

***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
<p><b>Pilot Clinical Trial Award</b></p> <p><b>Go to:</b></p> <ul style="list-style-type: none"> <li>• <a href="#">Program Announcement</a></li> <li>• <a href="#">General Application Instructions</a></li> </ul> <p><b>Grants.gov Funding Opportunity Number:</b></p> <p><a href="#">HT942524ALSRPPCTA</a></p>	<p>Independent investigators at any career level</p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Projects may propose interventions focused on improving existing clinical care and/or symptom management strategies.</li> <li>• Projects proposing a therapeutic intervention (drug, biologic and/or device) must incorporate biomarkers specific to the intervention into the trial design.</li> <li>• 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.</li> <li>• Must support a clinical trial and may not be used for preclinical research studies.</li> </ul> <p><b><i>New for FY24! Applications must address one focus area:</i></b></p> <ul style="list-style-type: none"> <li>• Biomarker-Driven Interventions: Disease-modifying interventions, with mechanism-specific predictive, efficacy, and/or pharmacodynamic biomarkers.</li> <li>• Clinical Care: Improving aspects of clinical care and symptom management for Amyotrophic Lateral Sclerosis (ALS).</li> </ul>	<ul style="list-style-type: none"> <li>• The maximum allowable funding for the entire period of performance is <b>\$2,000,000</b> for direct costs.</li> <li>• Indirect costs may be proposed in accordance with the institution’s negotiated rate agreement.</li> <li>• The maximum period of performance is <b>4</b> years.</li> </ul>	<p><b>Pre-Application (Letter of Intent):</b> June 18, 2024 5:00 p.m. Eastern time</p> <p><b>Application:</b> July 10, 2024 11:59 p.m. Eastern time</p>

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
<p><b>Clinical Outcomes and Biomarkers Award</b></p> <p><b>Go to:</b></p> <ul style="list-style-type: none"> <li><a href="#">Program Announcement</a></li> <li><a href="#">General Application Instructions</a></li> </ul> <p><b>Grants.gov Funding Opportunity Number:</b></p> <p><a href="#">HT942524ALSRPCOBA</a></p>	<p>Independent investigators at any career level</p>	<ul style="list-style-type: none"> <li>Supports the development and/or validation of clinical outcomes and biomarkers to enrich clinical trials in ALS.</li> <li>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.</li> <li>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.</li> <li>Data sharing plans are an important and scored component.</li> </ul> <p><b><i>New for FY24! Applications must address one or both focus areas:</i></b></p> <ul style="list-style-type: none"> <li><b>Clinical Biomarkers:</b> 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.</li> <li><b>Clinical Outcomes:</b> 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.</li> </ul>	<ul style="list-style-type: none"> <li>The maximum allowable funding for the entire period of performance is <b>\$750,000</b> for direct costs.</li> <li>Indirect costs may be proposed in accordance with the institution's negotiated rate agreement.</li> <li>The maximum period of performance is <b>3</b> years.</li> </ul>	<p><b>Pre-Application: (Letter of Intent):</b> June 18, 2024 5:00 p.m. Eastern time</p> <p><b>Application:</b> July 10, 2024 11:59 p.m. Eastern Time</p>

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<p><b>Therapeutic Development Award</b></p> <p><b>Go to:</b></p> <ul style="list-style-type: none"> <li>• <a href="#">Program Announcement</a></li> <li>• <a href="#">General Application Instructions</a></li> </ul> <p><b>Grants.gov Funding Opportunity Number:</b></p> <p><a href="#">HT942524ALSRPTDA</a></p>	<p>Independent investigators at any career level</p>	<ul style="list-style-type: none"> <li>• Supports secondary preclinical validation and/or Investigational New Drug (IND)-enabling studies of therapeutics for ALS.</li> <li>• 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.</li> <li>• Examples of activities that will be supported by this award include: <ul style="list-style-type: none"> <li>○ 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.</li> <li>○ 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.</li> <li>○ 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.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• The maximum allowable funding for the entire period of performance is <b>\$1,500,000</b> for direct costs.</li> <li>• Indirect costs may be proposed in accordance with the institution’s negotiated rate agreement.</li> <li>• The maximum period of performance is <b>3</b> years.</li> </ul>	<p><b>Pre-Application (Letter of Intent):</b> June 18, 2024 5:00 p.m. Eastern time</p> <p><b>Application:</b> July 10, 2024 11:59 p.m. Eastern time</p>

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<p><b>Therapeutic Idea Award</b></p> <p><b>Go to:</b></p> <ul style="list-style-type: none"> <li>• <a href="#">Program Announcement</a></li> <li>• <a href="#">General Application Instructions</a></li> </ul> <p><b>Grants.gov Funding Opportunity Number:</b></p> <p><a href="#">HT942524ALSRPTIA</a></p>	<p>Independent investigators at any career level</p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• While the inclusion of preliminary data is not prohibited, the strength of the application should rely on the approach.</li> <li>• <b><i>New for FY24!</i></b> All applications must include an aspect of biomarker development in parallel to the main therapeutic effort to qualify for funding.</li> <li>• Projects that focus primarily on pathophysiology of ALS without development of a therapy are outside the scope of this funding opportunity.</li> <li>• Data sharing plans are an important and scored component.</li> </ul>	<ul style="list-style-type: none"> <li>• The maximum allowable funding for the entire period of performance is <b>\$600,000</b> for direct costs.</li> <li>• Indirect costs may be proposed in accordance with the institution's negotiated rate agreement.</li> <li>• The maximum period of performance is <b>2</b> years.</li> </ul>	<p><b>Pre-Application: (Letter of Intent):</b> June 18, 2024 5:00 p.m. Eastern time</p> <p><b>Application:</b> July 10, 2024 11:59 p.m. Eastern Time</p>