# *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 |
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| **Pilot Clinical Trial Award**<br><br>**Go to:**<br>• Program Announcement<br>• General Application Instructions<br><br>**Grants.gov Funding Opportunity Number:**<br>HT942524ALSRPPCTA | Independent investigators at any career level | • 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.<br>• Projects proposing a therapeutic intervention (drug, biologic and/or device) must incorporate biomarkers specific to the intervention into the trial design.<br>• 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.<br>• Must support a clinical trial and may not be used for preclinical research studies.<br><br>***New for FY24!*** **Applications must address one focus area:**<br>• Biomarker-Driven Interventions: Disease-modifying interventions, with mechanism-specific predictive, efficacy, and/or pharmacodynamic biomarkers.<br>• Clinical Care: Improving aspects of clinical care and symptom management for Amyotrophic Lateral Sclerosis (ALS). | • The maximum allowable funding for the entire period of performance is **$2,000,000** for direct costs.<br>• Indirect costs may be proposed in accordance with the institution's negotiated rate agreement.<br>• The maximum period of performance is **4** years. | **Pre-Application (Letter of Intent):**<br>May 24, 2024<br>5:00 p.m. Eastern time<br><br>**Application:**<br>July 10, 2024<br>11:59 p.m. Eastern time |

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| **Clinical Outcomes and Biomarkers Award**<br><br>**Go to:**<br>• Program Announcement<br>• General Application Instructions<br><br>**Grants.gov Funding Opportunity Number:**<br>HT942524ALSRPCOBA | Independent investigators at any career level | • Supports the development and/or validation of clinical outcomes and biomarkers to enrich clinical trials in ALS.<br>• 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.<br>• Studies prospectively enrolling patients to collect biospecimens and/or data are allowed, such as stand-alone or add-on noninterventional clinical research studies to prospectively collect biosamples and/or clinical or digital biomarker data. However, clinical trials are not allowed under this mechanism.<br><br>***New for FY24!*** **Applications must address one or both focus areas:**<br>• Clinical Biomarkers: Identification, development, and/or validation of promising biomarkers for ALS. Biomarkers may include, but are not limited to, target engagement objective pharmacodynamic biomarkers to measure the biological effect of an investigational therapeutic, predictive/cohort-selective biomarkers, or digital health measures, including wearable devices, smart-phone sensors, video or voice recordings, imaging studies, or other devices which record disease-relevant physiological data.<br>• Clinical Outcomes: 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. | • The maximum allowable funding for the entire period of performance is **$750,000** for direct costs.<br>• Indirect costs may be proposed in accordance with the institution's negotiated rate agreement.<br>• The maximum period of performance is **3** years. | **Pre-Application: (Letter of Intent):**<br>May 24, 2024<br>5:00 p.m. Eastern time<br><br>**Application:**<br>July 10, 2024<br>11:59 p.m. Eastern Time |

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| **Therapeutic Development Award**<br><br>**Go to:**<br>• Program Announcement<br>• General Application Instructions<br><br>**Grants.gov Funding Opportunity Number:**<br>HT942524ALSRPTDA | Independent investigators at any career level | • Supports secondary preclinical validation and/or Investigational New Drug (IND)-enabling studies of therapeutics for ALS.<br>• 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.<br>• Examples of activities that will be supported by this award include:<br>  ○ 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.<br>  ○ 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.<br>  ○ 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. | • The maximum allowable funding for the entire period of performance is **$1,500,000** for direct costs.<br>• Indirect costs may be proposed in accordance with the institution's negotiated rate agreement.<br>• The maximum period of performance is **3** years. | **Pre-Application (Letter of Intent):**<br>May 24, 2024<br>5:00 p.m. Eastern time<br><br>**Application:**<br>July 10, 2024<br>11:59 p.m. Eastern time |

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| **Therapeutic Idea Award**<br><br>**Go to:**<br>• Program Announcement<br>• General Application Instructions<br><br>**Grants.gov Funding Opportunity Number:**<br>HT942524ALSRPTIA | Independent investigators at any career level | • 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.<br>• While the inclusion of preliminary data is not prohibited, the strength of the application should rely on the approach.<br>• ***New for FY24!*** All applications must include an aspect of biomarker development in parallel to the main therapeutic effort to qualify for funding.<br>• Projects that focus primarily on pathophysiology of ALS without development of a therapy are outside the scope of this funding opportunity. | • The maximum allowable funding for the entire period of performance is **$600,000** for direct costs.<br>• Indirect costs may be proposed in accordance with the institution's negotiated rate agreement.<br>• The maximum period of performance is **2** years. | **Pre-Application: (Letter of Intent):**<br>May 24, 2024<br>5:00 p.m. Eastern time<br><br>**Application:**<br>July 10, 2024<br>11:59 p.m. Eastern Time |