Fiscal Year 2024 Department of Defense Amyotrophic Lateral Sclerosis Research Program (ALSRP)
Reference Table of Award Mechanisms and Submission Requirements

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
Pilot Clinical Trial Award **Go to:** • Program Announcement • General Application Instructions **Grants.gov Funding Opportunity Number:** HT942524ALSRPPCTA	Independent investigators at any career level	• Projects may range from phase 1 to small-scale phase 2 trials and should aim to de-risk and inform the design of more advanced trials by investigating safety, feasibility, biomarker application and therapeutic efficacy in relevant patient populations. • Projects may propose interventions focused on improving existing clinical care and/or symptom management strategies. • Projects proposing a therapeutic intervention (drug, biologic and/or device) must incorporate biomarkers specific to the intervention into the trial design. • Research teams must name at least one Community partner (e.g., person with ALS, family member and/or caregiver, representative of a community-based organization) who will provide advice and consultation throughout the planning and implementation of the research project. • Must support a clinical trial and may not be used for preclinical research studies. ***New for FY24!*** **Applications must address one focus area:** • Biomarker-Driven Interventions: Disease-modifying interventions, with mechanism-specific predictive, efficacy, and/or pharmacodynamic biomarkers. • Clinical Care: Improving aspects of clinical care and symptom management for Amyotrophic Lateral Sclerosis (ALS).	• The maximum allowable funding for the entire period of performance is **$2,000,000** for direct costs. • Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. • The maximum period of performance is **4** years.	**Pre-Application (Letter of Intent):** June 18, 2024 5:00 p.m. Eastern time **Application:** July 10, 2024 11:59 p.m. Eastern time

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
Clinical Outcomes and Biomarkers Award **Go to:** • Program Announcement • General Application Instructions **Grants.gov Funding Opportunity Number:** HT942524ALSRPCOBA	Independent investigators at any career level	• Supports the development and/or validation of clinical outcomes and biomarkers to enrich clinical trials in ALS. • Studies prospectively enrolling patients to collect biospecimens and/or data are allowed, such as stand-alone or add-on noninterventional clinical research studies. However, interventional clinical trials are not allowed. • Research teams proposing prospective enrollment must name at least one Community partner (e.g., person with ALS, family member and/or caregiver, representative of a community-based organization) who will provide advice and consultation throughout the planning and implementation of the research project. • Data sharing plans are an important and scored component. ***New for FY24!*** **Applications must address one or both focus areas:** • Clinical Biomarkers: Identification, development, and/or validation of promising biomarkers for ALS. Biomarkers may include but are not limited to: susceptibility/risk, diagnostic, monitoring, prognostic, predictive, response, or safety biomarkers. Digital health measures, including wearable devices, smart-phone sensors, video or voice recordings, imaging studies, or other devices which record disease-relevant physiological data are allowed. • Clinical Outcomes: Identification, development, and/or validation of clinician-, observer-, or patient-reported, and/or performance outcome measures for ALS. Projects may include optimization of current outcome measures already in use.	• The maximum allowable funding for the entire period of performance is **$750,000** for direct costs. • Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. • The maximum period of performance is **3** years.	**Pre-Application (Letter of Intent):** June 18, 2024 5:00 p.m. Eastern time **Application:** July 10, 2024 11:59 p.m. Eastern Time

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline

Therapeutic Development Award
 	
Go to:
• Program Announcement
• General Application Instructions
 	
Grants.gov Funding Opportunity Number:
HT942524ALSRPTDA
	Independent investigators at any career level	• Supports secondary preclinical validation and/or Investigational New Drug (IND)-enabling studies of therapeutics for ALS.
		• Applications supported by this award must begin with lead compounds in hand and must include proof-of-concept efficacy data in at least one preclinical model system of ALS, including whole animal and cellular model systems.
		• Examples of activities that will be supported by this award include:
		  ○ Confirmation of candidate therapeutics obtained from screening or by other means, including optimization of potency and pharmacological properties and testing of derivatives and sister compounds.
		  ○ Validation of pilot efficacy studies (such as from an ALSRP Therapeutic Idea Award), including the use of additional ALS model systems and/or replicating preliminary data with more time points or additional doses.
		  ○ IND-enabling studies to include compound characterization; absorption, distribution, metabolism, and excretion (ADME) studies; studies on formulation and stability leading to Good Manufacturing Practice production methods; dose/response and toxicology studies in relevant model systems.
			• The maximum allowable funding for the entire period of performance is **$1,500,000** for direct costs.
			• Indirect costs may be proposed in accordance with the institution's negotiated rate agreement.
			• The maximum period of performance is **3** years.
				Pre-Application (Letter of Intent):
				June 18, 2024
				5:00 p.m. Eastern time
				
				Application:
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Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
Therapeutic Idea Award **Go to:** • Program Announcement • General Application Instructions **Grants.gov Funding Opportunity Number:** HT942524ALSRPTIA	Independent investigators at any career level	• Supports new, innovative, high-risk, high-gain ideas aimed at ALS drug or therapy discovery. The studies supported by this award mechanism are expected to be hypothesis-driven and generate preliminary data for future avenues of therapeutic investigation. • While the inclusion of preliminary data is not prohibited, the strength of the application should rely on the approach. • ***New for FY24!*** All applications must include an aspect of biomarker development in parallel to the main therapeutic effort to qualify for funding. • Projects that focus primarily on pathophysiology of ALS without development of a therapy are outside the scope of this funding opportunity. • Data sharing plans are an important and scored component.	• The maximum allowable funding for the entire period of performance is **$600,000** for direct costs. • Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. • The maximum period of performance is **2** years.	**Pre-Application (Letter of Intent):** June 18, 2024 5:00 p.m. Eastern time **Application:** July 10, 2024 11:59 p.m. Eastern Time