cortex (BA 17,18)	$40			
Superior parietal cortex (BA 7b)	$40			
Upper pons (level of locus cœruleus)	$60			
Lower pons at Vth cranial nerve	$60			
Medulla oblongata (including inferior olives)	$60			
Cervical spinal cord	$60			
Thoracic spinal cord	$60			
Lumbar spinal cord	$60			

☐ **Sacral spinal cord**	$60			
Cerebellar vermis	$60			
Cerebellum with dentate nucleus	$60			
BA 19	$40			

Comments/Special Instructions:

SURVEY DATA

*All specimen requests include demographics when available, including: age at diagnosis; age at first symptom; age at death; race; sex; family history of ALS; family history of other NGD; state of residence; ALSFRS closest to collection; and survival time.

Are you interested in additional Survey Data? Note, not all survey data may be available at this time**.**

☐ **Yes** ☐ **No**

If yes, please select from the options below:

☐ Demographics
☐ Occupational History
☐ Military History

CONTACT INFORMATION

Protocol #

Title of Study or Project

Principal Investigator or Project Director_

Organization_

Contact Phone Number

Email Address

SHIPPING INFORMATION

☐ Smoking/Alcohol History ☐ Physical Activity ☐ Disease Progression (ALSFRS) ☐ Family History of Neurological Diseases ☐ Clinical Data (e.g. devices used, body onset) ☐ Lifetime Residential History ☐ Lifetime Occupational History ☐ Residential Pesticide Use ☐ Hobbies with Toxicant Exposures ☐ Caffeine Consumption ☐ Reproductive History (women) ☐ Health Insurance Status ☐ Trauma History	LAB CONTACT: LAB TELEPHONE: LAB CONTACT EMAIL: LAB SHIPPING ADDRESS:

Part D – National ALS Registry Data only request

The National ALS Registry collects a variety of risk factor data.

Please select from the options below (mark all that apply):
Note that not all survey data may be available at this time.

- ☐ Demographics
- ☐ Occupational History
- ☐ Military History
- ☐ Smoking/Alcohol History
- ☐ Physical Activity
- ☐ Disease Progression (ALSFRS)
- ☐ Family History of Neurological Diseases
- ☐ Clinical Data (e.g. devices used, body onset)
- ☐ Lifetime Residential History
- ☐ Lifetime Occupational History
- ☐ Residential Pesticide Use
- ☐ Hobbies with Toxicant Exposures
- ☐ Caffeine Consumption
- ☐ Reproductive History (women)
- ☐ Health Insurance Status
- ☐ Trauma History