

Fiscal Year 2025 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: <ul style="list-style-type: none"> Program Announcement General Application Instructions Grants.gov Funding Opportunity Number: HT942525ALSRPPCTA	Independent investigators at any career level	<ul style="list-style-type: none"> 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. 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 amyotrophic lateral sclerosis (ALS), or family member and/or caregiver, or representative of a community-based organization) who will provide advice and consultation throughout the research project. Must support a clinical trial and may not be used for preclinical research studies. <p>Applications must address one focus area:</p> <ul style="list-style-type: none"> Biomarker-Driven Interventions: Disease-modifying interventions, with mechanism-specific biomarkers to predict which clinical trial participants are likely to respond, demonstrate target engagement, and effects on the intended biological pathway. Clinical Care: Improving aspects of clinical care and symptom management for ALS. 	<ul style="list-style-type: none"> The maximum allowable funding for the entire period of performance is \$2,800,000 for total 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 (Preproposal): June 6, 2025 5:00 p.m. Eastern time Application: August 27, 2025 11:59 p.m. Eastern time

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<p>Clinical Outcomes and Biomarkers Award</p> <p>Go to:</p> <ul style="list-style-type: none"> • Program Announcement • General Application Instructions <p>Grants.gov Funding Opportunity Number:</p> <p>HT942525ALSRPCOBA</p>	<p>Independent investigators at any career level</p>	<ul style="list-style-type: none"> • Supports the development and/or validation of clinical outcomes and/or biomarkers to enrich clinical trials in ALS. • Studies prospectively enrolling patients to collect biospecimens and/or clinical or digital data are permitted. The proposed studies may be stand-alone or add-on noninterventional clinical research studies. However, clinical trials are not allowed under this mechanism. • Research teams proposing prospective enrollment must include the name of at least one community partner (e.g., person(s) with ALS, or family member(s) and/or caregiver(s), or representative of a community-based organization or community advisory board) who will provide advice and consultation throughout the planning and implementation of the research project. • Data sharing plans are an important and scored component. <p>Applications must address one or both focus areas:</p> <ul style="list-style-type: none"> • Clinical Biomarkers: Identification, development, and/or validation of promising biomarkers for ALS. Biomarkers may include, but are not limited to susceptibility/risk, diagnostic, monitoring/disease progression, prognostic, predictive, response or safety biomarkers. • 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. 	<ul style="list-style-type: none"> • The maximum allowable funding for the entire period of performance is \$1,000,000 for total costs. • Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. • The maximum period of performance is 3 years. 	<p>Pre-Application (Preproposal): June 6, 2025 5:00 p.m. Eastern time</p> <p>Application: August 27, 2025 11:59 p.m. Eastern time</p>

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<p>Therapeutic Development Award</p> <p>Go to:</p> <ul style="list-style-type: none"> • Program Announcement • General Application Instructions <p>Grants.gov Funding Opportunity Number: HT942525ALSRPTDA</p>	<p>Independent investigators at any career level</p>	<ul style="list-style-type: none"> • Supports research ranging from preclinical validation of therapeutic leads through Food and Drug Administration Investigational New Drug (IND)-enabling studies. • Applications supported by this award must begin with lead compounds in hand and must already demonstrate proof-of-concept efficacy data in at least one appropriate preclinical model system of ALS, including whole animal and cellular model systems. • Examples of activities that will be supported by this award include: <ul style="list-style-type: none"> ◦ Lead optimization including 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 preliminary efficacy findings, building on initial discoveries from pilot studies (e.g., ALSRP Therapeutic Idea Awards) through expansion on assessed ALS model systems, extended dose-response characterization or extended timepoints to more robustly establish therapeutic potential. ◦ IND-enabling studies to include: compound characterization; absorption, distribution, metabolism and excretion studies; studies on formulation and stability leading to Good Manufacturing Practice production methods; dose/response and toxicology studies in relevant model systems. ◦ 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. ◦ Applications supported by this award must begin with lead compounds in hand and must include preliminary data relevant to the phase of development. 	<ul style="list-style-type: none"> • The maximum allowable funding for the entire period of performance is \$2,000,000 for total costs. • Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. • The maximum period of performance is 3 years. 	<p>Pre-Application (Preproposal): June 6, 2025 5:00 p.m. Eastern time</p> <p>Application: August 27, 2025 11:59 p.m. Eastern time</p>

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
<p>Therapeutic Idea Award</p> <p>Go to:</p> <ul style="list-style-type: none"> • Program Announcement • General Application Instructions <p>Grants.gov Funding Opportunity Number: HT942525ALSRPTIA</p>	<p>Independent investigators at any career level</p>	<ul style="list-style-type: none"> • 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. • Applicants are required to include the incorporation of rational biomarker(s) development to measure biological effects of study compound in parallel with their proposed Therapeutic Idea Award research for eventual clinical trials. • 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. 	<ul style="list-style-type: none"> • The maximum allowable funding for the entire period of performance is \$840,000 for total costs. • Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. • The maximum period of performance is 2 years. 	<p>Pre-Application (Preproposal): June 6, 2025 5:00 p.m. Eastern time</p> <p>Application: August 27, 2025 11:59 p.m. Eastern time</p>