

***Fiscal Year 2023 (FY23) 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>Pilot Clinical Trial 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>HT9425-23-ALSRP-PCTA</p>	<p>Independent investigators at or above the level of Assistant Professor (or equivalent)</p>	<ul style="list-style-type: none"> • Supports exploratory clinical trials of novel therapeutics to demonstrate feasibility and inform the design of more advanced trials in amyotrophic lateral sclerosis (ALS). • Must support a clinical trial and may not be used for preclinical research studies. • Biomarkers specific to the intervention must be incorporated into the trial design. • Preliminary data are required. • <i>New for FY23:</i> Applications are expected to name at least one community partner (e.g., person with ALS, family member or caregiver, representative of a community-based organization) who will provide advice and consultation throughout the planning and implementation of the clinical trial. <p>Clinical Care Tier:</p> <ul style="list-style-type: none"> • Applications not investigating a novel therapeutic but <u>proposing a clinical trial to optimize established ALS clinical care</u>, may submit under the Clinical Care Tier. • Examples of efforts that will be supported include: <ul style="list-style-type: none"> ○ Optimization of respiratory care strategies ○ Improvements to approved devices and assistive technologies ○ Specific symptom management strategies ○ Telemedicine strategies • <i>Pre-application submission is required; full application submission is by invitation only.</i> 	<ul style="list-style-type: none"> • The maximum allowable funding for the entire period of performance is \$2,000,000 for direct costs. • Clinical Care Tier: The maximum allowable funding for the entire period of performance is \$1,000,000 for direct costs. • Indirect costs may be proposed in accordance with the institution’s negotiated rate agreement. • The maximum period of performance is 3 years. 	<p>Pre-Application (Preproposal): April 13, 2023 5:00 p.m. Eastern time</p> <p>Application: July 13, 2023 11:59 p.m. Eastern time</p>

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<p>Clinical Biomarker Development 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>HT9425-23-ALSRP-CBDA</p>	<p>Independent investigators at all academic levels (or equivalent)</p>	<ul style="list-style-type: none"> • Supports development or improvement of clinical biomarkers to enrich clinical trials in ALS. • Biomarker analysis can be relevant to a specific therapeutic or a specific ALS subtype and does not have to broadly apply to all patients. • A description of the biomarker category and intended use in ALS therapeutic development, including regulatory considerations for use in ALS clinical trials or clinical practice, is an important component. • Examples of efforts that will be supported include: <ul style="list-style-type: none"> ○ Using patient-based resources to link biosamples to rigorous molecular data ○ Collecting and analyzing biospecimens as a companion to an anticipated/ongoing clinical trial ○ Correlating clinical trial-related data (e.g., biosample analyses, imaging, or epidemiological data) with clinical outcomes/ responses to therapies ○ Strategies to better measure disease progression, including development or use of digital biomarkers • <i>Pre-application submission is required; full application submission is by invitation only.</i> 	<ul style="list-style-type: none"> • 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 2 years. 	<p>Pre-Application: (Preproposal): April 13, 2023 5:00 p.m. Eastern time</p> <p>Application: July 13, 2023 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:</p> <p>HT9425-23-ALSRP-TDA</p>	<p>Independent investigators at all academic levels (or equivalent)</p>	<ul style="list-style-type: none"> • Supports secondary preclinical validation and Investigational New Drug (IND)-enabling studies of therapeutics for ALS. • Preliminary data are required, including therapeutic efficacy in at least one ALS-relevant model system. • Mechanism-specific predictive/cohort-selective, target engagement, or pharmacodynamic biomarker development, in parallel to the main therapeutic effort, is a critical component. If mechanism-specific biomarkers are already available or currently in development, how the existing biomarkers will improve trial design, patient selection, and efficiency or interpretation of the proposed ALS therapeutic approach must be described. • <i>Pre-application submission is required; full application submission is by invitation only.</i> 	<ul style="list-style-type: none"> • 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. 	<p>Pre-Application: (Preproposal): April 13, 2023 5:00 p.m. Eastern time</p> <p>Application: July 13, 2023 11:59 p.m. Eastern Time</p>
<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:</p> <p>HT9425-23-ALSRP-TIA</p>	<p>Independent investigators at all academic levels (or equivalent)</p>	<ul style="list-style-type: none"> • Supports highly innovative, hypothesis-driven preclinical therapeutic development in ALS. • Projects focusing primarily on investigating ALS pathophysiology, without consideration of therapeutic development, are outside the scope of this award mechanism. • Preliminary data are not required. • Early-Career Investigators are encouraged to apply. • Biomarker Option: Applications that include development of biomarkers in parallel to the main therapeutic effort and that meet criteria outlined in the Program Announcement, will qualify for a higher level of funding. • <i>Pre-application submission is required; full application submission is by invitation only.</i> 	<ul style="list-style-type: none"> • The maximum allowable funding for the entire period of performance is \$600,000 for direct costs. • Biomarker Option: 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 2 years. 	<p>Pre-Application: (Preproposal): April 13, 2023 5:00 p.m. Eastern time</p> <p>Application: July 13, 2023 11:59 p.m. Eastern Time</p>