

National ALS Registry Research Notification Application

National Amyotrophic Lateral Sclerosis (ALS) Registry Application Form: Requests for ALS registry to inform registrants about clinical research

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 Notification Application Form.
- 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.
- Recruitment letter and informational materials to be sent to potential study participants.
- Confirmation of IRB approval of full protocol and informational materials.
- Additional supporting document.

Date (mm/dd/yyyy):

Title of Study or Project:

Principal Investigator (or Project Director):

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. Describe the health, public health, medical, or emergency preparedness problem(s) addressed by your study or project. Provide sufficient detail to describe your study or project and how data obtained from the ALS registry 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 Institutional Review Board (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):

Other Uses of the Data:

Will any of the information (obtained from the 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 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 (e.g. 40-50, 50-60, 60-75):

Specific time period since diagnosis (e.g. 1 year, 2 to 4 years):

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.).

* Request 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 6pm 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).