

***Fiscal Year 2021 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 Deadlines
<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-21-ALSRP-TDA</p>	<p>Independent investigators at all levels</p>	<ul style="list-style-type: none"> • Supports secondary preclinical validation and IND-enabling studies of therapeutics for ALS. • Preliminary data are required, including efficacy of a lead molecule/class of compounds in at least one ALS-relevant model system. • Biomarker development and/or characterization, in parallel to the main therapeutic effort, is a critical component of the TDA. 	<ul style="list-style-type: none"> • Maximum funding of \$1.0 million for direct costs (plus indirect costs) • Maximum period of performance is 3 years 	<p>Pre-Application: April 9, 2021 5:00 p.m. Eastern time</p> <p>Preproposal is required; application submission is by invitation only.</p> <p>Application: July 15, 2021 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-21-ALSRP-TIA</p>	<p>Independent investigators at all levels</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. 	<ul style="list-style-type: none"> • Maximum funding of \$500,000 for direct costs (plus indirect costs) • Maximum funding of \$600,000 for direct costs plus indirect costs if applying for the Therapeutic Relevant Biomarker Option • Maximum period of performance is 2 years 	<p>Pre-Application: April 9, 2021 5:00 p.m. Eastern time</p> <p>Preproposal is required; application submission is by invitation only.</p> <p>Application: July 15, 2021 11:59 p.m. Eastern Time</p>

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<p>Clinical 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-21-ALSRP-CDA</p>	<p>Independent investigators at all levels</p>	<ul style="list-style-type: none"> • Supports correlative clinical research and leveraging of human-based ALS resources. • Types of efforts that will be supported include: <ul style="list-style-type: none"> ○ Using human subject-based resources to better define subtypes, predict therapeutic response, or assess prognosis; ○ Correlating clinical trial-related biosamples, imaging, or epidemiological data with clinical outcomes; ○ Adding a biomarker companion or observational aim to an anticipated/ongoing clinical trial; ○ Observational studies to optimize components of current ALS clinical care such as respiratory care strategies, use of approved devices, or specific symptom management strategies and assistive technologies. • Early Career Investigators and/or Early Career Physician Scientists are encouraged to apply. 	<ul style="list-style-type: none"> • Maximum funding of \$500,000 for direct costs (plus indirect costs) • Maximum period of performance is 2 years 	<p>Pre-Application: April 9, 2021 5:00 p.m. Eastern time</p> <p>Preproposal is required; application submission is by invitation only.</p> <p>Application: July 15, 2021 11:59 p.m. Eastern Time</p>
<p>NEW! Therapeutic/Biomarker Pilot 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-21-ALSRP-TBPTA</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 to demonstrate feasibility or inform the design of more advanced trials for the treatment or management of ALS. • Must support a clinical trial and may not be used for preclinical research studies. • Preliminary data are required. • Biomarkers must be incorporated into the trial design. Biomarkers may measure target engagement, drug pharmacodynamics, and/or be predictive/cohort-selective. 	<ul style="list-style-type: none"> • Maximum funding of \$2,000,000 for direct costs plus indirect costs. • Maximum period of performance is 4 years. 	<p>Pre-Application: April 9, 2021 5:00 p.m. Eastern time</p> <p>Preproposal is required; application submission is by invitation only.</p> <p>Application: July 15, 2021 11:59 p.m. Eastern Time</p>