

***Fiscal Year 2021 Department of Defense Amyotrophic Lateral Sclerosis Research Program (ALSRP)  
Reference Table of Award Mechanisms and Submission Requirements***

<b>Award Mechanism</b>	<b>Eligibility</b>	<b>Key Mechanism Elements</b>	<b>Funding</b>	<b>Submission Deadlines</b>
<b>Therapeutic Development Award</b> <b>Go to:</b> <ul style="list-style-type: none"> <li>• Program Announcement</li> <li>• General Application Instructions</li> </ul> <b>Grants.gov Funding Opportunity Number:</b> W81XWH-21-ALSRP-TDA	Independent investigators at all levels	<ul style="list-style-type: none"> <li>• Supports secondary preclinical validation and IND-enabling studies of therapeutics for ALS.</li> <li>• Preliminary data are required, including efficacy of a lead molecule/class of compounds in at least one ALS-relevant model system.</li> <li>• Biomarker development and/or characterization, in parallel to the main therapeutic effort, is a critical component of the TDA.</li> </ul>	<ul style="list-style-type: none"> <li>• Maximum funding of <b>\$1.0 million</b> for direct costs (plus indirect costs)</li> <li>• Maximum period of performance is <b>3 years</b></li> </ul>	<b>Pre-Application:</b> April 9, 2021 5:00 p.m. Eastern time  Preproposal is required; application submission is by invitation only.  <b>Application:</b> July 15, 2021 11:59 p.m. Eastern Time
<b>Therapeutic Idea Award</b> <b>Go to:</b> <ul style="list-style-type: none"> <li>• Program Announcement</li> <li>• General Application Instructions</li> </ul> <b>Grants.gov Funding Opportunity Number:</b> W81XWH-21-ALSRP-TIA	Independent investigators at all levels	<ul style="list-style-type: none"> <li>• Supports hypothesis-driven preclinical therapeutic development.</li> <li>• Projects focusing primarily on investigating ALS pathophysiology are outside the scope of this award mechanism.</li> <li>• Preliminary data are not required.</li> <li>• Early Career Investigators are encouraged to apply.</li> <li>• <b>Biomarker Option:</b> 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.</li> </ul>	<ul style="list-style-type: none"> <li>• Maximum funding of <b>\$500,000</b> for direct costs (plus indirect costs)</li> <li>• Maximum funding of <b>\$600,000</b> for direct costs plus indirect costs if applying for the Therapeutic Relevant Biomarker Option</li> <li>• Maximum period of performance is <b>2 years</b></li> </ul>	<b>Pre-Application:</b> April 9, 2021 5:00 p.m. Eastern time  Preproposal is required; application submission is by invitation only.  <b>Application:</b> July 15, 2021 11:59 p.m. Eastern Time

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadlines
<p><b>Clinical Development Award</b></p> <p><b>Go to:</b></p> <ul style="list-style-type: none"> <li>• Program Announcement</li> <li>• General Application Instructions</li> </ul> <p><b>Grants.gov Funding Opportunity Number:</b> W81XWH-21-ALSRP-CDA</p>	<p>Independent investigators at all levels</p>	<ul style="list-style-type: none"> <li>• Supports correlative clinical research and leveraging of human-based ALS resources.</li> <li>• Types of efforts that will be supported include: <ul style="list-style-type: none"> <li>◦ Using human subject-based resources to better define subtypes, predict therapeutic response, or assess prognosis;</li> <li>◦ Correlating clinical trial-related biosamples, imaging, or epidemiological data with clinical outcomes;</li> <li>◦ Adding a biomarker companion or observational aim to an anticipated/ongoing clinical trial;</li> <li>◦ 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.</li> </ul> </li> <li>• Early Career Investigators and/or Early Career Physician Scientists are encouraged to apply.</li> </ul>	<ul style="list-style-type: none"> <li>• Maximum funding of <b>\$500,000</b> for direct costs (plus indirect costs)</li> <li>• Maximum period of performance is <b>2 years</b></li> </ul>	<p><b>Pre-Application:</b> April 9, 2021 5:00 p.m. Eastern time</p> <p>Preproposal is required; application submission is by invitation only.</p> <p><b>Application:</b> July 15, 2021 11:59 p.m. Eastern Time</p>
<p><b>NEW! Therapeutic/Biomarker Pilot Trial Award</b></p> <p><b>Go to:</b></p> <ul style="list-style-type: none"> <li>• Program Announcement</li> <li>• General Application Instructions</li> </ul> <p><b>Grants.gov Funding Opportunity Number:</b> 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"> <li>• Supports exploratory clinical trials to demonstrate feasibility or inform the design of more advanced trials for the treatment or management of ALS.</li> <li>• Must support a clinical trial and may not be used for preclinical research studies.</li> <li>• Preliminary data are required.</li> <li>• Biomarkers must be incorporated into the trial design. Biomarkers may measure target engagement, drug pharmacodynamics, and/or be predictive/cohort-selective.</li> </ul>	<ul style="list-style-type: none"> <li>• Maximum funding of <b>\$2,000,000</b> for direct costs plus indirect costs.</li> <li>• Maximum period of performance is <b>4 years</b>.</li> </ul>	<p><b>Pre-Application:</b> April 9, 2021 5:00 p.m. Eastern time</p> <p>Preproposal is required; application submission is by invitation only.</p> <p><b>Application:</b> July 15, 2021 11:59 p.m. Eastern Time</p>