

***Fiscal Year 2022 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: W81XWH-22-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 ALS. • Must support a clinical trial and may not be used for preclinical research studies. • Preliminary data are required. • Applications investigating a therapeutic must include plans to generate biomarker data. Biomarkers may measure target engagement, pharmacodynamic effects, and/or be predictive/cohort-selective. <p>Clinical Care Tier:</p> <ul style="list-style-type: none"> • Applications not investigating a novel therapeutic, but proposing a clinical trial to optimize established ALS clinical care, may submit under the Clinical Care Tier. • Types 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 • <i>Pre-application submission is required; 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 29, 2022 5:00 p.m. Eastern time</p> <p>Application: July 28, 2022 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: W81XWH-22-ALSRP-CBDA</p>	<p>Independent investigators at all academic levels (or equivalent)</p>	<ul style="list-style-type: none"> • Supports maximization of clinical ALS resources and biorepositories to better define subtypes, predict therapeutic response, or assess prognosis. • Emphasis is on the <u>development of clinical biomarkers</u> to enrich clinical trials in ALS. Biomarkers may measure target engagement, pharmacodynamic effects, and/or be predictive/cohort-selective. • Data and resources sharing (biosamples/data sets/analyses) are important and scored criteria. • Types 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 • <i>Pre-application submission is required; application submission is by invitation only.</i> 	<ul style="list-style-type: none"> • The maximum allowable funding for the entire period of performance is \$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 2 years. 	<p>Pre-Application: (Preproposal): April 29, 2022 5:00 p.m. Eastern time</p> <p>Application: July 28, 2022 11:59 p.m. Eastern Time</p>

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
<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: W81XWH-22-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 strong rationale and efficacy data for the chosen therapeutic in at least one ALS-relevant model system. • Biomarker development and/or characterization (if not already validated), <u>in parallel to the main therapeutic effort</u>, is a critical component of the Therapeutic Development Award. • <i>Pre-application submission is required; application submission is by invitation only.</i> 	<ul style="list-style-type: none"> • The maximum allowable funding for the entire period of performance is \$1,000,000 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 29, 2022 5:00 p.m. Eastern time</p> <p>Application: July 28, 2022 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: W81XWH-22-ALSRP-TIA</p>	<p>Independent investigators at all academic levels (or equivalent)</p>	<ul style="list-style-type: none"> • Supports hypothesis-driven preclinical therapeutic development. • Projects focusing primarily on investigating ALS pathophysiology 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 Funding Opportunity Announcement, will qualify for a higher level of funding. • <i>Pre-application submission is required; application submission is by invitation only.</i> 	<ul style="list-style-type: none"> • The maximum allowable funding for the entire period of performance is \$500,000 for direct costs. • Biomarker Option: 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. 	<p>Pre-Application: (Preproposal): April 29, 2022 5:00 p.m. Eastern time</p> <p>Application: July 28, 2022 11:59 p.m. Eastern Time</p>