Fiscal Year 2024 (FY24) Amyotrophic Lateral Sclerosis Research Program Funding Opportunity Announcement Frequently Asked Questions Application Questions

1. What is the difference between a letter of intent and a pre-proposal? Which type of preapplication is the ALSRP using for FY24?

CDMRP utilizes two types of pre-application: a letter of intent, often called a LOI, and a pre-proposal. Each program announcement or PA will clearly state which type of pre-application that funding mechanism will be using.

The LOI is typically a single page, abstract-like description of the research project that is being proposed. This acts as an admission ticket – the program will not provide notification of invitation, as all applicants who submit a LOI by the stated deadline are eligible to submit a full proposal. This document is used purely to assist with recruiting appropriate peer review expertise and is not reviewed by any panel.

The pre-proposal is typically a few more pages with some additional specific information requested. Unlike the LOI, a pre-proposal is reviewed by the programmatic panel, and applicants will need to receive an invitation for their preproposal to be eligible to submit a full proposal. However, no specific feedback is provided from the pre-proposal apart from the invite/no invite status.

For FY24, the ALSRP will be utilizing the LOI method of pre-application for all posted funding mechanisms. Please don't hesitate to reach out to the ebrap helpdesk (<u>help@ebrap.org</u>) should you have any questions.

2. I'm new to the ALS field, do I need a collaborator to provide ALS expertise?

Each program announcement or PA will clearly state whether specific expertise is required. There are no requirements for ALS expert collaboration in any of the FY24 ALSRP funding opportunities; however, there are requirements in some PAs regarding ALS-relevant models, and reviewer criterion may include weighing the strength of the ALS models being proposed and the research team's expertise in the proposed subject matter.

3. Is preliminary data required?

Each PA will clearly state whether preliminary data is required. The requirement is described in the PA in Sections II.B Award Information as well as II.D.2.b.ii. Full Application Submission Components, Attachment 1: Project Narrative.

4. Can I submit the same application to multiple PAs, such as to ALSRP and another CDMRP program? Can you help me decide how to choose?

The CDMRP)/ALSRP cannot advise on which program or funding opportunity is best aligned to your research or would increase your chance of success. Interested researchers are encouraged to review the many resources, including the Strategic Plan, pre-announcement/mechanism synopsis, and program announcements on the individual <u>CDMRP program webpages</u>.

Unless otherwise stated in the funding opportunity announcement, submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s). Applicants may submit identical projects to multiple programs or non-CDMRP agencies if appropriate; however, if the project is recommended for funding by different programs or agencies, the duplicative application(s) must be withdrawn, or scientific overlap must be removed in consultation with both funders.

5. Are small businesses eligible to apply?

Yes, any organization that is registered in <u>SAM.gov</u>, received confirmation of an "Active" status, and meets the award mechanism-specific eligibility criteria is eligible to receive Federal funding. For more information, please refer to the <u>General Application Instructions</u> or GAI.

6. Do small businesses have to be collaborating with an academic institution?

There are no requirements for institutional collaboration in any of the FY24 ALSRP funding opportunities. In recent years, the success of industry applicants has increased, with greater representation from small businesses throughout the mechanisms in the ALSRP portfolio.

7. Does the Department of Defense require a negotiated rate agreement, even for small businesses?

In accordance with Code of Federal Regulations, Title 2, Part 200.414, a non-Federal entity that has never received a negotiated indirect cost rate may elect to charge a de minimis rate of 10% of modified total direct costs. Costs must be consistently charged as either indirect or direct costs but may not be double charged or inconsistently charged as both. If chosen, this methodology, once elected, must be used consistently for all Federal awards until such time as the non-Federal entity chooses to negotiate for a rate. For more information, please refer to the <u>GAI</u>.

8. What is the industry equivalent of the academic positions, i.e., an assistant professor level researcher?

CDMRP does not follow National Institutes of Health guidelines for role designation of project participants. Unless otherwise noted in the PA/Funding Opportunity, applicants should assign the role of each participant in accordance with the participant's respective involvement in the project. The ALSRP does not require academic-level equivalencies for investigators to be eligible to serve as principal investigator, only that the individual is considered an independent investigator by their organization. The Principal Investigator on an application will be required to submit a Biosketch and past/current/pending support documentation to establish their qualifications to serve as the project lead. If needed, the Degree Type and Degree Year fields on the Research and Related Senior/Key Person Profile will be used by the DOD as the source for career information.

9. Does my research have to involve Veterans or Service Members only?

Research funded by the CDMRP must have relevance the health care needs of Service Members, Veterans, and the American public. ALSRP encourages research that can benefit military and civilian populations. There is no requirement as to which populations an investigator may choose. Note the ALSRP uses the term, "military," in the broadest possible context and includes Families or other DOD beneficiaries in this definition.

10. I'm new to community collaboration. Does the community partner need to be part of the research population?

Not necessarily. The goal of the community collaboration is to maximize the impact and translation of the research to the community that the research should benefit. What this may mean is involving people living with ALS, their families and/or caregivers, trusted community members and/or other individuals relevant to the ALS community in the research design, strategy, and execution of the proposed research. It is expected these community collaborators will enter a partnership with the research team to ensure that the needs and input of the individuals who stand to benefit from the proposed research are included throughout the planning, execution, and dissemination of the research.

11. If I'm a preclinical researcher, do I need to have a community collaborator?

Community collaboration is only required for the FY24 <u>Pilot Clinical Trial Award</u> and <u>Clinical Outcomes</u> <u>and Biomarkers Award</u>. The other ALSRP award mechanisms do not require community collaboration for the application.

12. Are postdocs eligible to apply?

Postdoctoral fellows whose institutions verify their ability to be an independent investigator are eligible to apply as PI.

13. Can international applicants apply? If so, is it recommended to have a partner researcher in the U.S.?

Yes, international applicants may apply to CDMRP funding opportunities if they are registered as an entity in <u>SAM</u> and receive confirmation of an "Active" status. Once registered, the same eligibility criteria apply to domestic and international applicants; please refer to Section II.C. Eligibility Information of the program announcement, as well as the <u>GAI</u> and <u>ALSRP funding opportunity website</u> for information specific to the award mechanism. For eligible international applicants, partnership with a U.S. entity is neither required nor a review criterion.